WHO NTD DIAGNOSTIC TECHNICAL ADVISORY GROUP (DTAG)
SUB-GROUP TERMS OF REFERENCE

Background

Accurate and reliable diagnostic tools are a requirement for neglected tropical disease (NTD) programs. Although classical clinical and parasitological techniques are often adequate for mapping disease distribution and for monitoring the progress of NTD interventions, 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 programs are currently facing several problems that require urgent solutions, including the under-performance of existing diagnostic tests to support many NTD programs and dependence on clinical and classical parasitological techniques for routine diagnosis and program monitoring, among other well recognized challenges.

In response to these challenges, WHO has convened a new NTD Diagnostic and Technical Advisory Group (DTAG) to assist WHO with new efforts to:

- Review and prioritize the diagnostics needs for NTD programs
- Define the use cases and target product profiles (TPPs) for the needed diagnostic tools
- Link with key partners, including NTD programs from endemic countries, to support test development and validation
- Provide WHO with guidance and strategies on the utility of and access to 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 sub-groups that will focus more narrowly on single diseases or specific cross-cutting topics with additional expertise provided by persons with the requisite background and experience. Sub-group topics will be established by WHO based on input and recommendations from DTAG members.

Role of the Sub-Groups

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. Develop new or review existing TPPs using the WHO TPP guidance and process 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 Roadmap.

4. Provide expertise advise and recommendations in the areas of surveillance, surveillance platforms, improving the quality of microscopy and clinical diagnosis, and manufacturing and regulatory pathways.

Sub-Group Membership

- Each Sub-group should include one or more DTAG members.

- Ad hoc members of the Sub-Group are engaged by the Secretariat based on the recommendation of the NTD Director

- Members will be selected based on their expertise in one of the following areas relevant to the theme of the sub-group:
  - Disease-specific expertise with assay development or program monitoring and evaluation and policy advices
  - Large scale production of quality-assured diagnostic tests
  - Manufacturing and regulatory pathways
  - Introduction of new tools for programmatic use

- Sub-groups 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 sub-group. Once the scope of work has been completed the group may be disbanded by the DTAG.

- Sub-groups 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, NTD Department, WHO.