



Report of the third meeting of the WHO Diagnostic Technical Advisory Group for **Neglected Tropical Diseases**

Virtual meeting, 3 June 2021



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ISBN 978-92-4-005373-1 (electronic version)

ISBN 978-92-4-005374-8 (print version)

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Suggested citation. Report of the third meeting of the WHO Diagnostic Technical Advisory Group for Neglected Tropical Diseases: virtual meeting, 3 June 2021. Geneva: World Health Organization; 2022. Licence: CC BY-NC-SA 3.0 IGO.

Cataloguing-in-Publication (CIP) data. CIP data are available at <http://apps.who.int/iris>.

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Abbreviations and acronyms

CDIM	clinical diagnosis, imaging and microscopy
CL	cutaneous leishmaniasis
DTAG	Diagnostic Technical Advisory Group for Neglected Tropical Diseases
EDCTP	European and Developing Countries Trials Partnership
EQA	external quality assessment
FIND	Foundation for Innovative New Diagnostics
HAT	human African trypanosomiasis
IVDR	In Vitro Diagnostics Regulation (European Union)
M&E	monitoring and evaluation
MARP	monitoring and regulatory pathways
NIH	National Institutes of Health
NTD	neglected tropical disease
PKDL	post-kala-azar dermal leishmaniasis
QA	quality assurance
QC	quality control
RDT	rapid diagnostic test
STAG	Strategic and Technical Advisory Group for Neglected Tropical Diseases
TPP	target product profile
VL	visceral leishmaniasis
WHO	World Health Organization

1. Introduction

Due to the ongoing coronavirus disease (COVID-19) pandemic, the third meeting of the Diagnostic Technical Advisory Group for Neglected Tropical Diseases (DTAG), an advisory group to the World Health Organization's Department of Control of Neglected Tropical Diseases (WHO/NTD), was held virtually, on 3 June 2021.

The meeting was opened by Dr Mwelecele Ntuli Malecela, Director, WHO/NTD, who offered thanks and congratulations to members of the DTAG and its subgroups on progress made since the DTAG began its work in October 2019. The DTAG plays an essential role in ensuring that diagnostics are available, field-ready and capable of supporting programme needs, while disease-specific subgroups have made significant progress in elaborating target product profiles (TPPs) for the development of crucial new diagnostics. The cross-cutting subgroups have now been launched and are poised to address critical issues in diagnostics that span the entire portfolio of NTDs.

The ongoing COVID-19 pandemic was seen to be a demonstration of what is possible in the diagnostics field when investment, innovation and collaboration combine. The DTAG is key to harnessing these resources to fill the diagnostic needs of NTD programmes.

The participants are listed in the Annex.

1.1 Declarations of interest

All the invited experts and observers were asked to declare any conflict of interest before the meeting. No conflicts of interest were declared.

2. Background

WHO/NTD manages a diverse portfolio of 20 diseases and disease groups, each with its own unique epidemiology and diagnostic challenges. Programmes to address each disease have different goals: disease control, elimination as a public health problem, elimination of transmission, or eradication. These programmatic goals may change over time as new tools are developed and global attention brings increased support.

In this context, the DTAG was set up to provide end-to-end support to WHO and the diagnostics community around the diagnostics agenda needed to facilitate progress towards achieving the targets set out in WHO/NTD's high-level document, *Ending the neglect to attain the Sustainable Development Goals: a road map for neglected tropical diseases 2021–2030* ("the road map").

The DTAG's brief includes more than just the tools themselves; it encompasses everything from biomarker discovery and assay development to laboratory and field validation leading to WHO endorsement, and issues relating to manufacturing, procurement, supply and deployment.

2.1 Meeting objectives

The objectives of the third DTAG meeting were described to the assembled participants. They heard that the subgroup chairs would provide updates on the progress of their groups and of the TPPs under development. The subgroup chairs were asked also to raise any issues or recommendations that amounted to key cross-cutting challenges requiring that they be addressed by the parent-level DTAG. Issues to be discussed at the third DTAG meeting included the need for biobanks to make samples available for test development and validation, and the need for standardized processes for laboratory and field validation.

The meeting was told that achieving real progress would require identification and engagement with new and existing donors to ensure that adequate resources were available to meet the needs of the various programmes. The DTAG would be asked to consider what steps the group might take to work alongside WHO on a shared advocacy strategy. The DTAG, it was stated, could play a vital role in supporting WHO as it made its case for investment in such tools.

2.2 Priorities for 2021

The following were identified as priorities for the DTAG in 2021:

- Draft a position paper or provide other technical support on how to deal with the challenge of imperfect gold standards in the context of test development.
- Standardize processes for test validation and WHO endorsement.
- Improve sample availability (biobanking).
- Coordinate with the Working Group on Monitoring, Evaluation and Research of WHO's Strategic and Technical Advisory Group for Neglected Tropical Diseases (STAG) on the definition of new programmatic use cases.
- Work with WHO to make the investment case to advocate for new resources for diagnostics development.
- Support WHO to host a webinar to communicate diagnostic needs.

3. Global investment case

Dr Xiaoxian Huang presented an update on the global NTD investment case. This companion document to the road map estimates the funding required to address the critical gaps identified in the road map, and identifies and assesses the feasibility of mechanisms to raise additional funds and attract new partners.

The meeting heard that although funding requirements had previously been estimated, feedback suggested that it was difficult to make informed decisions based solely on lump sum figures. The investment case, therefore, would seek to focus on concrete investments needed to address the four critical priorities identified in the road map. The following questions were deemed key in terms of evaluating financial need:

- What are the priority actions that need to be supported with investments?
- How much is needed?

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