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

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
We aim to save the lives of hundreds-of-thousands of people with drug resistant tuberculosis (DR-TB), by

AMBITION

SHORT, SIMPLE & SAFE contribute significantly to decreasing morbidity and mortality, thereby halting the global DR-TB epidemic.

AFFORDABLE AND EASY TO SCALE-UP CARE

We 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.

AVAILABLE TO PATIENTS WORLDWIDE

We aim to save the lives of hundreds-of-thousands of people with drug resistant tuberculosis (DR-TB), by

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 unacceptable 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).

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/. To read more about the courage to the World Health Assembly in 2013, delivered the ‘Test Me Treat Me’ Manifesto supported by 55,291 signatures, msfaccess.org, of people under-going standard care compared with the World Health Organization recommended standard of care used locally.

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

Stage one of the study plans to identify regimens containing two of the study, which will evaluate the 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.

CUTTING EDGE CLINICAL RESEARCH

TB PRACTICAL 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 OR-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.
- Identify a six-month regimen to dramatically reduce treatment time, to tackle the spectrum of drug-resistant strains, increasing the potential to radically improve treatment.
- 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.
- Build on the study’s success by recruiting 14 countries in 2016/2017 and 12 in 2017/2018, increasing the potential to radically improve treatment.
- For good clinical practice in TB trials.

Phase II/III Clinical Research

Drug-Resistant Tuberculosis Treatments Inadequate

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