

# WHO DIAGNOSTIC TECHNICAL ADVISORY GROUP FOR NEGLECTED TROPICAL DISEASES

## SUBGROUP TERMS OF REFERENCE

### Background

Accurate and reliable diagnostic tools are a requirement for neglected tropical disease (NTD) programmes. Although classical clinical and parasitological techniques are often adequate for mapping disease distribution and for monitoring the progress of interventions against NTDs, the need for improved diagnostics comes into much sharper focus as infection prevalence declines and case-finding becomes more difficult. Diagnostic tests are required to support programmatic decisions on changing treatment frequency or stopping mass treatment, to carry out surveillance and to validate or verify elimination. Reports from the field indicate that NTD programmes are currently facing several problems that require urgent solutions, including the under-performance of existing diagnostic tests to support many NTD programmes and dependence on clinical and classical parasitological techniques for routine diagnosis and programme monitoring, among other well recognized challenges.

In response to these challenges, WHO has convened a new Diagnostic Technical Advisory Group for Neglected Tropical Diseases (DTAG) to assist WHO with new efforts to:

- review and prioritize the diagnostics needs for NTD programmes;
- define the use cases and target product profiles (TPPs) for the needed diagnostic tools;
- link with key partners, including NTD programmes from endemic countries, to support test development and validation; and
- provide WHO with guidance on the utility of new tools to support NTD control and elimination.

DTAG members appointed by WHO (12 plus 1 alternate) reflect a broad array of expertise on clinical diagnosis, epidemiology, monitoring and evaluation, diagnostic assay development and validation. Despite this wealth of knowledge, providing in-depth expertise across all 20 NTDs in WHO's portfolio and across all stages of assay development is beyond the capacity of a group with limited membership.

Consequently, WHO is developing time-limited DTAG **subgroups** that will focus more narrowly on single diseases or specific topics, with additional expertise provided by people with the requisite background and experience. Subgroup topics will be established by WHO based on input and recommendations from DTAG members.

## **Role of the subgroups**

1. To work with the DTAG and WHO to understand the current diagnostics landscape and set diagnostic priorities within the specific subject or disease.
2. To prepare new or review existing TPPs using the WHO guidance on and processes for TPPs to help test developers focus energies appropriately on tests needed by programmes.
3. To develop detailed descriptions of the programmatic use case to provide useful context and guidance for scientists and product developers working to support the 2030 NTD road map.

## **Subgroup membership**

- Each subgroup should include one or more DTAG members.
- Ad hoc members of the subgroup are engaged by the Secretariat based on the recommendation of the Director, WHO Department of Control of Neglected Tropical Diseases.
- Members will be selected based on their expertise in one of the following areas relevant to the theme of the subgroup:
  - disease-specific expertise with assay development or programme monitoring and evaluation;
  - large-scale production of quality-assured diagnostic tests;
  - regulatory pathways; and
  - introduction of new tools for programmatic use.
- Subgroups will have 6–12 members and may participate for up to 3 years or for shorter periods depending upon the scope of work for the subgroup. Once the scope of work has been completed the group may be disbanded by the DTAG.
- Subgroups may invite individual experts on an ad hoc basis as the disease-specific portfolio requires.

## **Reporting**

Subgroup recommendations will be submitted to the DTAG for consideration and recommendation to the Director, WHO Department of Control of Neglected Tropical Diseases.