

## INDIAN COUNCIL OF MEDICAL RESEARCH

Department of Health Research - Ministry of Health & Family Welfare Government of India

## PRESS RELEASE

## INDIA MOVING FORWARD IN RESEARCH TOWARDS NEW TOOLS FOR TUBERCULOSIS

- Indigenously developed point-of-care (POC) molecular diagnostic test validated through multicentric studies and found to be comparable with internationally approved molecular diagnostic test
- New vaccine candidates identified for designing a Phase-III clinical trial for prevention of disease in healthy household contacts of TB patients
- Clinical trial of new drug combinations planned to shorten treatment of TB and Drug Resistant TB

**02 NOVEMBER 2017, NEW DELHI:** The India Tuberculosis Research Consortium (ITRC), formed by the Indian Council of Medical Research (ICMR), Delhi convened its second International Scientific Advisory Group (ISAG) meeting on 31<sup>st</sup> October and 1<sup>st</sup> November 2017. The ISAG comprises global experts in the areas of TB research and has been formed to advise the ITRC on developing and translating, research & development leads across four key thematic areas – diagnostics, vaccines, therapeutics and implementation research – taking into account the research leads in each area, available both nationally and internationally.

**Dr. Soumya Swaminathan** (Secretary, Department of Health Research, Ministry of Health & Family Welfare and Director General, ICMR) said, "India's National Health Policy recognizes the key role that research plays in the development of a nation's health. The India TB Research Consortium brings together diverse stakeholders to develop new tools – diagnostics, vaccines and drugs – to enable India to take a leadership role in fast-tracking translational TB research and find solutions for the world."

Speaking on the occasion, **Dr. Barry R. Bloom** (Distinguished Service Professor, Harvard University and Chair, ISAG) said, "TB is now the largest single cause of death in the world from an infectious disease. India has the highest number of TB cases in the world. It is widely recognised that the field needs new tools to make a greater impact on this disease, including more sensitive diagnosis, preventive vaccines and new drugs to treat MDR-TB. Hence the Government of India has made a significant commitment to support research to prevent and control the disease in India."

India's National Strategic Plan 2017 for TB elimination aims to achieve and maintain a cure rate of >85% in new sputum positive patients for TB and reduce incidence of new cases, to reach elimination status by the year 2025. Towards this end, along with strengthening the Revised National Tuberculosis Control Programme (RNTCP), the Government of India has set up ITRC to address India's TB Challenge through research, innovation and partnerships. ITRC has adopted an interdisciplinary collaborative approach by harnessing national and international expertise to advance technology as well as product development by delivering effective diagnostics, shorter drug regimens, efficacious vaccines along with newer interventions for TB control and subsequent elimination of the disease. The Consortium is being supported by the Government of India as well as partner agencies and philanthropy to ensure that adequate resources in terms of both technical and financial support are available. Since its inception in August 2016, ITRC has made considerable progress in terms of taking forward its mandate across its thematic areas. *An update on progress made so far*.

**Diagnostics**: India has relied heavily on smear microscopy technology for decades, and case detection continues to be a major gap in the cascade of care. While a Cartridge-based Nucleic Acid Amplification test (CBNAAT) has been successfully rolled-out as a tool to detect drug resistance, it remains expensive and largely inaccessible as a front-line TB test. The Truenat test is a novel, point-of-care, molecular test that is made in India, with chips for TB and a variety of diseases (e.g. malaria, dengue, HIV). It is a multi-disease

platform designed for decentralized settings (e.g. microscopy centres or Primary Health Centres) with demonstrated capability for linking results to online patient records, remote notification, remote usage monitoring, and the costs are expected to be lower than currently used imported tests.

Based on a review of the results of evaluation studies done in India, the ISAG will recommend to RNTCP, that for case detection, the roll out of the POC MTB test to demonstrate its wider application to diagnose TB across the country be evaluated at the Designated Microscopy Centre (peripheral laboratory) level. It was suggested that all patients testing positive for TB by POC test, may also be tested by another nationally endorsed rapid test for diagnosing drug resistance TB. The Committee also recommended a cost-effectiveness analysis and optimization of the POC test for rifampicin resistance. It was suggested that India should consider leveraging this Indian innovation for other public health conditions such as malaria, HIV, dengue etc. at the primary care level.

Inspired by this early success, several other innovative technologies are being taken forward by the Consortium for further testing and validation.

Therapeutics: A key challenge is the long treatment period endured by the patients, which often leads to poor treatment adherence by patients. This may also lead to drug resistance. India has a large and expanding population of MDR-TB patients. New TB drug regimens with a combination of multiple new drugs are the need of the hour. Shorter, safer and more effective regimens are needed. A few new and repurposed anti-TB drugs have emerged, offering the opportunity to develop shorter, multi-drug treatment protocol that pre-empts the threat of MDR-TB entirely with new drug, along with existing drug treatments and also to use repurposed drugs for TB treatment. ITRC has shortlisted four key clinical trials to be conducted for drug sensitive and drug resistant TB.

Vaccines: There is a critical need for new TB vaccines that are more effective than BCG in preventing pulmonary as well as extra pulmonary forms of TB in all age groups. ITRC is developing a protocol for prevention of disease study in healthy household contacts of TB patients with selected new vaccines in India – one of these vaccine candidates has been developed indigenously.

**Implementation research:** Evidence is being generated to ensure that the most vulnerable have access to critical TB health services. Key areas of focus include active case finding, private sector engagement and use of ICT in TB control and elimination strategies.

Capacity building: Going forward, ITRC will also be focusing on adopting an integrated approach to building trial site capacity for research by strengthening resource and infrastructure, manpower training, creating better understanding of the regulatory environment as well as the ethical dimensions of drugs and vaccine development.

•

**About** Indian Council of Medical Research: ICMR is the apex body in India for the formulation, coordination and promotion of biomedical research, is one of the oldest medical research bodies in the world. ICMR's research priorities align with the national health priorities. These efforts are undertaken with a view to reduce the total burden of disease and to promote health and well-being of the population. ICMR promotes biomedical research in the country through both intramural and extramural research. Visit us at <a href="http://icmr.nic.in/">http://icmr.nic.in/</a> for details.

## **Media Contacts:**

**Rina Sinha**Communications and Media Advisor

Syed Adil Shamim Andrabi Information Interface Officer/PRO

Email: proicmr@gmail.com I Phone: 011–26588980 (Extn. 243)

Website: http://www.icmr.nic.in Twitter: @ICMRDELHI Facebook: https://www.facebook.com/ICMROrganisation