

# Vaccines, Clinical Trials & B2B

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## The current status, challenges and future developments of new tuberculosis vaccines

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Tuberculosis (TB) is an infectious disease caused by *Mycobacterium tuberculosis* complex (MTBC) whose natural history traces back 70,000 years ago. In 2016, there were an estimated 10.4 million new TB cases globally, 1.3 million TB-associated deaths, and an additional 374,000 deaths from TB patients with co-infection of HIV-MTBC. Although the number of TB deaths decreased, TB remained one of the top 10 causes of death worldwide. To address TB challenges, the World Health Organization (WHO) has introduced the “End TB Strategy”, which indicates that the phased strategy has progressed from controlling the prevalence of TB (before 2015) to ending the prevalence of TB (2016-2035). The target for 2035 is a 95% reduction in TB deaths and a 90% reduction in the TB incidence rate compared to levels in 2015, and the target for 2050 is less than one TB patient per million people each year. However, challenges of controlling TB infection and developing more effective vaccines remain, and concerted effort will be required to achieve the global TB control strategy formulated by WHO. Vaccination is the most effective way to prevent and control TB. As early as 1890, Robert Koch proposed the first immunotherapy against TB. However, bacilli Calmette-Guérin (BCG) is the only licensed preventive vaccine against TB and has existed for 96 years. Although BCG vaccination can effectively protect infants and young children from TB infection, and prevent severe diseases such as disseminated TB and tuberculous meningitis, it has variable efficacy against pulmonary TB, particularly in adults. Clinical trials conducted on adults in the United Kingdom (UK) have shown that the protective effect of BCG was 60 to 80%. However, studies performed with South African infants have shown that BCG had no protective effect. Reasons for this variability could be explained by several factors, including genetic differences, environmental factors, co-infection, production methods, the diversity of BCG strains, and the impact of poverty and nutrition. The BCG vaccine does not effectively stimulate the T cell mixed population (especially for CD8<sup>+</sup> T cells), and the immuno-protective effect of BCG vaccination only persists for 10 to 15 years. Researchers worldwide have reached consensus that the development of more effective vaccines is necessary to compensate for the limitations of the BCG vaccine. With rapid developments in immunology and molecular biology, some novel TB vaccines have become available, including inactivated vaccines, recombinant live vaccines, attenuated live vaccines, subunit vaccines, and DNA vaccines. At present, there are 25 new TB vaccines in clinical trials, of which three vaccines (Vaccae in patients with latent TB infection (LTBI), *Mycobacterium indicus pranii* (MIP)/Mw, and VPM1002) have reached Phase III clinical trials. Three vaccines (Vaccae, Utilins, and BCG-PSN) have obtained registration certificates from the China Food and Drug Administration and have been widely used to clinically treat TB in China. However, three vaccines (rBCG30, AERAS-422, and H1:LTk63) have been terminated for their disappointing issues after phase I clinical trials. Herein, we review the developmental progress and challenges of these new TB vaccines, and we will also introduce five novel TB vaccines (Utilising, *M. smegmatis*, AEC/BC02, BCG-PSN, and GX-70) for the first time, which may give a fresh perception into the TB vaccine research field.

### Biography

Wenping Gong has completed his PhD at the age of 26 years from Academy of Military Medical Sciences (AMMS, China). Currently, he is an assistant professor in 309th Hospital of Chinese PLA, and his studies focus on developing novel TB vaccines. Furthermore, he is academic secretary of the tuberculosis branch of China International Exchange and Promotion Association for Medical and Healthcare, academic secretary of Beijing Key Laboratory of New Techniques of Tuberculosis Diagnosis and Treatment. He has published more than 20 SCI cited papers in reputed journals and has been serving as an editorial board member of Journal of Bacteriology and Vaccine Research and GSL Journal of Vaccines and Vaccinations.

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