

# Guide for clinical studies in difficult field conditions

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Dit is de omschrijving

**Clinical innovation is essential in order to tackle neglected tropical diseases, which threaten one billion people worldwide. A group of international scientists, led by the Antwerp Institute of Tropical Medicine, has published a guide for clinical studies in difficult field conditions in *PLOS Neglected Tropical Diseases*.**

[NIDIAG](#) is an EU-funded consortium of scientists from 13 institutes and universities in Europe, Africa and Asia, led by Prof. Marleen Boelaert, epidemiologist at the Antwerp Institute of Tropical Medicine (ITM). Over the past six years, NIDIAG has tried to bridge the gap between innovation and practice in the diagnosis of neglected tropical diseases. The scientists have now published a set of seven articles in *PLOS Neglected Tropical Diseases*, which describe the specific challenges, propose solutions and provide working documents for implementing quality assured clinical research into neglected tropical diseases.

“The path from technological innovation to saving lives passes along field work, which is the speciality of the teams involved in these clinical studies. The difficult field conditions are a typical characteristic of the environment in which neglected tropical diseases occur, but our message is that it is possible to perform this clinical research in accordance with ethical standards and international rules. By sharing our experiences, our aim is to facilitate new research projects into neglected disease,” said ITM’s Dr Tine Verdonck .

## One billion people are threatened by neglected tropical diseases

[Neglected tropical diseases](#) still cause suffering and death, often in vulnerable population groups or in remote areas. In total, more than one billion people are affected globally. It is nevertheless possible to trace and treat some of these diseases. Significant progress has been made in recent years, and the arsenal of diagnostic tests and treatment options for neglected tropical diseases has grown.

However, the step from innovation to saving lives is not self-evident. A whole range of questions needs to be answered along the way, and this requires conducting scientific research in remote, resource-constrained settings. “This type of clinical research, about introducing new tests and techniques in a patient-centred approach, does not make the news very often. It is easier to propose a new idea in a newspaper headline than to describe the path towards implementation of this idea in the complex reality of a real-life patient setting,” says Verdonck.

## The potential of rapid tests

Rapid tests for the diagnosis of infectious diseases are an example of a technological development with great potential. These tests usually focus on one specific disease per test. For example, rapid tests for HIV and malaria have been used on a large scale across the world for several years now, and they have fundamentally changed the diagnostic approach to these infectious diseases. Such rapid tests are now also available for neglected tropical diseases such as visceral leishmaniasis (also called black fever) and African sleeping sickness.

Consider the rapid test for visceral leishmaniasis as an example. This is an infectious disease that causes symptoms such as prolonged fever and an enlarged spleen. This disease is fatal if not treated. Effective treatment for this disease does exist, although it is quite toxic. Until recently, it was not easy to diagnose black fever with certainty; a biopsy of the spleen was often required, which is a diagnostic test with inherent risks.

## The real-life challenges of field research

New rapid tests are now available, which can give a result within half an hour and using only one drop of blood. This raises a number of questions, including:

- How reliable is this test in practice, when performed by a local nurse in a remote village in Sudan where the disease occurs?
- Does a positive result provide enough certainty to start the treatment? And what happens if the result is negative?
- Is a negative result on this rapid test sufficient to rule out the diagnosis of black fever?
- If a patient with chronic fever tests negative for visceral leishmaniasis, what are the most important alternative diagnoses?
- The test has so far been evaluated in patients who had a fever for two weeks; does the test work equally well in patients who have only had one week of fever?

The NIDIAG scientists performed a series of studies in Africa and Asia precisely to answer these types of research questions for three different clinical situations: the situation of a patient with fever for more than one week, or with neurological problems, or with abdominal pain or diarrhoea for more than two weeks. They encountered a range of challenges, such as the limited access to study sites, the lack of research infrastructures and the weakness of local health systems. The number of patients presenting for treatment increased as a result of the improved care during the study, and so did the workload.

Overall, [the international guidelines for clinical research](#) had to be translated to the context of the participating study sites, without compromising on the quality of the research and on the protection of participants and their communities.

## Links

- [The complete collection 'Good Clinical Practice' on PLOS](#)

The seven articles in the collection:

- [Clinical Research in Neglected Tropical Diseases: The Challenge of Implementing Good Clinical \(Laboratory\) Practices](#)
- [Rapid Diagnostic Tests for Neglected Infectious Diseases: Case Study Highlights Need for Customer Awareness and Postmarket Surveillance](#)
- [The Challenges of Conducting Clinical Research on Neglected Tropical Diseases in Remote Endemic Areas in Sudan](#)
- [Diagnosis of Persistent Fever in the Tropics: Set of Standard Operating Procedures Used in the NIDIAG Febrile Syndrome Study](#)
- [Experiences and Lessons from a Multicountry NIDIAG Study on Persistent Digestive Disorders in the Tropics](#)
- [Clinical Research on Neglected Tropical Diseases: Challenges and Solutions](#)
- [The Art of Writing and Implementing Standard Operating Procedures \(SOPs\) for Laboratories in Low-Resource Settings: Review of Guidelines and Best Practices](#)