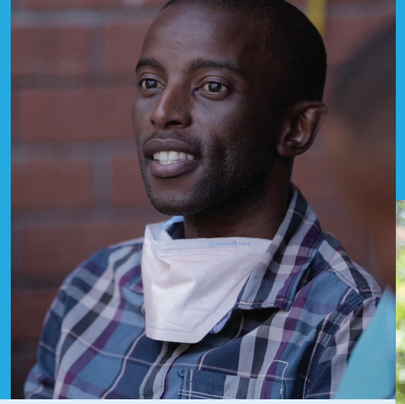
COMMUNITY ENGAGEMENT (CE)

The study comprises a strong CE component aimed at respectful, beneficial and transparent partnerships that address the interests of all stakeholders, increase the beneficence and relevance of the research and support its ethical and scientifically rigorous conduct, including:

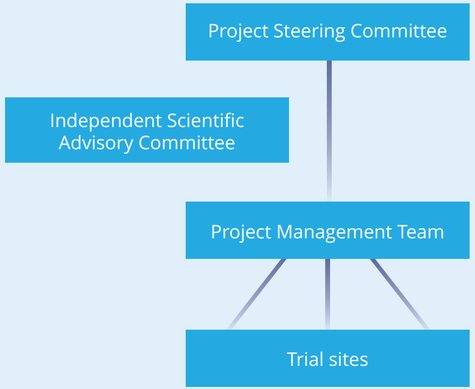
- **Two-way dialogue**
- **Community Advisors**
- **Research literacy**
- **Timely and open communications**
- **Appropriate and easily understandable tools**



TB Practecal
Innovating MDR-TB Treatment

GOVERNANCE

The Project Management Team, housed in MSF UK, leads the study day-to-day overseen by a strong governance structure made-up of global TB and research experts, to ensure that the highest patient safety, medical and scientific standards are met throughout.



GLOBAL COLLABORATION

The study draws upon vast experience and expertise from a global collaboration of leaders in DR-TB care, research and innovation. Trial sponsor and lead investigator Médecins Sans Frontières and the London School of Hygiene and Tropical Medicine work closely with partners, including ministries of health in affected countries, the Republican Specialized Scientific Research Medical Centre Of Tuberculosis And Pulmonology (TBI) in Uzbekistan, and international specialists:

www.msf.org.uk/tb-practecal

UCL

ERT
Getting It Done. Right.

DNDi AFRICA
Drugs for Neglected Diseases *initiative*

TB ALLIANCE
GLOBAL ALLIANCE FOR TB DRUG DEVELOPMENT

Swiss TPH
Swiss Tropical and Public Health Institute
Schweizerisches Tropen- und Public Health-Institut

TDR For research on diseases of poverty
UNICEF • UNDP • World Bank • WHO

TB Practecal
Innovating MDR-TB Treatment

MEDECINS SANS FRONTIERES

LONDON SCHOOL of HYGIENE &TROPICAL MEDICINE

SHORT, SIMPLE & SAFE DR-TB TREATMENT

AFFORDABLE AND EASY TO SCALE-UP CARE

AVAILABLE TO PATIENTS WORLDWIDE

AMBITION

We aim to save the lives of hundreds-of-thousands of people with drug resistant tuberculosis (DR-TB), by identifying a dramatically shortened, safe and effective patient friendly treatment. If successful, we will advocate for its affordability and accessibility worldwide. Timely diagnosis and better treatments could contribute significantly to decreasing morbidity and mortality, thereby halting the global DR-TB epidemic.

People with TB, their families, communities and medical staff worldwide are calling for better treatment!

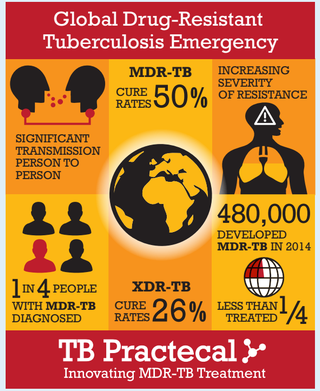
Cured XDR-TB patient Phumeza Tisile delivered the 'Test Me Treat Me' Manifesto to the World Health Assembly in 2013, supported by 55,291 signatures, *msfaccess.org/TBmanifesto*. To read more about the courage of people under-going standard DR-TB treatment, along with the terrible side effects and psychological toll, visit patient blog TB&ME at *blogs.msf.org/tb*.

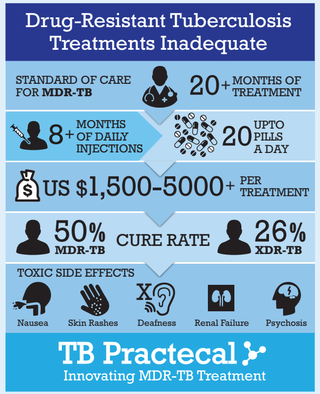
GLOBAL EMERGENCY

DR-TB is one of the foremost public health threats worldwide today. Yet, the global response is a fraction of what is needed to meet the 90% targets in the Global Plan to End TB, 2016-2020.

Today's complex, costly and inadequate standard treatment for DR-TB is a big part of the problem. Not only does it cause inexcusable suffering for patients but it also poses a significant obstacle to the increase of care worldwide.

In 2012, new anti-TB drugs brought hope for the first time in half a century. Yet, many patients remain years from getting better treatments due to the slow roll out of these drugs and a lack of research into new regimens (combinations).





CUTTING EDGE CLINICAL RESEARCH

TB PRACTECAL is a multi-country, multi-arm, open label, randomised, controlled, phase II-III trial to identify dramatically shortened, safe and effective new treatment regimen(s) for adults with pulmonary DR-TB; in accordance with the Declaration of Helsinki and international standards for good clinical practice in TB trials.

Designed to maximise the possibility of finding patient centred treatments and to speed progress, we intend to:

- **Combine two new and highly promising anti-TB drug classes**, diarylquinolines and nitroimidazoles, increasing the potential to radically improve treatment,
- **Target both MDR-TB and XDR-TB** to tackle the spectrum of drug-resistant strains,
- **Identify a six-month regimen** to dramatically reduce treatment time,
- **Utilise a pragmatic and adaptive trial design** to speed progress and ensure that a new regimen is relevant for the people who need it most.

This has multiple potential benefits for patients, communities, TB programmes and public health alike.

Stage one of the study plans to identify regimens containing new drugs bedaquiline and pretomanid for further evaluation based on safety and efficacy outcomes after eight weeks of treatment. This will lead seamlessly to stage two of the study, which will evaluate the safety and efficacy of the best performing new regimens, at 72 weeks, compared with the World Health Organization recommended standard of care used locally.

Before being allowed to commence, the research will go through a rigorous national and international approval process by independent ethical review boards in MSF, LSHTM and regulatory authorities in participating countries.