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BEST PRACTICES IN PRIVATE SECTOR ENGAGEMENT TO ADVANCE THE FIGHT AGAINST TB
The current COVID-19 pandemic has required and received immense attention and investment from the global health community. However, efforts to combat other infectious diseases have suffered. As an infectious respiratory disease, COVID-19 exhibits many of the same challenges posed by TB (tuberculosis). TB has continually fought for global attention and investments since its relative disappearance from the Global North. As a result, high-burden, low-and-middle-income countries (LMICs) continue to lack the resources to effectively combat and eradicate deadlier drug-resistant strains of TB. The Stop TB Partnership’s Private Sector Constituency (PSC) recognizes the challenge and is wholeheartedly invested in eradicating TB worldwide.

Private sector engagement is key to addressing TB in high-burden countries. This is why the PSC engages in activities to eliminate TB. Having 61 members from 17 regions, across 5 continents gives the PSC a global character and direct engagement with communities. The Constituency has access to uniquely suited knowledge, skills, and products that can be leveraged to support TB diagnosis and treatment efforts in these communities. The PSC membership not only is committed to the cause, but they understand the crucial role the private sector must play in alleviating the burden of TB.

Private sector engagement with TB provides a variety of expertise, resources, access, and knowledge that are often underutilized, fragmented, unconsolidated, or sometimes even non-existent in the public sphere of LMICs. The private sector is a key actor that can leverage its unique attributes to bolster and uplift efforts within LMICs to combat infectious diseases like TB. Naturally, these efforts from the private sector need to be targeted and executed to most benefit the communities they serve.

To ensure this is the case, the PSC has developed the following collection of best practices. They are intended to demonstrate the importance and effectiveness of private sector efforts, highlight their innovative nature, promote those taking steps to fight TB, and inspire others with the capability to take action.

The private sectors’ efforts are by no means homogeneous. On the contrary, they are variable and tailored to specific contexts, which is one of their many advantages. For the sake of organization, we have segmented private sector efforts into a series of categories: research and development (R&D) oriented, infrastructure and capacity building focused, diagnostic and surveillance measures, enabling access, providing knowledge and guidance, and multilateral efforts more broadly. These
categories are not exhaustive, and certainly private sector engagements can often touch upon more than one of these areas. However, it provides a baseline framework to assess how the private sector has and can fight against TB.

Observed R&D efforts often center around the need for new TB treatment regimes. Current courses are long, require strict adherence, can cause unappealing side-effects, and can be ineffective with the rise of drug-resistant TB (DR-TB). A majority of these efforts are multistakeholder in nature and involve an intensive level of collaboration between global partners in academia and the pharmaceutical industry.

Initiatives to bolster infrastructure and increase capacity are quite palpable; common examples are efforts to aid in implementing national or regional action plans, establishing laboratories or other relevant facilities, and providing necessary tools or instruction of practices.

Engagements focused on diagnostics and surveillance can be split into two interconnected areas: ‘on the ground’ efforts and systematic efforts. On the ground efforts usually consist of providing testing to groups that suffer from a lack of access, such as remote rural environments. While, systematic efforts tend to involve the training, teaching, and sharing of knowledge and resources to enable better national or regional surveillance efforts or testing in standard healthcare settings.

One of the more direct forms of engagement, enabling access, is mostly driven by the donation of products (therapeutics, diagnostic equipment, etc.) and the adoption of innovative pricing mechanisms to ensure LMICs can access life-saving health products.

The private sector shares knowledge and expertise with national TB programs and NGOs through trainings and workshops to develop regional or national policies, practices, or further programs. These often are conducted with the private sector assuming an advisory or consultant style role to shape and direct public efforts in the most efficient, safe, and expert manner.

Finally, multistakeholder efforts are engagements driven by private consortiums or multiple private sector actors partnering with government or NGOs. As previously stated, multistakeholder efforts are common in the R&D field as collaboration drives innovation while diffusing the incumbent investment costs of research.

Above are examples of how the private sector has sought to take charge against TB. This persistent, deadly disease has faced waning attention compared to other causes. There are myriad of options for private sector TB engagement, and it will continue to be a crucial facet of the continued fight against TB. The best practices below should signal to other private sector entities how they can contribute to this cause and signal to other key stakeholders how the private sector contributes to TB efforts.
Multistakeholder Efforts to Accelerate the Fight Against TB

**EDCTP-TDR**

*GSK and J&J*

EDCTP-TDR Clinical Research Development Fellowships seeks to provide specific, competency enhancing training in clinical trials for medicines, vaccines, and diagnostics for several infectious diseases, including TB. Building more robust research capabilities in LMICs reduces bottlenecks as life-saving drugs enter the development pipeline.

The Training in Tropical Diseases (TDR) program, founded by the World Health Organization (WHO) in 1999, was created to improve research competencies in LMICs. The European & Developing Countries Clinical Trials Partnership (EDCTP) was founded in 2012, building a partnership between Europe and sub-Saharan Africa. Like the TDR, this fellowship program sought to improve research capabilities through placements with pharmaceutical companies. In 2014, the two merged, forming the EDCTP-TDR to better streamline and synergize the two programs with the same goal.

GSK, in particular, has received two EDCTP grants: one to achieve a proof of concept for the use of meropenem and another to study combinations of TB treatments under a phase 2a study design.

**ERA4TB**

*GSK and J&J*

The ERA4TB (European Regimen Accelerator for Tuberculosis) project is a public-private partnership and a part of the EU’s Innovative Medicines Initiative (IMI) Antimicrobial Resistance (AMR) Accelerator. It is committed to accelerating new TB drug development. ERA4TB aims to construct an open platform to accelerate novel TB drug development in Europe. The project will assist with early development, from the initial lead-up to the end of the first-in-human trials (FTiH) stage.

Six foundational objectives support this: implementing innovative tools onto an open platform to evaluate drug candidates; developing better modelling tools alongside artificial intelligence for pharmacokinetic-pharmacodynamic relationships; effective and efficient data management; a flexible management structure to allow for adaptive capacity and resource allocation; sustainability considerations to ensure longevity; and effective communications to increase the project’s potential impact.

ERA4TB’s open platform will represent a novel accelerator for TB drug development and is intended to remain active beyond the...
specific timeline of the project. The open philosophy of ERA4TB applies not only to capacity but also to tools, which will help ensure the project’s continued relevance. In this way, the project is inspired by initiatives like CERN, the European Organization for Nuclear Research, which demonstrate the harnessing of a lively and competitive European community. The ERA4TB’s platform is modelled off a ‘progression pipeline’ that can address various molecules throughout the development process.

EU-PEARL

*J&J, Otsuka, & Sanofi*

Launched in 2019, the EU Patient-Centric Clinical Trial Platforms (EU-PEARL) is a cross-company initiative funded by the IMI. Its focus is to create new frameworks to support the development of adaptive clinical trial platforms. As part of the EU’s IMI AMR Accelerator, the project aims to add uniformity to and understanding of adaptive clinical trials that simultaneously test candidate compounds belonging to different pharmaceutical companies.

Stakeholders believe that adaptive clinical trials can reduce overall drug development times and improve the patient experience by increasing the likelihood that patients will benefit from a promising drug in place of a placebo. Therefore, the project team is focused on progressing early and efficient identification of optimal drug regimens for four disease areas: major depressive disorder, TB, non-alcoholic steatohepatitis (NASH) and neurofibromatosis.

In the case of TB, EU-PEARL believes that collaboration amongst public-private stakeholders and increased consideration of patient voices can accelerate phase 2 and phase 3 trials reducing the overall length and expense.
**TREATS**

*Delft Imaging and Qiagen*

The Tuberculosis Reduction through Expanded Antiretroviral Treatment and Screening for Active TB (TREATS) project is currently determining the success of PopART’s (a universal test and treat project) efforts to reduce TB prevalence and incidence in Zambia and South Africa. TREATs is gathering evidence on the efficacy of PopART to provide the necessary data to promote widespread adoption of similar initiatives, aiming to accelerate the government’s adoption of this type of program.

The project being evaluated, PopART, provided universal testing and treatment for TB and HIV through home-to-home visits in 14 communities between 2014-2018. Early results from the PopART intervention have demonstrated success in reducing rates of HIV across the participating communities in Zambia and South Africa.

Additionally, TREATs is using existing TB testing facilities in the Bwacha–Ngungu community of Kabwe, Zambia to study and measure the spread of COVID-19. Thus, hoping to extrapolate the data to the broader Zambian population through mathematical modelling to understand the virus’s epidemiology in sub-Saharan Africa. Further, TREATs has sought to increase TB and HIV awareness through community engagement efforts.

As a consortium member, Delft Imaging provided the program’s “OneStopTB clinic.” The project was the first TB prevalence survey that solely used CAD4TB to detect presumptive TB cases, without the involvement of human expert readers. Additionally, the project conducted follow-up testing for those who had high CAD4TB abnormality score or a positive GXP test after six months, using the Delft Light (backpack X-ray) with CAD4TB to screen people at the community- and household-level.

Finally, during the ongoing COVID-19 pandemic, the OneStopTB vans and Delft Light have been used together with Delft’s CAD4COVID software to triage suspected COVID-19 cases rapidly.

**PAN-TB**

*GSK, J&J, and Otsuka*

The Project to Accelerate New Treatments for Tuberculosis (PAN-TB) is a collaborative effort through the EU’s IMI AMR Accelerator to aid in developing novel drug regimens for TB by leveraging members’ assets, resources, and scientific expertise. PAN-TB aims to accelerate drug regimens ready for phase 3, which are designed to be active against resistant strains of TB, be better tolerated in patients, have a shorter treatment length, and have greater treatment simplicity than existing regimens. As a result, this treatment would become the new universal standard for both drug-resistant and drug-susceptible TB. Furthermore, it would not require additional tests for resistance before treatment begins to select the right drugs for the regimen.

The PAN-TB collaboration believes that these innovative drug regimens will prove to be crucial in the fight against TB, citing the many complexities currently incumbent in treating TB and ensuring treatment adherence. The creation and adoption

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1. UNAIDS (Joint United Nations Programme on HIV/AIDS), PEPFAR (President’s Emergency Plan for AIDS Relief), EGPAF (Elizabeth Glaser Pediatric AIDS Foundation), WHO (World Health Organization), and His Eminence Peter Cardinal Turkson, Prefect of the Discastery for the Promotion of Integral Human Development
of the regimens sought by the PAN-TB collaboration would provide immense value to patients and health systems.

Using phase 2 clinical efficacy studies, the PAN-TB collaboration can investigate and assess TB regimen candidates. Pre-clinical research through PAN-TB has already commenced, and resulting clinical trials will be announced shortly.

**Predict-TB Consortium**

*J&J and Sanofi*

Implemented by African, American, Asian, and European partners, Predict-TB was a 5 ½-year long project initiated in 2013 to shorten TB treatments for drug-sensitive patients via individualized therapy. In South Africa and China, the Predict-TB Consortium performed a phase 2B clinical trial. The Consortium also set criteria to shorten TB treatment times by utilizing data from scans, assays and cultures to assess inflammation and lung pathology leading to shorter-than-normal treatment options for eligible patients.

There were three key objectives for the Consortium: trial implementation, sample collection and storage, and test development. Predict-TB enrolled patients with drug-sensitive pulmonary TB in a clinical trial to validate biomarkers and establish the criteria. The project also collected biological samples from Africa and Asia for further biomarker research.

**Rome 5**

*Cepheid, J&J, & Otsuka*

Since 2016, members of the Rome 5 initiative, a collaboration between UNAIDS, PEPFAR, EGPAF, WHO, Stop TB, Faith-Based Organizations, and His Eminence Peter Cardinal Turkson, have worked to advance prevention, diagnosis and treatment of HIV and TB in children. In 2020, for the first time, the coalition of public and private organizations, governments, and regulatory authorities expanded its focus to include TB in children. The result, the Rome Action Plan 2020, outlines stakeholder commitments to overcome bottlenecks to HIV and TB services for children.

**TB Alliance**

*GSK and Viatris both have portfolios with the Alliance*

The TB Alliance (Global Alliance for TB Drug Development) was formed in February 2000, at a meeting in Cape Town, South Africa. Here, 120 representatives from academia, industry, agencies, NGOs, and donors gathered to discuss the urgent need for novel and highly effective TB treatments. At this point, there were no new TB drugs in the pipeline. Given the increasing incidence of TB in LMICs, a global and collective response was necessary. As a result, the ‘Declaration of Cape Town’ was finalized, providing a roadmap for TB drug development that led to the inception of the TB Alliance.

The TB Alliance is a not-for-profit product development partnership (PDP) that has successfully transformed TB drug development through internal expertise and a vast global network of partners in academia, philanthropy, private and public sectors. The TB Alliance pioneered TB regimen development, accelerating breakthroughs by advancing multiple drug candidates as part of combination regimens. In 2015, the TB Alliance developed child-friendly formulations of first-line TB medicines. Over 1.2 million...
treatment courses have been procured by more than 90 countries that bear over 75% of the global childhood TB burden.

In 2019, the TB Alliance became the first not-for-profit to register an anti-TB drug with a stringent regulatory authority, earning the 2020 Prix Galien for this achievement. The novel compound, pretomanid, received approval for the treatment of highly drug-resistant forms of TB as part of an all-oral, three-drug, six-month combination regimen with a reported cure rate of 90% in the pivotal Nix-TB clinical trial.

The TB Alliance granted nonexclusive licenses of pretomanid to multiple manufacturers as part of the BPaL regimen in LMICs, keeping its commitment by making its products accessible to those who need them. This strategy is intended to generate competition and incentivize a sustainable supply of high-quality, affordable drug product available to patients in countries with high TB burdens.

The TB Alliance developed the largest portfolio of TB drug candidates and continues to innovate, bringing new and transformative products to market.

**TB Drug Accelerator Program**

*GSK and J&J*

The TB Drug Accelerator (TBDA) program is a cross-sectoral consortium that helps accelerate novel TB drug discovery and development. Launched in 2012, the partnership’s main objective is to create an ultrashort TB drug regimen instead of the standard six-month treatment course. To date, the program counts eight pharmaceutical companies and five academic institutions as members. The program facilitates the sharing of data and compound libraries between members. In October 2020, the TBDA’s Collaborative Drug Discovery received a supplemental grant of nearly $1.5 million to provide secure data sharing and analytic support.

**Unite4TB**

*GSK, J&J, & Otsuka*

The Academia and Industry United Innovation and Treatment for Tuberculosis (UNITE4TB) initiative aims to advance the clinical development pipeline for TB regimens and contribute to the EU’s ambition of becoming a best practice region for addressing antimicrobial resistance. As part of the EU’s IMI AMR Accelerator, UNITE4TB is improving adaptive clinical trial designs to identify and ultimately implement efficient and accessible drug regimens for drug-resistant TB. In addition, UNITE4TB is developing innovative tools, clinical trial designs, imaging technology, biomarkers and pharmacogenomics diagnostics. Also, they aim to create new clinical candidates and combinations using artificial intelligence.

The project team expects to enable selective administration of drugs to populations based on host genomic factors, thus matching patients to the most promising drug regimens and proper dosing to optimize treatment options. In combination with ERA4TB, this initiative is expected to advance several drug compounds in the coming year.

**WIPO Re:Search**

*GSK and J&J*

WIPO Re:Search aids early-stage R&D efforts combating neglected tropical diseases, malaria, and TB. It facilitates
organizational sharing of IP, compounds, compound libraries, expertise, and facilities to provide royalty-free access for qualified researchers seeking to fight these diseases. Despite innovative R&D models, research gaps exist, making knowledge sharing a crucial part of efforts. The intersection of academic, non-profit, and private sector partners under the WIPO Re:Search project can help facilitate these necessary efforts.

WIPO Re:Search can improve the chances of developmental success and reduce costs through accelerated research brought about through knowledge-sharing. WIPO Re:Search connects over 150 academic, governmental and private pharmaceutical organizations worldwide, currently providing support for over 50 innovative collaborative projects.

Working Group on New TB Drugs
GSK, J&J, & Otsuka

The Working Group on New TB Drugs (WGND), part of the Stop TB Partnership, seeks to advance new therapies for TB through coordination, guidance, and efforts to accelerate the development of new TB drugs. The pursuit of shorter and simpler TB treatment regimens is necessary, as current regimens take between 6 months to 2 years, are complicated, difficult to administer, and even toxic.

The WGND consists of a varied membership: R&D professionals, regulators, public health workers, funders, community representatives, advocates and policymakers. These stakeholders all see the increasingly difficult struggles against TB globally. Membership to the WGND is open and inclusive to all stakeholders, with annual meetings to evaluate activities and strategy, while also measuring progress against the goals outlined in the Global Plan to Stop TB. Further, subgroups of the WGND dedicate focus to specific challenges within the TB drug development process.
Private Sector Constituency members engage in several high-impact, bilateral programs to advance the global fight against TB. All PSC members work to push forward TB research and development efforts to expand access to diagnostic and drug treatments in high-need, resource-limited settings. In the research and development space, bilateral partnerships between health product providers and research institutions have accelerated the development of novel TB drugs and diagnostic technologies. Similar collaborations with NGOs has increased access and affordability of life-saving health products.

Outside of research and development efforts, PSC members are working to strengthen health system infrastructure and human resource capacity in countries affected by TB. Through technical assistance and data provision, PSC members work with national TB programmes to increase efficacy and efficiency, ensuring that programmes make the most of available funding. Finally, several PSC members focus their partnership efforts on new, mobile technologies that are user-friendly and easily transported, unlocking TB diagnostic and treatment care for remote communities that have historically been underserved.
Access Pricing Program with FIND

In 2007, BD partnered with FIND — a global alliance aimed at ensuring equitable access to reliable diagnostics—to increase access for high-burden countries that could not afford critical technologies to fight TB. In 2017, this partnership expanded access to a further 40 LMICs. Now, 85 countries are eligible for access pricing and can utilize BD diagnostic technologies. This asset pricing agreement can strengthen national efforts to combat TB with high-quality TB diagnosis available in high-need, low-income settings.

USAID Global Accelerator to End TB Co-Financing in Indonesia

In 2019, USAID and BD entered into a three-year partnership to develop TB case detection infrastructure in Indonesia, a high-burden country, under the auspices of the Global Accelerator. Better case detection improves lab ecosystems bolstering Indonesia’s National TB Program through quality assurance measures, specimen referral processes, and new systems for data collection. Further, BD’s phenotypic testing expertise and capabilities will help assist the National Program more broadly.
STRIDES Project with USAID in India

BD and USAID established STRIDES (Strengthen TB Resistance Testing and Diagnostic Systems) to work with the Indian NTEP (National TB Elimination Program) to bring technical expertise and innovative solutions to improve culture and drug-susceptibility testing all 55 labs within the national network. This partnership is one of many steps to assist NTEP in meeting its goal of eradicating TB by 2025. In addition, they are working to enhance detection efforts and treatment identification for drug-resistant TB patients throughout India.

As part of this work, an assessment of the specimen referral system was conducted. Now, the partners are working to strengthen data management systems for TB within labs.

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Cepheid® has been a partner in High Burden and Developing Countries (HBDC) since the launch of its first molecular test for MTB detection (Xpert® MTB/RIF) in 2010. Cepheid® offers concessional pricing and active collaboration and participation through their partnership with HBDC for the International Strategy to End TB. The discounted price for MTB and Rifampicin resistance detection test enhances its accessibility for Governments, non-for-profit organizations and Global Health Funders that support HBDC countries. To date, the program has placed thousands of GeneXpert® Systems and delivered millions of Xpert® cartridges to some of the most TB-challenged geographies in the world.

Due to increased innovation, product launches and partnerships over the years, Cepheid® extended the Xpert test menu available to HBDC customers to Xpert MTB/RIF Ultra and Xpert MTB/XDR for a discounted price. The discount enables access to life-saving technologies and products, ensuring solutions reach where they are most needed.

The Global Access team works in close partnership with international stakeholders to learn policies and processes, facilitate accessibility, and promote suitability of high-impact diagnostics for HBDC markets.

CONTRIBUTES TO SDG:
Chevron

Global Fund Corporate Champion

As a long-time partner of the Global Fund’s Corporate Champions program, Chevron makes medium to long term investments to combat disease in countries where they operate. Chevron has invested USD $60 million in Global Fund programs against HIV, TB and malaria in Angola, Indonesia, Nigeria, the Philippines, South Africa, Thailand and Vietnam since 2008.

The programs enable companies to create links with their volunteering and community programs. The company also invests in staff management skills and business infrastructure to help develop and implement national strategies on the diseases.
Chevron’s TB Program

Chevron’s TB programs are regionally targeted towards their workforces’ families and communities in high-risk countries. The education and awareness materials are available to all employees across the globe. They are tailored to the regional communities, aligned with current surveillance and exam programs, complementary to the existing healthcare infrastructure and local partnership initiatives.

Throughout the organization, the program improves awareness and education, addresses related stigma, prevents new cases, minimizes severe outcomes, and ensures consistency among prevention and treatment approaches. It utilizes risk, situational and data analysis of TB and its impacts on the workforce and their families.

Internally, the company advocates for non-discriminatory work practices related to TB. Externally, it partners with governments to strengthen health systems to reduce TB and other infectious diseases, like HIV and malaria, in the countries where it operates.

CONTRIBUTES TO SDG:
Delft Imaging supports the Zero TB Cities Initiative in Pakistan with its CAD4TB technology. The globally active Zero TB Cities Initiative fights TB by creating “islands of elimination” governed by strong local ownership through coalitions of local governments, businesses, and civil society in high burden settings. Delft Imaging supports the initiative by installing 80 CAD4TB boxes (offline solution) in hospitals, primary health clinics, and mobile clinics to detect active TB quickly and accurately. The program screens more than 60,000 people per month with CAD4TB and has screened more than 2.5 million people in total.

CAD4TB is an artificial intelligence software to detect and quantify abnormalities suggestive of active TB automatically. CAD4TB enables TB programs to perform large-scale, accurate, systematic screening in risk groups to detect presumptive TB earlier. It does this almost entirely without requiring human resource support. The technology can be used for all men,
women, and children above four years old. It’s available as an online and offline version which enables AI algorithms to perform rapid automated chest radiograph readings without an internet connection.

Wellness on Wheels (WoW)

Delft Imaging leads partner, KNCV Tuberculosis Foundation, with its Wellness on Wheels (WoW) trucks, as part of the Challenge TB project—the primary vehicle for delivering USAID’s objective of a world free of TB. In Nigeria, the WoW trucks are deployed across the country to locate TB cases in TB hot spots and hard to reach locations, assisting in case detection and reducing the turn-around-time of test results. Additionally, in response to COVID-19, testing capacity integrated into the WoW trucks enables bi-directional screening and diagnosis of TB and COVID-19.

The WoW trucks leverage Delft Imaging’s OneStopTB clinic technology. The OneStopTB clinic is a mobile all-in-one diagnostic, testing and treatment center designed to be taken to remote and hard-to-reach areas. OneStopTB combines digital X-ray with the proven CAD4TB and Xpert MTB/RIF test. In the absence of human expertise, the CAD4TB program enables speedy and accurate TB detection with high daily throughput of up to 300 people.
Uganda National Tuberculosis & Leprosy Programme

Delft Imaging’s Delft Light, Delft Ultra, and CAD4TB solutions help the Uganda National Tuberculosis and Leprosy Programme (NTLP) fight TB and leprosy. Delft Imaging offers two portable battery-powered digital X-ray systems for TB screening: Delft Light (backpack X-ray) and Delft Ultra (ultra-portable X-ray). The system includes a powerful and portable X-ray that produces high-quality X-ray images. It can be carried by a small group of healthcare workers set up within 30 minutes.

The NTLP uses these portable backpack solutions to help enhance TB diagnosis in five regions where radiologists and other resources are scarce. By bringing state-of-the-art TB detection services closer to distant locations and high-risk groups, the NTLP hopes to cut TB incidence by 20% under the new National Strategic Plan.
Dimagi is collaborating with ADPP Mozambique, a non-governmental organization that promotes quality education, health and well-being, environmental protection, and sustainable agriculture. Dimagi is also working with members of the Infomovel consortium to improve, construct, and assist the integration of TB components into their existing digital platform. This work will contribute to USAID’s TB Local Response project, a five-year initiative aimed at empowering local institutions and communities to provide high-quality TB services based on patient-centered care. The project also enhances Mozambique’s overall TB response operations, enhancing the reporting and success of recognized TB and MDR TB cases, which will have an impact on the formulation of a new national TB strategy.

By using existing Infomovel workflows and expanding app usage to 400 more users in other regions, these software changes will integrate TB treatments on the ground with the Ministry of Health’s TB program, improving early detection and treatment of TB cases across Mozambique.
Mobile phones promise better TB care for Indian hard-to-reach districts

In 2013, the International Union Against Tuberculosis and Lung Disease, in conjunction with Eli Lilly and Dimagi, started a pilot initiative to deploy mobile phone technology to improve TB care in the Indian tribal district of Khunti. Rural health care providers (RHCPs), lab technicians, and nongovernmental organization workers have all received Commcare-enabled phones as part of the programme. This open-source mobile application allows health workers to track potential TB patients within a given area. RHCPs can use the app to submit patient information into a referral database. Once patient’s tests are completed, lab technicians can use the same database to inform the RHCPs and patients of the results so that treatment can begin if necessary. The project, which benefits over 300,000 people, shortens the time it takes for test results to be communicated and improves access to healthcare in rural areas.
Digital Adherence Technologies to support patients during recovery: 99DOTs, Video-observed Therapy (VOT), and evriMED devices

In Ukraine, through a grant from the Stop TB Partnership’s funding mechanism, TB REACH, a consortium of partners with TB and technology experience, supports the adoption of digital adherence technologies (DATs) to help patients recover from TB. Ukraine is one of the five countries in the WHO Euro Region with the most people living with TB.

Ukraine’s grant funds 4 programs that are core to strengthening TB response:

1. PATH, a global health-focused international non-profit, leads project activities
2. Labor and Health Social Initiatives (LHSI), a Ukrainian NGO, implements field activities, trainings and facility-based monitoring
in Ukraine.

3. Everwell Health Solutions develops, customizes, and deploys the Everwell Hub open-source platform to support the project’s technical infrastructure and give expertise and experience in deploying DAT solutions at scale.

4. KNCV, a collaborative effort by several private local TB control initiatives in the Netherlands provides technical assistance. KNCV supports PATH in the demonstration of automatic dose monitors called evriMED devices (locally called medication “smartboxes”) and video-supported treatment (video DOT or VOT) to assist patients in treatment adherence.

Before a patient moves to ambulatory (outpatient) care, they are provided an evriMED electronic dose monitor box. Medical personnel fill the boxes with medication, activate the device, and instruct the patient on how to use it. When the box is opened, a sensor in the device sends a signal to the central system, signaling that a dose has been taken. This allows for remote monitoring of the patient’s medicine intake. The device is designed to create audio and visible (LED light) reminders for dosing, needed prescription refills, and low battery alarms to assist the patient with treatment adherence.

PATH, LHSI, and KNCV’s application in Ukraine is only one example of how DATs are being used to help patients. India used DATs to help over 300,000 patients, and other countries such as Myanmar, the Philippines, Bangladesh, Kyrgyzstan, Uganda, Tanzania, Ethiopia, Namibia, and many others have deployed DATs with Everwell’s help.
The TCOLF (Tres Cantos Open Lab Foundation) was founded by GSK in 2010 to provide funding and support to researchers from universities, not-for-profit organizations, other research institutes, and industry to develop and advance ideas that could lead to new medicines to treat diseases that primarily affect the developing world.

External scientists can use the TCOLF model to travel to GSK’s Tres Cantos R&D campus and work from the Open Lab for an extended period, using GSK’s compound library, screening tools, disease models, and discovery and development expertise to advance their own research priorities and projects as part of an integrated team. GSK has also donated GBP 15 million to the project since 2010, in addition to its space and scientific research resources. Contributions were provided in two tranches: a GBP 10 million contribution in 2010 and a GBP 5 million contribution in 2018. Malaria, TB, kinetoplasms (such as Leishmaniasis and Chagas disease), and gut health are currently the focus of TCOLF studies. Its founders believe that the unique model will help accelerate SDG 3 by shortening long R&D cycles.
10-year Initiative

To end TB, Johnson & Johnson is collaborating with governments and local partners in high-burden countries like India, China, South Africa, Ukraine, and Southeast Asia. Johnson & Johnson launched a 10-year effort to combat TB in September 2018. The program focuses on three main areas: better diagnosis, increased access to medicines, and aiding the research and development of new TB treatments.

Finding the Missing Millions of Undiagnosed People Living with TB

Johnson & Johnson has engaged in multiple collaborations aimed at advancing efforts to find and provide care for millions of undiagnosed adults and children living with TB.
**MTV Nishedh Initiative in India**
With the help of a Johnson & Johnson educational grant, the MTV Staying Alive Foundation and Viacom18 Media Pvt Ltd created MTV Nishedh, a groundbreaking national media and “edutainment” campaign that reaches young people through TV, radio, and digital content to combat stigma in India. The show uses dramatic storylines and fictional characters to educate viewers about the realities of living with TB, including how to be tested and access treatment. It also highlights the common myths and misperceptions that prevent people from seeking the help and support they require.

**Project inSight collaboration on adult patient finding**
Johnson & Johnson is improving TB detection programs for adults. In selected high-burden countries, Johnson & Johnson is collaborating with the Global Fund to fight AIDS, TB, and Malaria to raise awareness on the difficulties in identifying DR-TB patients. By combining the Global Fund’s scale and reach with Johnson & Johnson’s unique expertise in consumer and patient insights, new strategies are amplifying efforts to identify, engage and support people living with DR-TB.

**Collaborating to Diagnose More Children with TB**
To combat pediatric TB, Johnson & Johnson is collaborating with USAID, PATH, and Aquity Innovations. The partnership with USAID builds local capacity to combat pediatric DR-TB in high-burden nations, by assisting local healthcare practitioners to develop programs that better identify children with the disease. In Vietnam, Johnson & Johnson expanded its Breath 4 Life partnership with PATH, helping to scale successful pediatric DR-TB case finding initiatives first piloted in rural parts of the country. In South Africa, Johnson & Johnson is working with Aquity Innovations to support capacity building and enhance contact tracing efforts focused on adolescents and children with DR-TB.

**China Case Finding Strategic Partnership Program**
In 2018, Johnson & Johnson partnered with the National Health Commission (NHC), China CDC and Cepheid to improve TB/MDR-TB patient detection for 10 million individuals in impoverished areas by introducing quick diagnostic technology and performing medical trainings for local health care providers.
Sirturo® Access and Stewardship

Johnson & Johnson works with partners to make MDR-TB medicine available, affordable and accessible to patients in need around the world. To date, more than 390,000 courses of Sirturo® (bedaquiline) have been delivered to 95% of the global distribution of global DR-TB disease burden, that is 146 countries including the 30 highest-burden countries for TB.

Johnson & Johnson and the Stop TB Partnership, with additional support from the Global Fund and USAID, announced joint efforts aimed to accelerate scale-up of WHO-recommended all-oral treatment regimens in resource-limited settings in July 2020. The partnership not only helps to reduce the price of Sirturo®, but it also allows them to offer a higher percentage of free commodities if annual volume targets are met. These targets are set during the UN High-Level Meeting on TB.

Johnson & Johnson promotes the safe and appropriate use of Sirturo® in collaboration with multisectoral partners, with a focus on TB drug stewardship through continuing medical education (CME) activities and the dissemination of relevant resources to physicians who request information about the product. Johnson & Johnson sponsors virtual CME programs with a focus on how to implement WHO guidelines on all-oral MDR-TB regimens into national treatment paradigms, leveraging the expanding usage of online platforms. For example, in the Philippines, Johnson & Johnson and local partners created the TB Academy, an online learning platform targeted at furthering the education of Filipino healthcare practitioners and specialists in treating MDR-TB, with backing from the International Union against TB and Lung Disease. For clinical officers and nurses, clinicians, and DR-TB experts, the TB Academy program offers three levels of certification training.

Johnson & Johnson also supported an initiative by USAID to strengthen national capacity for pharmacovigilance in high MDR-TB incidence countries. The initiative included three regional workshops (in Asia, Eastern Europe and Africa) during which countries developed pharmacovigilance roadmaps to guide the implementation of WHO’s active TB drug-safety monitoring and management (aDSM) framework. The framework helps incorporate reporting structures for enhancing coordination and partnership to introduce and scale-up new TB drugs. Johnson & Johnson also conducts a TB drug resistance surveillance program in collaboration with WHO-recognized reference laboratories and is supporting development of drug susceptibility testing modalities in collaboration with external partners.

CONTRIBUTES TO SDG:

3. Good Health and Well-Being
4. Quality Education
9. Industry, Innovation and Infrastructure
Since 2015, Otsuka’s FighTBack Initiative has worked to increase delamanid access in all LMICs with high TB burdens, as well as pursue novel TB R&D for safer and shorter oral pan-TB regimens. The initiative’s overarching goal is to ensure that at least 20% of persons diagnosed with and treated for MDR-TB can get delamanid as part of their treatment.

The initiative has four key prongs: innovative R&D, increasing responsible access, improved patient management, and collaborative capacity building. As part of the initiative Otsuka also participates in a number of collaborative studies, such as MSF’s endTB project. Further, Otsuka announced in 2016 that it would partner with the Stop TB Partnership’s Global Drug Facility, allowing about 100 LMIC eligible countries to access delamanid.
Mycobacteriology Laboratory Manual

Otsuka partnered with the WHO’s Global Laboratory Initiative (GLI) working group of the Stop TB Partnership to develop and launch a Mycobacteriology Laboratory Manual. The Manual was developed to ensure high-quality and comparability of data between leading TB laboratories in China, Egypt, Estonia, Japan, Korea, Latvia, Peru, the Philippines and the United States. Provided in the Manual are standard processes for sputum collection, handling, analyses, and reporting, focused on testing related to MDR-TB clinical trials. The standardized procedures in this manual will help global efforts to strengthen testing and surveillance measures, while also providing best practices from an R&D perspective.

CONTRIBUTES TO SDG:

3. GOOD HEALTH AND WELL-BEING
4. QUALITY EDUCATION
9. INDUSTRY, INNOVATION AND INFRASTRUCTURE
10. REDUCED INEQUALITIES
17. PARTNERSHIPS FOR THE GOALS
Memorandum of Understanding with FIND

In 2015, QIAGEN entered into a five-year memorandum of understanding (MoU) with FIND to accelerate the development and uptake of new diagnostics for TB. FIND is a Geneva-based NGO that works towards the faster development and delivery of high-quality, affordable diagnostic tests for diseases of poverty. The five-year agreement between FIND and QIAGEN specifically aimed to address three key diagnostic areas. The key diagnostic area of being pursued by QIAGEN are tests to enable targeted TB preventive therapy.

FIND and QIAGEN aligned on definitions and standards for evaluating diagnostic technologies that can detect latent to active illness progression as the first engagement under the MoU. QIAGEN focused on developing additional tests to detect resistance to specific components of new TB treatment regimens later in the relationship, and FIND gave QIAGEN access to its biobank of TB specimens to help in this project.

CONTRIBUTES TO SDG:

10

QIAGEN

- 3 Good Health and Well-Being
- 9 Industry, Innovation and Infrastructure
- 17 Partnerships for the Goals
Workshop on TB Infection

In 2017, QIAGEN partnered with Friends for International TB Relief (FIT) to host a workshop in Vietnam on TB management. The workshop brought together key stakeholders from two major TB projects in the country: Zero TB Viet Nam and IMPACT TB. In addition to representatives from the two TB projects, the workshop also welcomed TB experts, public health practitioners, community representatives, technicians, and leaders from Vietnam’s National Tuberculosis Programme. Workshop participants brainstormed solutions to common problems, shared information on emerging best practices in TB care, and learned about new technologies for both diagnosing and treating TB.

IMPACT TB and Zero TB Viet Nam both focus on case-finding through contact-tracing and screening for latent TB utilizing tuberculin skin tests and interferon gamma release assays. Participants in the workshop addressed strategies for increasing latent TB infection screening and heard about new screening modalities, such as QuantiFERON Gold Plus.

At the conclusion of the workshop, participants were aligned around the prioritization of the following three interventions: 1) patient and household contact counseling; 2) the use of alternative, shortened treatment regimens; and 3) capacity-building for community- and district-level TB officers.

In December 2020, QIAGEN collaborated with the APEC STOP TB Partnership to host an APEC TB virtual event to discuss TB preventive initiatives. Expert panel discussions were held to learn how countries may continue to fight TB in the COVID era.
Latent TB Screening on the workplace

In May 2019, QIAGEN and Sante En Enterprise (SEE), a French non-governmental organization, signed an MoU to tackle latent TB in the workplace. The partners undertake events and activities to raise awareness of latent TB and to reduce TB in the workplace as part of the MoU. Latent TB testing is now included in SEE’s multi-disease screening package for firms in West and Central Africa via mobile screening units. The project educated company HR managers and occupational health doctors about latent TB Infection and the cost-effectiveness of prevention strategies. As a result, several companies have joined the project, which includes annual screenings. The program is so influential that the National TB Program of Cote D’Ivoire has requested funding to ensure the projects long-term viability.

Additionally, on World TB Day 2021, QIAGEN and SEE worked with five major companies to screen their workers for latent TB. People found positive were given counselling via their company’s occupational health doctor, to ensure appropriate follow-up and preventive treatment if necessary.

CONTRIBUTES TO SDG:

- Good Health and Well-being (3)
- Industry, Innovation, and Infrastructure (9)
- Reduced Inequalities (10)
- Partnerships for the goals (17)
Sanofi

Optimizing access to TB treatment

In October 2019, at the UNION conference, Sanofi and their partners signed a landmark agreement with Unitaid, the Global Fund, and several other funders and programs. Thanks to this innovative agreement, Sanofi will offer a significant discount on the price of rifapentine, a critically important drug used to prevent TB. In the public sectors of 100 LMICs burdened by TB and TB/HIV co-infection, the volume-based agreement reduced the price of a three-month treatment course of rifapentine by about 70%, from approximately US$45 to US$15. The agreement should help to boost efforts to cure latent TB infection by increasing access to better preventive medicine.

Stakeholders praised the new agreement, expecting that effective TB prevention will be a game-changer in the worldwide campaign to eradicate TB. The commercial approach widens access to the new standard of care for latent TB infection. The substantially lower cost of rifapentine allows the Global Fund, PEPFAR, USAID and the Stop TB Partnership’s Global Drug Facility, to make it more widely available in LMICs.
Partnership with Weill Cornell

Sanofi and Weill Cornell Medical College entered a knowledge sharing agreement in 2011 to develop a shorter treatment course for TB with funding from the Bill & Melinda Gates Foundation. Under the terms of the collaboration, Sanofi provided 80,000 chemical compounds to Weill Cornell’s laboratory for screening to discover new agents that show promise for optimization and further development. The goal is to create new therapeutic approaches to treating TB.

In 2019, researchers at Weill Cornell published a study on the success of one such drug candidate (8918) in blocking the activity of an enzyme called phosphopantetheinyl transferase that is essential for building the waxy coating that protects the bacterium and contributes to its virulence.

Sanofi and Weill Cornell expanded their partnership through the TB Drug Accelerator Program in 2012, joining other pharmaceutical companies and research institutions aiming to speed discovery of new treatments for TB.
SureAdhere

TB REACH’s Wave 6 & 9, UNITAID ASCENT Project

As part of TB REACH’s Wave 6 & 9 programs, and the UNITAID funded ASCENT project, SureAdhere is partnering with the StopTB Partnership and Everwell Health Solutions to promote video observed therapy (VOT) supporting adherence to TB treatment regimens for both DR- and DS-TB patients globally. Medical providers can use VOT to support patients who are having trouble adhering to rigorous treatment requirements by adjusting as needed.

SureAdhere’s VOT platform was robustly evaluated in several high- and low-TB burden settings in the U.S., Mexico, the United Kingdom, Vietnam, and Uganda. As a result of this experience and strong evidence base, the company is supporting programmatic evaluations and county-wide VOT adoptions for TB in Eswatini, Haiti, Ukraine, Philippines, Kyrgyzstan, Singapore, Ireland and Switzerland.

SureAdhere is also a technical partner with the UNITAID-funded ASCENT (Adherence Support Coalition to End TB). Through this grant, VOT will be implemented with over 10,000 TB patients in South Africa, Ukraine, Philippines, Tanzania and Ethiopia.
SystemOne

Aspect and Aspect Reporter in Nigeria

SystemOne is working with NTBLCP (the National Tuberculosis, Leprosy and Buruli-ulcer Control Program) to upgrade Nigeria’s existing GxAlert network to SystemOne’s new disease intelligence software platform, AspectTM. Aspect is a multi-disease, multi-device connectivity solution that allows real-time result reporting through a powerful notification engine for rapid delivery of results to healthcare providers, patients and other stakeholders. Aspect is supporting the entire GeneXpert testing fleet and will also integrate with E-TB Manager and DHIS to improve the management of TB patients in Nigeria. In addition, SystemOne is deploying Aspect Reporter, a mobile application, to 1050 DOTs centers (across 201 sites in five states) for faster results reporting and more accountability by ensuring that positive TB results are linked to treatment.

CONTRIBUTES TO SDG:

- Good Health and Well-being
- Decent Work and Economic Growth
- Industry, Innovation and Infrastructure
- Partnerships for the Goals
Improving TB patient management in Philippines

The impact of linked diagnostics on TB and DR-TB patient treatment is being assessed by innovative research as part of the 2020 partnership between the Philippines National TB Control Program and the National TB Reference Laboratory. Although the Philippines has a high TB burden and a high frequency of MDR-TB, diagnostic reporting is currently paper-based, resulting in considerable delays in results and treatment, especially in remote facilities. The project integrates Aspect to a subset of GeneXpert and MGIT culture devices, as well as the line probe assay (used for drug resistance testing). The aim of the project is to deliver rapid digital results directly to patient care, reducing patient loss to follow-up and improving turnaround times for TB and DR-TB treatment initiation.

CONTRIBUTES TO SDG:
Pretomanid Commercialization Collaboration with the TB Alliance

In April 2019, Viatris (through its subsidiary Mylan) entered a global partnership with TB Alliance, a not-for-profit drug developer, to make the investigational drug pretomanid accessible to those who need it. The TB Alliance has been developing pretomanid since 2002, and the partnership with Viatris marked a major milestone towards its commercialization. The partnership provided Viatris with a global license to manufacture and commercialize pretomanid as part of two-regimens: an all-oral, six-month treatment consisting of bedaquiline, pretomanid and linezolid (“BPaL” regimen) to treat highly drug-resistant form of TB; and, an oral, 4-6 month treatment consisting of bedaquiline, pretomanid, moxifloxacin, and pyrazinamide (“BPaMZ” regimen) to treat drug-sensitive and MDR-TB.

In August 2019, the partnership obtained their first stringent regulatory approval for pretomanid as part of the BPaL regimen, followed by authorization by the EMA in August 2020. Viatris has led filings for the product in 26 LMICs and approvals by the Drug Controller General of India in July 2020 and South Africa in April 2021. Pretomanid is only the third drug developed to treat DR-TB in over 40 years.
Supporting the Indian Government’s Mission to End TB

In support of the Indian government’s National Strategic Planning efforts for 2017-2025, Viatris started a pilot project with AIDENT, a Delhi-based social welfare organization, to eradicate TB in a district of Uttar Pradesh. The initiative received policy support from the NITI Aayog, a local think tank. The program focuses on active case discovery and raises community awareness about the necessity of early TB diagnosis and treatment.

After a TB case is confirmed, active case finding includes case identification through family contact tracing and the distribution of door-to-door delivered questionnaires. Public awareness of TB rose through the distributing educational materials. The project also offered resources for healthcare staff to improve their TB management skills.

The survey efforts of the initiative reached almost 1 million people, and active case finding reached 1,235,280. Between December 2018 and May 2019, 969 new TB cases were reported and over 700 new TB patients were connected to the public health system.

To ensure equitable access around the world, Viatris took a tiered pricing approach to pretomanid. Pretomanid was made available to 150 nations through the Global Drug Facility only two months after receiving its first regulatory approval, for a cost of $364 per treatment course, or $2 per day. Taken with other drugs in the approved regimen, this made BPaL significantly more affordable than other competing regimens. As a result, Viatris, TB Alliance, and other partners supported a number of operational research programs across the CIS, South and Southeast Asia, and Sub-Saharan Africa, donating products to India, South Africa, Kyrgyzstan, and Uzbekistan, allowing for further research and access.
Conclusion

The WHO’s Global Tuberculosis Report 2021 – released in October 2021 – delivered alarming news to the global community: TB deaths are on the rise for the first time in over a decade, and we can reasonably expect deaths from the disease to continue to climb through 2021. Within the report, WHO Director-General Dr. Tedros Adhanom Ghebreyesus writes “the struggle to end TB is not just a struggle against a single disease. It’s also the struggle to end poverty, inequity, unsafe housing, discrimination and stigma, and to extend social protection and universal health coverage.” These are incredibly ambitious and worthy goals that will unequivocally require cooperation across sectors and disciplines. The TB challenge is urgent and complex. Decades of progress in the global fight against the disease have been undone in a mere 18 months, and regaining ground will require levels of commitment and cooperation across sectors that have been heretofore unseen in the infectious disease space.

Fortunately, private sector players like those companies engaged in the Stop TB Private Sector Constituency have a long track-record of engagement in the fight against TB, and can offer a blueprint for new players who wish to get involved. The private sectors’ efforts to end TB include making immense investments into R&D to bring new tools to the fight against TB, partnering with regional and national players to strengthen infrastructure and build health system capacity, offering diagnostics and surveillance solutions that are tailored to the often complex operating environments where TB is endemic, enabling access to life-saving treatments through product donations and the use of innovative pricing mechanisms, and offering trainings and workshops for local implementing partners and organizations.

Consortiums like the Stop TB Partnership’s Private Sector Constituency provide a forum for companies to come together, pool their resources, and share their unique areas of expertise with the aim of accelerating the fight against TB.

Join us!
The Private Sector Constituency to the Stop TB Partnership
Uniting Private Sector to Stop TB

The PSC is the private sector constituency to the Stop TB Partnership. We unite private-sector companies who have come together from all walks of life, leveraging shared knowledge, capabilities and commitment, to fight the tuberculosis epidemic. We do so through individual and collective action, awareness raising and, shaping global strategies - providing unique perspectives to the Stop TB Partnership.