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Groundbreaking South African study transforms TB treatment globally including children and pregnant women

- **New treatment endorsed by the WHO**

Johannesburg - Wednesday, 28 August 2024: A groundbreaking initiative, BEAT Tuberculosis, has become the world's first initiative in the fight against drug-resistant tuberculosis (DR-TB) for all population groups, influencing the World Health Organization policy on treating TB internationally.

While TB remains a threat to global public health and - the second leading cause of death in South Africa, the BEAT Tuberculosis clinical study conducted at the [Clinical HIV Research Unit \(CHRU\)](#) Isango Lethemba TB Research Unit in the Eastern Cape and KwaZulu-Natal over the past six years. The study was born from a South African need to find better treatment options for DR-TB. The main intention was to inform local guidelines but international guidelines have also been changed.

As all stakeholders celebrate a breakthrough in eradicating TB, BEAT Tuberculosis is a local research study, in collaboration with the National Department of Health, funded by the [United States Agency for International Development \(USAID\)](#) and executed by the University of the Witwatersand.

The results from the study have influenced the World Health Organization policy on the treatment of TB, and at the same time put the Global South centre stage for driving improved treatment for all.

"The BEAT Tuberculosis study represents a groundbreaking approach in the fight against tuberculosis, particularly with its inclusive research methodology. By incorporating pregnant women and children into the clinical trials, the study has expanded the understanding of TB treatment's efficacy and safety across broader demographics. The study's success in demonstrating safety and effectiveness of the new short oral regimen in these key populations marks a pivotal step towards a more comprehensive and equitable healthcare strategy for tuberculosis management," says Dr Francesca Conradie, the principal investigator who led this study.

The primary aim was to evaluate the effectiveness and safety of a novel shortened treatment regimen for DR-TB compared with the established standard of care. The standard treatment comprised a seven-drug regimen administered over a minimum of nine months. This was

compared with a streamlined regimen of four to five medications, including newer agents like bedaquiline and delamanid, administered over only six months.

A second objective of the BEAT Tuberculosis study aimed to enhance research capacity for DR-TB, within the Eastern Cape and KwaZulu-Natal, by fostering community engagement and providing training to healthcare personnel in clinical research methodologies for TB treatment. "This collaborative effort received crucial support from the National and Provincial Departments of Health that provided essential medication and laboratory infrastructure for safety and efficacy assessments," adds Conradie.

The study began in 2019 and despite the formidable challenges posed by COVID-19, over 400 participants were enrolled across study sites in the Eastern Cape and KwaZulu-Natal.

Prof Norbert Ndjeka, Chief Director TB Control and Management of the National Department of Health adds, "In South Africa in 2022, an estimated 280,000 people developed TB, and 54,000 died from the disease. With this concerning observation in mind, we acknowledge the BEAT Tuberculosis project as an exemplary and concerted effort to advance TB treatment and research capabilities, poised to bring about transformative changes in RR-TB management worldwide. While the study was originally intended to inform local treatment guidelines, the results are now set to benefit patients everywhere."

The United States Agency for International Development (USAID) is a key funding partner for the BEAT Tuberculosis initiative. USAID Southern Africa Mission Director, Leslie Marbury, highlights, "In partnership with South Africa's National Department of Health, USAID has improved Tuberculosis patient care worldwide. We celebrate the 400 participants who made this trial possible and brought the world closer to ending Tuberculosis. We also thank all BEAT Tuberculosis stakeholders, including the National Department of Health, the Eastern Cape and KwaZulu-Natal Health Departments, and local medical facilities, for their dedication and commitment to this globally recognized study."

TB symptoms

The most common symptoms of TB are a cough that lasts more than two weeks, weight loss, drenching night sweats and a fever. If you have any of these, go to your local clinic. You will be asked to produce sputum or phlegm which will be tested for TB. If the test is positive, the correct treatment will be started.

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A photograph of Dr Francesca Conradie, principal investigator, BEAT TB:
<https://drive.google.com/drive/folders/17ES39J6ALzQVjDgP-3-OGxb1mDrldoyw?usp=sharing>

About those involved in the BEAT TB study

SOUTH AFRICAN NATIONAL DEPARTMENT OF HEALTH

The South African National Department of Health (SA-NDoH) and its provincial departments of health in Eastern Cape and KZN participated in the clinical trial. Treatment sites and access to drugs were provided. This collaboration helped achieve the smooth running of the clinical trial and strengthening of clinical services at the participating sites. The SA-NDoH is very supportive of research. The DR-TB National Clinical Advisory Committee advises the SA-NDoH on RR-TB operational research, programmatic and clinical management of RR-TB.

USAID

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CHRU

The Clinical HIV Research Unit ([CHRU](#)) is a division of the Wits Health Consortium. It was established in 2001 and has been focused on the optimization of treatment for HIV and other diseases in resource limited settings. CHRU has completed several large-scale antiretroviral therapy trials. In 2008 CHRU shifted the emphasis in clinical research activities to include the treatment of TB. The first MDR TB trials conducted by CHRU which started in 2008 were the registrational trials for bedaquiline. CHRU then expanded to other centres. In 2015, CHRU took over the management of the MDR TB research site at the King DiniZulu Hospital Complex in Durban, KwaZulu Natal. In 2017/8, CHRU under the leadership of Dr Francesca Conradie established a research site in Nelson Mandela Bay, Eastern Cape where BEAT Tuberculosis was conducted at Isango Lethemba TB Research Unit.

Wits Health Consortium

The [Wits Health Consortium \(Pty\) Limited \(WHC\)](#) is wholly owned by the University of the Witwatersrand. WHC supports operations through which the university - primarily its Faculty of Health Sciences - conducts research, manages donor-funded activities, pursues entrepreneurial innovation in health and supports clinical trials. The key task of WHC is to provide the governance, legal framework, human resource management, financial and grant management to over 100 research entities, including the Clinical HIV Research Unit (CHRU), in various academic departments. This role is performed through WHC's Shared Services Centre (SSC) which employs over 200 skilled staff.

For further information, interviews please contact NDoH and Turquoise PR:

- Foster Mohale +27 72 432 3792 Foster.Mohale@health.gov.za
- Isadora Isaacs +27 83 925 9676 isadora@turquoisepr.co.za
- Michelle K Blumenau +27 83 273 9891 michelle@turquoisepr.co.za