TBVI

TuBerculosis Vaccine Initiative

New TB vaccines: investing in the future

TuBerculosis Vaccine Initiative (TBVI), an independent not for profit organization, supports development of urgently needed new vaccines to protect future generations from tuberculosis (TB).

Network of the best researchers

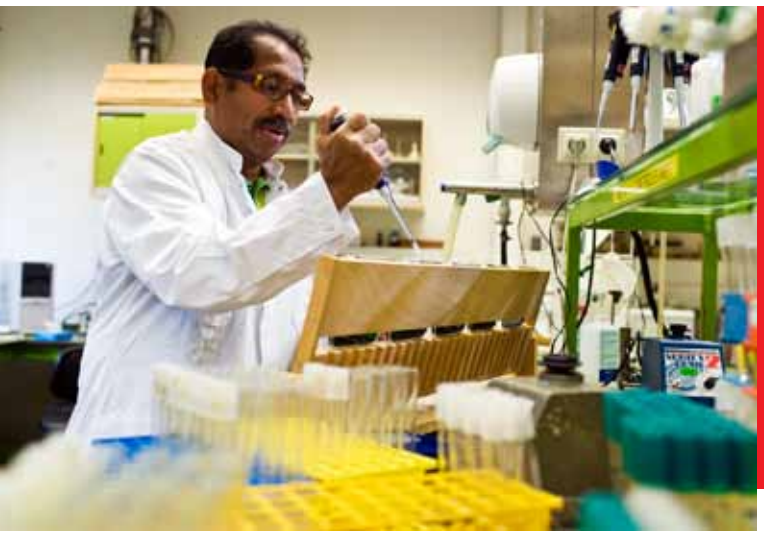
TBVI facilitates, supports and brings expertise to an integrated European network of over 40 universities, institutes and industries to develop more effective, safe vaccines that will be globally accessible and affordable. By supporting the best, most renowned researchers, TBVI increases the chances and likelihood of finding the best solutions.

The TBVI foundation evolved from the successful TBVAC project (2004-2009), a Framework Program funded by the European Union to identify new TB vaccine candidates. The TBVAC project brought together many partners in Europe and Africa with complementary expertise, creating a unique, ambitious and expanding network.

Outstanding track record

The TBVAC project has resulted in an outstanding track record of four new vaccine candidates in preclinical and non clinical stages, four new vaccine candidates in clinical phase I to II (testing safety and immunogenicity), fifteen candidate biomarkers (used to monitor the effectiveness of new vaccines) with potential to be used in monitoring of clinical trials and three adjuvant molecules (used to enhance the immunogenicity and therefore the efficacy of vaccines), one of which in clinical phase I studies. The most advanced vaccine candidate is currently being tested for efficacy in a phase IIb study. If successfully tested in further clinical stages this vaccine could hopefully be licensed by 2017.

TBVI is the only existing pan-European organization of its kind, with a working-model based on transparency and collaboration. The portfolio is managed by our Steering Committee of leading experts in the field of TB: they decide on the funding and monitor the progress of research projects. Furthermore, the advancement of each vaccine or biomarker development is supervised and guided by our product development teams and clinical development teams.



TBVI's objectives are:

1. Stimulate research and discovery on TB vaccines
2. Assure preclinical and early phase clinical development
3. Guarantee that promising projects result in affordable vaccines as soon as possible
4. Develop biomarkers that will increase performance and speed of vaccine development
5. Increase capacity of existing clinical trial sites in developing countries
6. Raise political and public awareness on the global health threat of TB and the need for new vaccines

Every 18 seconds somebody dies of TB

Two million deaths a year

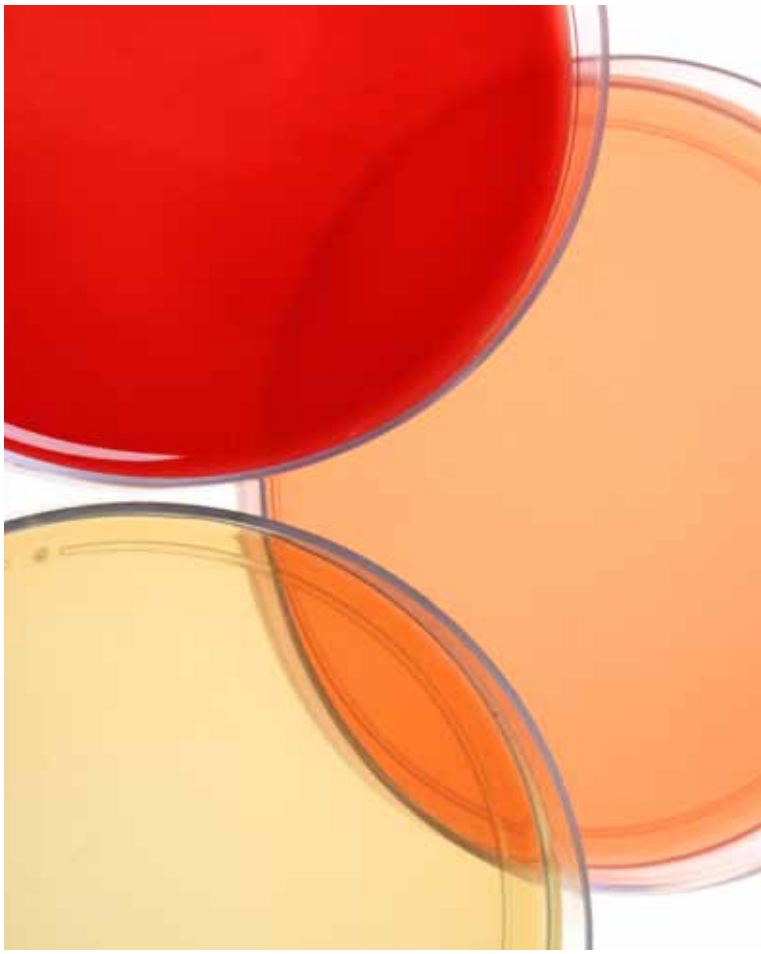
Tuberculosis (TB) is a leading killing disease in the world today. Every second somebody in the world gets newly infected with TB bacilli, every 18 seconds somebody dies of the infectious disease. TB causes almost 2 million deaths a year, equaling one jumbo jet crashing every two hours.

TB is contagious and spreads through the air. Around two billion people, or one third of the world's population, are estimated to be infected with the bacterium that causes the disease. The overall lifetime risk of developing TB disease following infection is estimated to be approximately 10%. Every year around 9 million new cases of TB disease are recorded, overall almost 14 million people have the disease.

The increased mobility of the world's population intensifies the spread of the airborne infectious disease. If not treated, each person with active TB infects on average 10 to 15 people per year. Although poverty-related and mostly affecting developing countries, TB is prevalent in all continents. The situation is turning serious in Europe, is alarming in Africa and extremely worrisome in Russia, China and India.

Drug resistant TB: a global threat

The HIV/AIDS epidemic has fuelled a dramatic resurgence of TB. People living with HIV are 20 to 40 times more likely to suffer from TB once they are infected with the bacteria than people without HIV. TB is a leading cause of death among people living with HIV.



Multidrug-resistant TB (MDR-TB) and extensively drug-resistant TB (XDR-TB) are a growing threat for all countries in the world. These forms of TB are expensive and extremely difficult or virtually impossible to treat. Per year an estimated 500,000 new cases of MDR-TB and 50,000 new cases of XDR-TB are recorded in a growing number of both developing and developed countries.

Human and economic disaster

Next to being a huge cost to humanity, TB also undermines the capacity of nations to escape poverty and is an enormous drain on the global economy. The burden of TB is estimated at hundreds of billions of dollars every year. The economic loss amounts to 0.52% of the world's gross national income.

The world needs new TB vaccines

Ultimate goal: elimination

Elimination of TB by 2050: that's the ultimate goal of more than 1,000 governments, NGO's and other donors from public and private sectors united in the Stop TB Partnership. More specific targets are to halve TB prevalence and halve TB mortality by 2015 compared to their levels in 1990.

It is already clear that Africa and Eastern-Europe will not achieve the goals of 50% reduction in prevalence and mortality, mainly due to the spread of HIV/TB and MDR- and XDR-TB. But, even if these challenging 2015 goals would be achieved worldwide, still about one million people would die of TB every year.

No elimination without new vaccines

The development of faster diagnostics, better drugs and more effective, safe vaccines is urgently needed. Eliminating TB by 2050 can only be achieved when such new tools are available. Finding new vaccines is particularly important as various studies show their impact will be significant, being able to save tens of millions of lives. Vaccines will also be especially crucial in combating MDR- and XDR-TB.

Bacille Calmette-Guérin (BCG), currently the only available TB vaccine, is widely used and effective in preventing severe forms of TB in children. However, BCG has little to no efficacy in preventing pulmonary TB, the most common and most infectious form of TB among adults and adolescents worldwide. Furthermore, BCG may be unsafe in newborns with HIV.

Several types of vaccines needed

The world needs new vaccines to replace or improve BCG. These vaccines should also prevent TB in people with a latent or 'sleeping' TB infection (which is not contagious but can still develop into TB later in life) and be safe in people living with HIV.

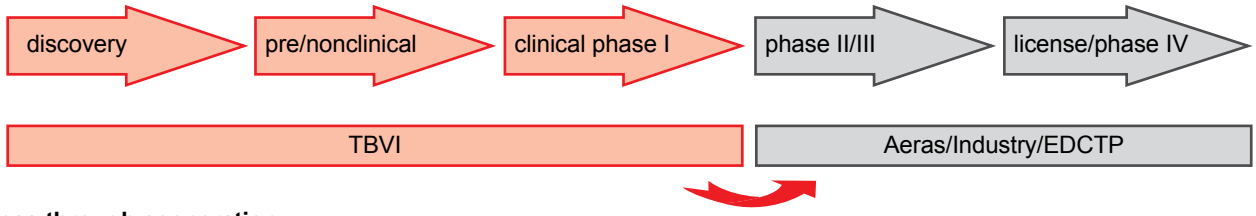
TBVI aims to develop two types of vaccines:
1) priming vaccines that could be given to newborns, which are also protective in latently infected persons and safe in persons with HIV.
2) boosting vaccines to be used in infants, adolescents or young adults, protecting both non-infected as well as latently infected persons from developing TB.

Furthermore, we have a program to develop biomarkers and one program for infrastructure supporting activities to improve the capacity of existing clinical trial sites.
For its proposed portfolio, TBVI aims to raise €200 million over the next 10 years (see table):

Program	Includes (approximate)	Expected output	Costs (in mln €)
1. Boosting vaccines	18 vaccines	5 vaccines ready for Phase II (2009-2020)	71.4
2. Priming vaccines that could replace BCG	19 vaccines	3 vaccines ready for Phase II (2009-2020)	64.95
3. Biomarkers	30 biomarkers /correlates	3 assays (2015-2020)	34.2
4. Infrastructure supporting activities	1-3 existing clinical trial sites		30
Total			200.55

Turning scientific potential into industrial reality

Figure: vaccine development chain



Progress through cooperation
TBVI links with other partners (such as Aeras Global TB Vaccine Foundation, private industry and EDCTP (European and Developing Countries Clinical Trials Partnership)) to move promising candidates into costly Phase II/Phase III efficacy trials.

Access and affordability of TB vaccines for the developing world are a statutory objective of TBVI and a commitment that is part of each agreement for support. We want those people around the world who need the vaccines most to have them as soon as possible, without (financial) barriers.

The responsibility and ownership of vaccines and biomarker candidates always remain with the individual partners. TBVI does not claim any rights, but aims to serve as an honest broker to turn scientific potential into industrial reality and facilitate the development of more effective, safe vaccines.

More investment needed
Although extremely valuable and essential, investments done by EU institutions and research partners alone are not enough to continue our research and development. Without additional involvement of governments, companies, foundations and private donors, new vaccines can not be developed.

Investing in TB vaccines is an investment in the future with tangible results. Not only will it save lives, prevent health disasters and relieve poverty, it also contributes to building knowledge-based economies, creating jobs and sustainable growth. With that, TBVI promotes international plans and policies, such as the Millennium Development Goals, the Stop TB Partnership, and the Lisbon Agenda, which aims to establish a European Area of Research and Innovation.

TBVI's unique network and outstanding track record shows that new effective, safe vaccines can be developed. If we can generate sufficient resources, we might see the dawn of an era in which TB really is a disease of the past.