

Bestuursverslag(narrative) 2019

Highlights of TBVI activities 2019

A Research and Innovation Partnership that Works to Discover and Develop New TB Vaccines

TBVI support to R&D partners

In 2019, TBVI provided project coordination and technical services to TBVI's R&D partners to accelerate the development of promising TB vaccine candidates and to continue to innovate and diversify the TB vaccine and biomarker pipeline.

The R&D activities of the EC Horizon2020 TBVAC2020 project were finalized June 2019 and in September the final progress report was submitted for review to the European Commission. Outcome of the review process is expected Q1 2020.

The annual TBVAC2020 project meeting was successfully organized in Les Diablerets from 28 January - 31 January 2019.

Vaccine specific product and clinical development teams provided services to 6 preclinical and clinical stage candidate TB vaccines.

The Portfolio Management Committee (PMC) conducted a final TBVAC2020 portfolio evaluation on the candidates resulting from the project. In total 44 different novel vaccine concept and formulations were tested to provide safety, immunogenicity data and or efficacy data, of which 13 vaccine concepts showed similar protection compared to the control and 7 showed improved protection compared to BCG. Overall it was concluded that progression of promising candidates across all parts of the pipeline took place, including diverse candidates across the three target product profiles (infant, adolescents/adult, therapeutic) and across different vaccine categories (live attenuated, killed inactivated, protein/adjuvant/subunit, vector).

TBVI support to Global Partners

As highlighted in the paragraph on resource mobilization (below) , TBVI received a grant from the Bill & Melinda Gates Foundation to cover specific services to Global Partners. US-based partner organization IAVI is subcontractor for several activities in the grant – most of the activities are executed in partnership between TBVI and IAVI. The grant is linked to the Global TB Vaccine Partnership (GTBVP). One of the key activities covered by the grant is dedicated for TBVI to serve as a secretariat to the GTBVP. Having TBVI (and partner organization IAVI) serve as the secretariat will enable the GTBVP partners to meet on a more regular basis, and to jointly identify important gaps in the TB vaccine R&D field in order to then consequently take steps to address these gaps / barriers.

In 2019 and 2020 GTBVP activities will focus on setting up communication around GTBVP and its activities, adding new members (primarily funders) to the GTBVP group, and addressing previously identified gaps for the field.

Two of these gaps identified and being addressed by TBVI are the TB vaccine development pathway (an online guide that provides an assessment process to track progress and make decisions on the advancement of tuberculosis vaccine candidates to the next stage of

development) and a business case for investment in TB vaccine R&D. Both of these activities are developed in collaboration with IAVI and funded under the BMGF grant as well.

As a last activity under the BMGF grant, TBVI will work with IAVI to organize the 6th Global Forum on TB vaccines. TBVI will be involved primarily for the scientific content, resource mobilisation and shaping the agenda for the high-level session of the global forum – another service to its global partners. Additional potential support activities from TBVI were discussed with its global partners (ranging from Portfolio Assessment, organization of technical and scientific meetings, overview of the global TB vaccine R&D funding ask, and harmonization around the communication of the global TB vaccine pipeline) and are potentially further developed (pending on funding) in the coming year(s).

In 2019 Q3 TBVI received a grant from EDCTP for the Development of tools and documents to support the coordination of EDCTP TB vaccine funded research. The activities are contributing to enhanced coordination and collaboration between research actions by the European & Developing Countries Clinical Trials Partnership (EDCTP) in TB vaccine research and development (R&D). It will further facilitate the coordination of EDCTP funded actions with the Global TB Vaccine Partnership (GTBVP) and other global research initiatives of relevance to TB vaccine development.

Knowledge development, exchange and networking

In 2019, TBVI continued to support the exchange and translation of knowledge within the R&D community, with funders and other policy stakeholders:

From 28th to 31st January 2019 in Les Diablerets, Switzerland, the TBVI symposium and TBVAC2020 annual meeting brought together 120 scientists and policy makers from 70 research institutes, universities, industry, funding agencies, technical agencies from 17 countries. The meeting provided the opportunity to hear from key global stakeholders about their current activities in the field and get an update on recent advances in TB Vaccine R&D. Theme of the symposium was ‘TB Vaccines: Global Collaboration and Recent Advances in the Field

In October, a joint workshop with three H2020 funded projects, TBVAC2020, EMI-TB and STriTuVaD, was organized. This workshop entitled “Maintaining European scientific excellence and global leadership in TB Vaccine R&D EU funded collaborative research and innovation” brought together scientists, policy makers, funders and other key stakeholders. They discussed the impact and results of these projects and how collaborative research effort that underpins these results can be taken forward in the next two years and be imbedded in FP9.

TBVI participated in several meetings such as the annual CTVD meeting in Seattle, the European R&I meetings in Brussels, a network meeting for ‘Indian-Dutch cooperation in the vaccine sector, the World Vaccine Congress in Barcelona, the Global Vaccine Summit in Brussels and several meetings at the WHO in Geneva (Public Health Value Proposition meeting, PDVAC meeting). TBVI also presented on several occasions for example during the Global Fund Replenishment Forum in Lyon France.

The TB Vaccine Development Pathway is updated in 2019 with Stage Gates for vaccine registration and launch, as well as guidance specific to the development of TB vaccines for

adolescent/ adults, neonates, and for vaccines to be used in a therapeutic setting. At several meetings the Pathway is presented.

Resource Mobilization

During the year 2019, TBVI continued its work with funding agencies in order to create funding opportunities and apply for grants for:

- TB vaccine product development activities
- TB vaccine collaborative research and innovation activities
- TBVI services

With the finalization of the TBVI-led EU Horizon2020 collaborative R&I project TBVAC2020, and the final calls for product development under the EDCTP programme in 2019 and early 2020, TBVI has primarily focused its 2019 resource mobilization activities to shape the agenda for future funding opportunities for TB vaccine R&D under the next EU Horizon Europe Framework Programme – ‘Horizon Europe’ (2021-2027). These RM activities include interactions with EU member states, the European Commission, Members of the European Parliament, the EDCTP and other stakeholders (e.g. Global Health Advocacy organizations, other Product Development Partnerships (PDPs)) in and outside of Europe that will provide input into the development of the new EU Framework Programme.

In 2019, TBVI has continued interactions with vaccine industry partners (both major companies as well as SMEs) to discuss renewal of existing sponsorships, and setting up of new sponsorship agreements.

TBVI during 2019 has continued to work with the Dutch Government (Ministry of Health) in order to extend the current subsidy from the Ministry to TBVI for an additional 2 years. Discussions with several other EU Member States were held regarding similar financial support from these countries for the TBVI foundation – in particular to cover the funding gap between Horizon2020 and Horizon Europe.

During the course of 2019 – TBVI received a grant for 4 years (total amount of \$1.399.521 for the years 2019-2022) from the Bill & Melinda Gates Foundation linked to 4 specific activity areas related to TBVI services. In addition, TBVI received a contract from the EDCTP as well for several technical activities to the TB Vaccine R&D field (total amount of € 130.000 for the years 2019-2021).

Both the BMGF grant and the EDCTP grant are (partially) linked to the TBVI involvement with and support to the Global TB Vaccine Partnership (GTBVP). TBVI continues to work with the different funders part of GTBVP (EC, EDCTP, NIH-NIAID, BMGF, Wellcome Trust, South African Government, GMRI, and others) to shape and create funding opportunities for the TB vaccine R&D field as a whole, and for TBVI and its R&D partners in specific.

Finance

TBVI being a not for profit foundation aims, and succeeded in 2019, to maximise the annual expenditure (to 97 %) to the statutory and social goal " Stimulate research and discovery on TB vaccines". The remaining 3% of the total cost were essential for the non-social mission. A new project activity funded by the BMGF started in 2019 and led to an increase of activities called "Uitbesteed werk " which are the project activities performed by an external partner. In line with the approved budget for 2019, the costs for Sr. Management were in 2019 drawn from the organisational reserve. This financial year closed with a surplus. The withdrawal and surplus lead to a new organisational reserve of € 72.611.

Governance

The TBVI Governance Board (GB) met 3 times in the Netherlands (Schiphol Airport) on April 8, June 12 and November 7 2019- as part of the regular Board meetings.

The TBVI Advisory Committee (AC) met in the Netherlands (Schiphol Airport) on April 9, June 11 and November 6 2019 -as part of their regular Committee meetings.

The TBVI R&I group met FTF in the Netherlands on April 9, June 11 November 6 and during TCs to develop TBVI strategic areas of focus for 2020 and beyond (see below focus for 2020)

Focus for 2020

In 2020, TBVI will continue to provide its R&D partners with project coordination services, technical support services, knowledge exchange and networking activities, and resource mobilization activities supported by ongoing project and sponsor funds.

In view of the completion of TBVAC 2020 project in June 2019 and the resulting shortfall of resources for collaborative R&D activities – an increased effort will continue to be made to engage TBVI's R&D partners to keep together the successful R&D consortium and build on results achieved. This effort includes the continued meeting of the R&I group (see Governance), the convening of technical meetings including the Global Forum scheduled for April 2020 and the continuation of resource mobilisation efforts

TBVI will continue to give special attention to working with EC and with individual European member states to sustain the funding level for TB vaccine R&D at the required level, and ensure that funding of TB vaccine R&D will remain part of a future FP9 program.

Following an intermediate evaluation of the objectives of TBVI's current R&D strategy (2018-2022), the gap of support for collaborative R&D projects between Horizon2020 and Horizon Europe (2020-2022), and the recommendations of the R&I group, TBVI's areas of work in the next two years will focus on:

Product development – moving current leading TB vaccine and biomarker candidates and fast followers through the pipeline.

Collaborative research and innovation - continuing to innovate and diversify the TB vaccine and biomarker pipeline and TB vaccine platforms; develop and test alternative vaccine routes and delivery mechanisms; develop and validate pre-clinical models; develop human challenge models; develop next generation portfolio management tools; and harness the power of AI for TB vaccine and biomarker research and clinical trials.

Global and European Cooperation and Coordination of TB vaccine R&I efforts, including identifying and addressing key gaps to move the TB vaccine R&I field forward.

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