

INDIA
HEALTH
FUND

A TATA TRUSTS INITIATIVE

INTERIM UPDATE

APRIL 2023





Contents

The IHF story: Catalysing India’s progress towards elimination of infectious diseases	1
Why we do what we do? – The Problem	2
What we do and How we do it?	2
Areas of our work: Identifying and enabling innovations across five key pillars	3
Our Portfolio	
1. Truenat– a fast PCR-based TB detection method to find the missing millions	4
2. qXR: an automated chest X-ray screening solution for tuberculosis	5-7
3. Moskeet: an intelligent surveillance solution to classify and predict mosquito-borne disease outbreaks	8
4. TMEAD: A digital pill-box that helps TB patients adhere to their treatment	9-11
5. Cutting down cattle to human transmission of TB	12
6. A 1-minute \$2 point-of-care differential diagnosis of Malaria	12-13
7. The world’s first point-of-care biomarker-based test to enable rapid and low-cost triage of potential TB patients	13-14
8. OmiX: A low-cost multiplex platform to detect and distinguish respiratory ailments COVID-19, influenza and TB	14
9. Autogene TB: An automated one-stop shop for TB diagnosis	14-15
10. A breakthrough RT-PCR test to speed the detection of drug resistance in TB patients from 4 months to 2 weeks	15-16
11. Specially designed non-invasive device to aid sputum sample collection in children to improve diagnosis of paediatric TB	16-17
12. Artificial Intelligence-based detection, parasitic load calculation and species differentiation for faster and accurate diagnosis of malaria	17-18
13. A fever panel to detect dengue, chikungunya, and malaria	18
14. Non-invasive patient-friendly AI-led platform that can detect active TB cases in minutes on mobile phones by reading cough signatures	18-19
Partnerships – Stronger together	20-21

The IHF story: Catalysing India’s progress towards elimination of infectious diseases



In 2015, the United Nations set the Sustainable Development Goals (SDGs) as ambitious targets for a better and more sustainable future by 2030. Among the 16 Global Goals, SDG3 was to be a roadmap for “good health and wellbeing”. SDG 3.3 specifically was set to “Fight Communicable Diseases” and to end by 2030 the epidemics of AIDS, tuberculosis, malaria and neglected tropical diseases and combat hepatitis, water-borne diseases and other communicable diseases. Infectious diseases were, and continue to be, a burden not just to health and wellbeing of countries but also to economies, with India bearing large proportion of the global burden of disease.

It was at this juncture in 2016, that the Tata Trusts launched the India Health Fund (IHF) in a strategic partnership with The Global Fund to Fight AIDS, Tuberculosis and Malaria. IHF was to be a pioneering vehicle designed to serve as a trusted mechanism to generate significant impact in addressing key health challenges in the country – starting with infectious diseases malaria and tuberculosis.

Since then, IHF has been de-risking the development of promising technology and science-led solutions that have the potential to make a significant difference in the diagnosis, treatment, and prevention of communicable diseases. IHF collaborates with the public and private sectors to facilitate the development, adoption, and scaling of these solutions. IHF’s aim is to improve health outcomes, with a focus on primary care and in low-resource settings.

On the launch of IHF,
Mr. Ratan Tata,
the chairman of Tata Trusts, had said:

“The India Health Fund is an ambitious project undertaken by Tata Trusts along with The Global Fund and the Government of India. Infectious diseases such as Malaria and Tuberculosis though widespread are treatable and controllable. In order to overcome the challenges associated with this issue, we should use innovations to create models that are not geographically bound and can be replicated anywhere in the world. The India Health Fund will endeavour to combine innovation and effort for the implementation of the project at a large scale.”



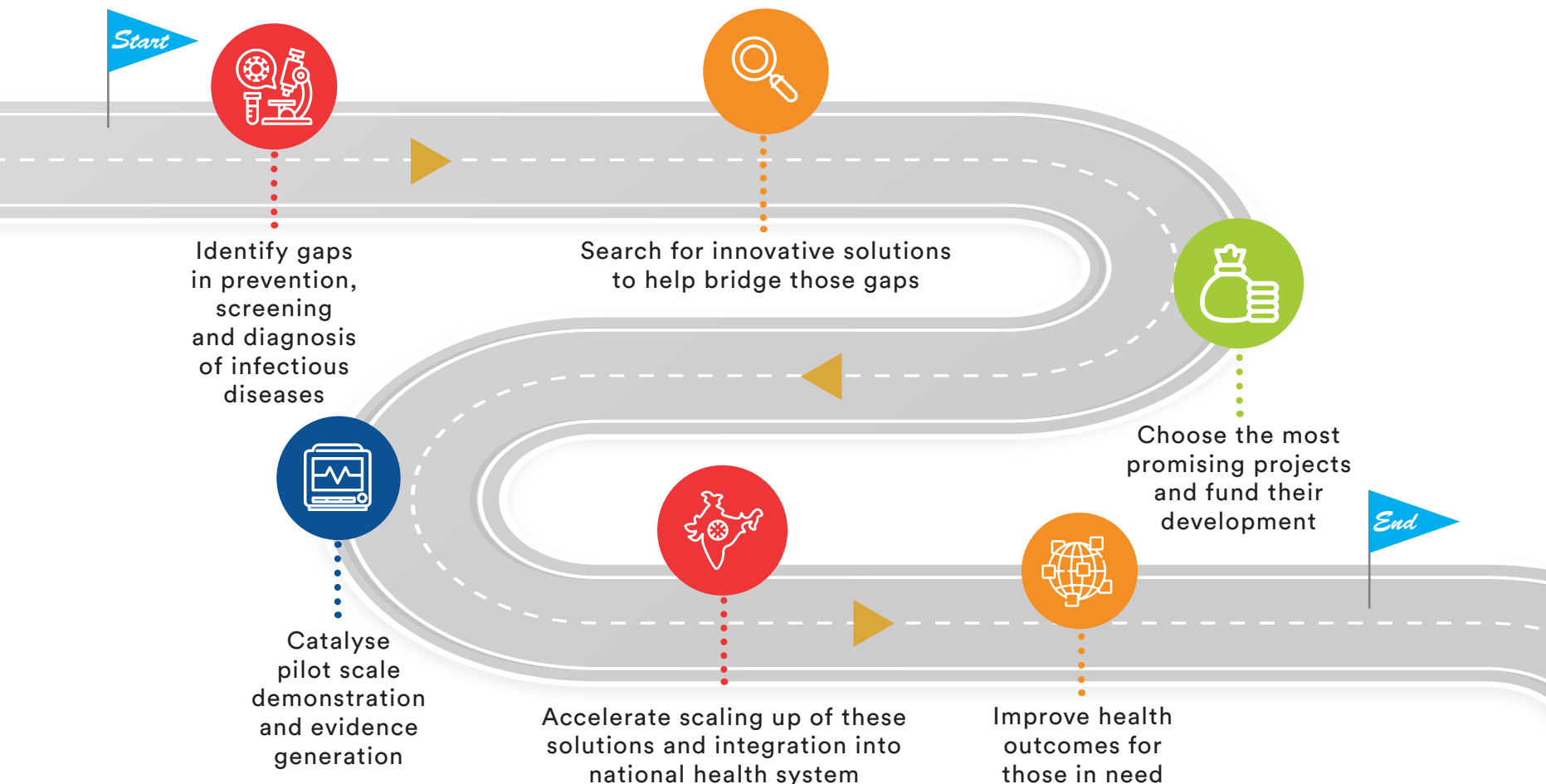
WHY WE DO WHAT WE DO? – The Problem

The United Nations set SDG goal 3.3 in 2015 towards the global elimination of communicable diseases by 2030. Yet, communicable diseases continue to be 4 of the top 10 causes of death in low- and middle-income countries with India accounting for >25% of world's TB burden and bearing 82% of South-East Asia's malaria deaths. Even though the SDG 3.3 roadmap is in place since 2015, current programmatic approaches have fallen short in achieving the global and national goals of elimination of communicable diseases. This situation has been worsened by COVID-19; e.g. there was an annual decline of 24% in TB notifications and TB-related deaths increased by 13%. Infectious diseases are also a threat multiplier with ~150-200 million Indians likely to fall into poverty from the impact of infectious diseases. Science and technology can play the powerful role of a force-multiplier for programmes. This is where India Health Fund steps in.

WHAT WE DO and HOW WE DO IT?

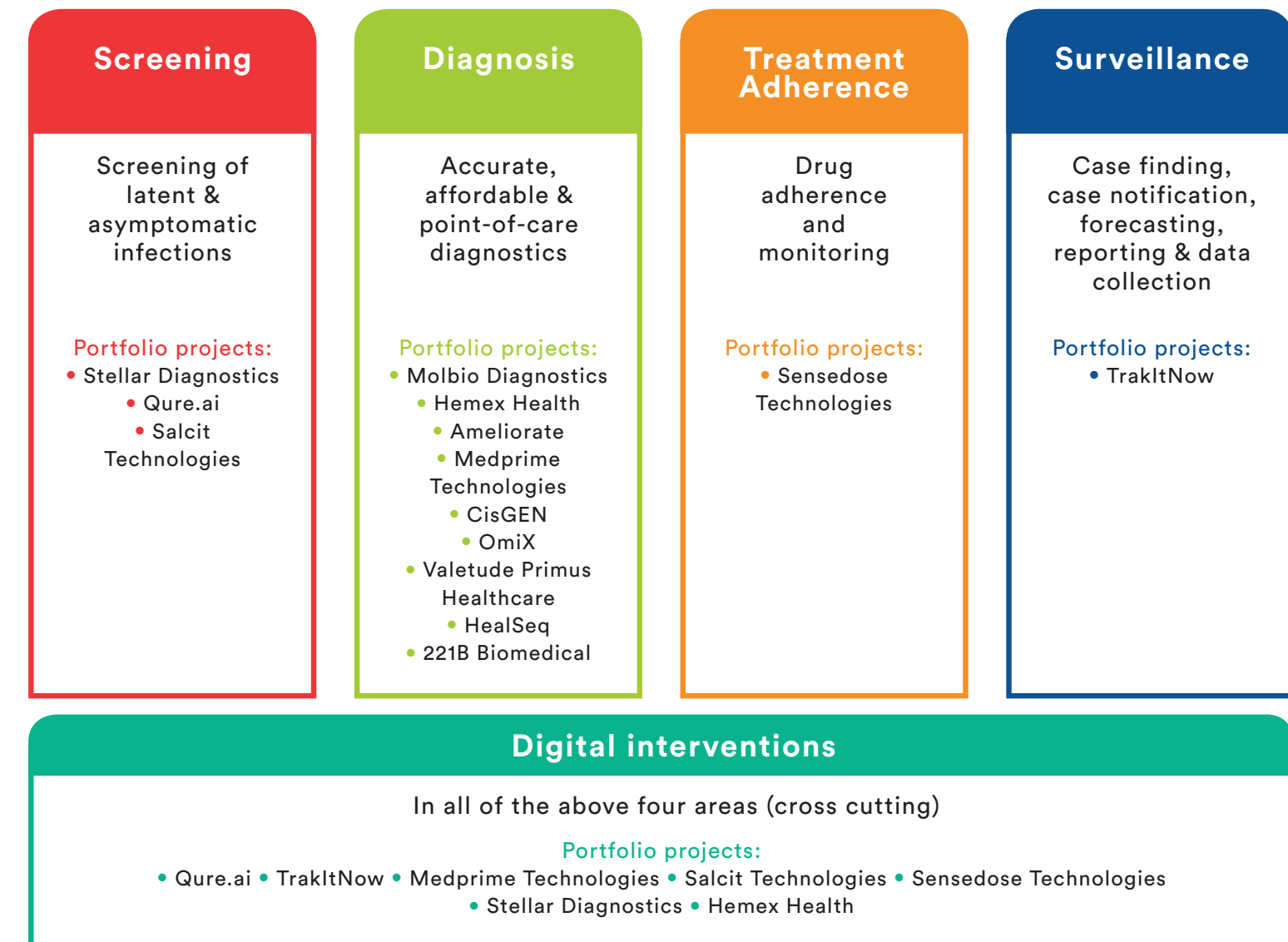
End-to-end support for transforming an idea to large-scale impact

As a partner, financing mechanism, connector and ecosystem facilitator, IHF enables the lab to last mile journey for game-changing innovations through the following steps:



AREAS OF OUR WORK:

Identifying and enabling innovations across five key areas





Our Portfolio

1. Truenat – a fast PCR-based TB detection method to find the missing millions

The absence of specialized testing facilities and skilled technicians to diagnose TB, results in several cases going undiagnosed (“the missing millions”), thereby hampering efforts to eliminate the disease around the world. TB patients in low-resource settings lack access to accurate and rapid TB diagnostic tests at point of care leading to delay in diagnosis and treatment initiation.

To address this need, IHF engaged with Molbio Diagnostics for validation of Truenat. Truenat is a compact, chip-based, battery-operated RT-PCR system which provides test results at the point of care within 90 minutes. This enables same day reporting and initiation of evidence-based treatment of TB, which reduces the risk of infection spreading while waiting for test results and facilitates faster recovery due to early initiation of treatment. It is significantly cheaper per test than other RT-PCR tests and needs minimally trained manpower at community health centres. Furthermore, Truenat is a multiplexing platform which supports tests for several diseases, including COVID-19, making it a cost effective and capital efficient solution.

How Truenat is making an impact?

- IHF-supported deployment of Truenat in two districts in Uttar Pradesh demonstrated significant improvement in testing presumptive TB patients – with 92% of the samples tested reporting results on the same day. Treatment initiation time improved by 45% as compared to the baseline, and 96% patients initiated their treatment within seven days of

test results. Truenat was also validated for effectiveness as a TB/COVID-19 diagnostic test at community health centres in Uttar Pradesh with support from India Health Fund.

- IHF with The Foundation for Innovative New Diagnostics (FIND) and Municipal Corporation of Greater Mumbai (MCGM) successfully implemented India’s largest bi-directional testing for TB and COVID-19 using Truenat in five high volume COVID-19 tertiary hospitals. The initiative screened more than 17,000 antigen negative symptomatic patients, and 13,500 COVID-19 OPD walk-ins went through the TB questionnaire followed by diagnosis using Truenat. Of these, 2.7% (379) were identified as TB presumptive and 78% (297) were tested for TB (until September 2021).
- Truenat is currently in use nationally by Central TB Division with 5000+ machines being deployed for TB diagnosis¹.
- Through a global pricing agreement signed in March 2023, Truenat has just been approved for worldwide adoption by the Global Fund, StopTB Partnership and USAID².



¹https://www.business-standard.com/article/companies/molbio-diagnostics-looking-to-expand-test-menu-on-its-truenat-platform-122083100814_1.html

²Global Fund, USAID and Stop TB Partnership’s New Collaboration With Molbio Diagnostics Will Increase Access to Rapid Molecular Tests for TB - News Releases - The Global Fund to Fight AIDS, Tuberculosis and Malaria



2. qXR: an automated chest X-ray screening solution for tuberculosis

Quick diagnosis of TB continues to be a challenge. Screening an X-ray to look for changes in the appearance of lungs that are suggestive of TB is a workforce-heavy and time-consuming process. With India facing an acute shortage of trained radiologists, getting confirmed TB diagnosis can take weeks leading to missed TB cases, increased disease spread, delayed initiation of treatment and higher risk of mortality.



IHF and Qure.ai identified this problem and developed a breakthrough AI-based chest X-ray screening software – qXR. qXR rapidly classifies X-ray scans, identifies lung abnormalities and highlights them

on the X-ray, enabling the detection of TB within minutes, and linkage to treatment on the same day. The trained AI algorithm-based software identifies abnormalities from the chest x-ray for TB with 90% sensitivity, which is equivalent to that of radiologists as evaluated by WHO. CE certified, the qXR software, is trained and tested on over 4.2 million chest X-rays using deep learning. qXR is not only more accurate with upto 33% additional TB cases detected, but also affordable projected at INR 100 per test and can be used easily at primary health centres, without need for radiologists.

How qXR is making an impact?

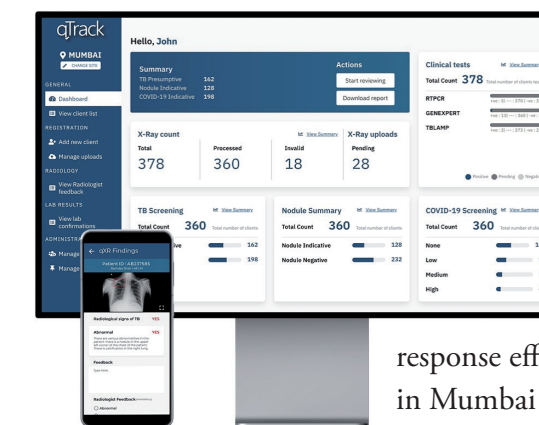
- Under IHF supported pilot, around 54,000 patients have

³Case study template_Baran_Redigned_20_07_2022 (qure.ai)

⁴[https://www.thelancet.com/journals/landig/article/PIIS2589-7500\(21\)00116-3/fulltext](https://www.thelancet.com/journals/landig/article/PIIS2589-7500(21)00116-3/fulltext)

been screened for TB using qXR in more than 72 sites across 14 Indian states and 17500 TB cases have been identified as presumptive TB cases.

- With qXR there has been a reduction in diagnosis turnaround time, with referral for confirmatory diagnosis becoming possible within 2 mins and time for linking the patient to TB care continuum on same day of screening. A comparative analysis of the treatment enrolment time before and after the software was deployed in a tertiary care centre in Rajasthan showed a 2.5 day reduction in treatment enrolment time, from 5.7 days to 3.2 days after introduction of qXR³.
- Owing to its high sensitivity (more than 90%), the use of qXR has reduced the requirement of follow-on testing by 50%.⁴
- qXR’s deployment has led to 20% increase in identification of incidental cases in seven peripheral hospitals in Mumbai.
- qXR has been independently evaluated by WHO against a library of digital radiographs and associated clinical data that has included it as part of its updated guidelines on TB screening
- qXR was adapted for triaging COVID-19 along with TB. IHF facilitated the fundraising and deployment of the qXR



solution for COVID-19 with the Municipal Corporation of Greater Mumbai (MCGM) bolstering its COVID-19

response efforts across 15 sites in Mumbai and resulting in processing of 25000 chest X-rays and reduction in COVID-19 detection time to under a minute.



Partnership Of Hope: A photo story on how Qure.ai & India Health Fund are revolutionizing TB Care in Nagaland

Nagaland's District Mon is one of the remotest parts of India where mountainous terrain brings difficulties in daily life and healthcare.



District Hospital, Mon is a prime location not only for TB patients from Nagaland but also from Myanmar.

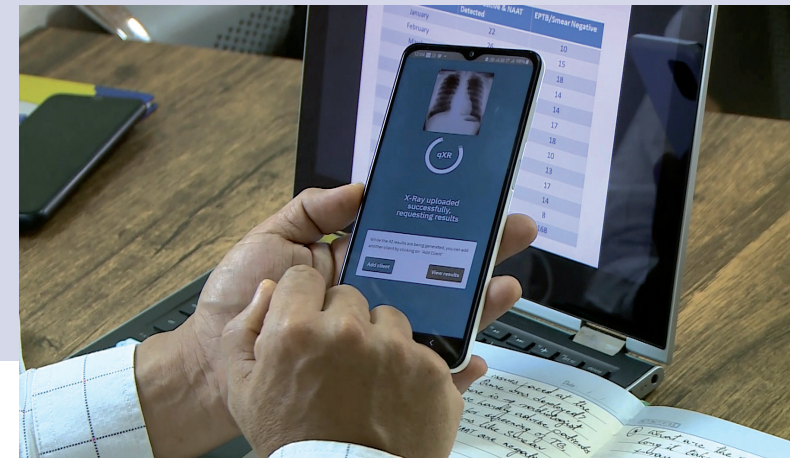
A remote geography with an understaffed hospital mean long patient queues, lag in diagnosis of transmissible diseases like TB, missed diagnosis, and delays in treatment.



Even for those who do manage to go through TB testing, the process in Mon TB center is long and complicated.



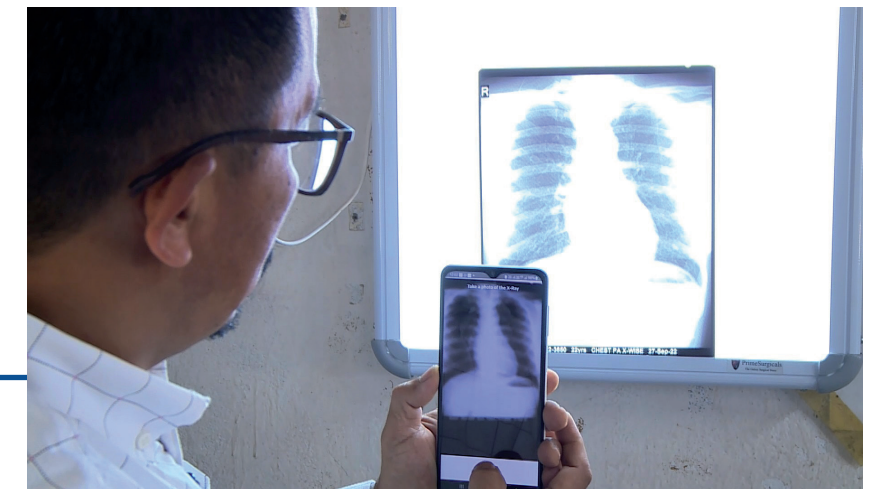
Meet Dr Tinenlo James Katiwa, Mon District TB Officer. *“We have a lot of patients, especially from remote places. We do not have a radiologist in Mon District hospital or in any other hospital here. (Thus) using simple X-ray as a screening tool (for TB) was not possible. We went for other more complex and expensive tests”.*



It was at this juncture that qXR came to the notice of the authorities. qXR classifies X-rays, identifies lung abnormalities, enabling TB detection within minutes.

qXR has brought hope to hundreds of patients and supported the burdened health workers like Dr. Tinenlo. *“After qXR was introduced, we started to use X-rays and it has helped our TB programme.”*

“In a remote place like Mon, it (qXR) has benefited many patients. This has reduced the testing turnaround time”.



Mon is one of the many success stories in the Qure. AI – IHF partnership to empower remote and resource-constrained hospitals in TB-burden areas in India to tackle the problem of missed cases and improve clinical decision-making.



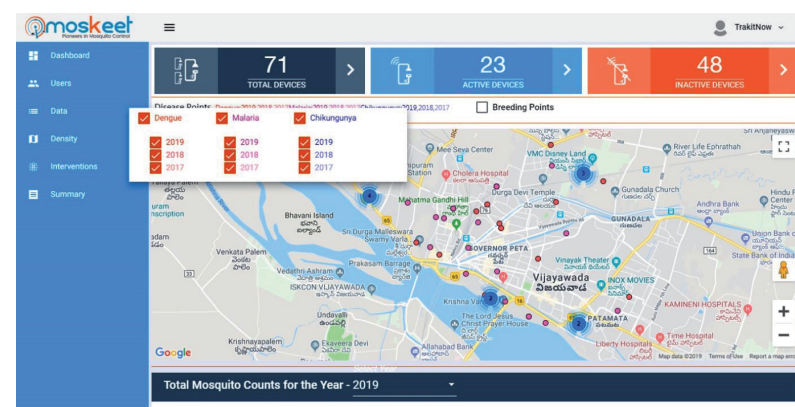
3. Moskeet: an intelligent surveillance solution to classify and predict mosquito-borne disease outbreaks

The mosquito is the most dangerous animal on Earth due to its ability to transmit vector-borne diseases like Malaria, Dengue and Zika. In India alone, there were 3.37 lakh cases of malaria and 1.30 lakh cases of dengue between April 2020 and March 2021. Moreover, the elimination of malaria by 2030 is estimated to add \$4 trillion to the Indian economy.

Most vector-borne diseases are not preventable by vaccines and can be controlled only through an integrated approach that includes surveillance, vector control, prompt case detection, and health awareness.

Currently, vector surveillance depends on manual methods to catch, collect, count and classify mosquitoes, and requires expert entomologists for analysis and reporting. The delay caused by manual processes and the shortage of entomologists makes timely vector control activities difficult to implement.

To tackle this problem IHF engaged with TraktItNow to develop Moskeet, which is the world's first commercially available smart



mosquito trap that can autonomously identify and count broad spectrum of mosquito species based on their wing beat frequencies using artificial intelligence and internet of things. By transmitting live data to central surveillance centres, Moskeet enables effective vector surveillance, determines hotspots in real time and ensures fast and efficient management of Malaria, Dengue, Chikungunya, Japanese Encephalitis and Zika Virus. Moskeet



gathers and interprets disease surveillance data 20 times faster, 3 times more accurately, and at 15% of the current cost of manual methods.

How Moskeet is touching lives?

Moskeet is being used by several communities across five cities in India (Hyderabad, Thiruvananthapuram, Panjim Smart city, Vijaywada, Yanam-Puducherry), touching lives of 3,25,000 people so far. The

innovation has already shown:

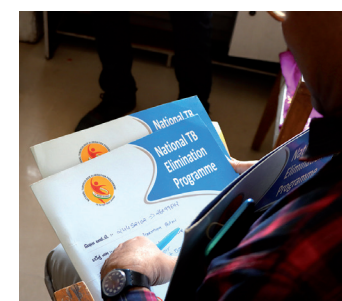
- Nearly 85% savings on surveillance with value addition of real-time data;
- Reduction in fumigation costs by 20% through identification of more effective pesticides; and
- Helped focus resources on high-risk areas, thereby reducing the mosquito populations by 60% and decreasing the disease burden by 40%

On the global stage, Moskeet was listed in the United Nations Development Program (UNDP) Solution Catalog, which is accessible by 170 country offices, where it can be considered for adoption and scaling up.

4. TMEAD: A digital pill-box that helps TB patients adhere to their treatment

One of the difficulties in TB treatment is its long duration, where patients must take medicines anywhere from 6 months-2 years. The side effects linked to the medications often drive patients to stop or skip doses. Globally, it is estimated that 30-50% of medication prescribed for long-term illness is not taken as directed. According to the WHO, around 10% of people with TB worldwide do not complete their treatment. As a result of treatment non-adherence, the illness returns, and the bacteria get an opportunity to develop drug resistance, making treatment difficult, and increasing disease spread. Currently, checking adherence depends on healthcare workers following up manually with patients.

IHF engaged with SenseDose Technologies on TMEAD (Tuberculosis Monitoring Encouragement Adherence Drive), which is a physical reusable device that helps TB patients successfully complete their treatment using digital adherence technology. The smart pillbox comes preloaded with 15 days of



prescribed pills that can dispense 18 tablets at a time, which are also pre-sorted by dose. Using Internet of Things & cellular network technology, TMEAD box reminds patients, dispenses medicines, monitors their uptake and rings a physical alarm as well

as sends digital reminders when patients miss their medication. Moreover, the pill box also notifies health workers in real time about patients' adherence to treatment, thereby easing their workload, enabling remote patient monitoring and improving case tracking. By categorizing patients based on their level of adherence, TMEAD helps healthcare workers provide differentiated care. It also helps them keep a track of patient prescription, which reduces the time a certain patient has to

spend at primary healthcare center, thus reducing the risk of spreading the disease. Finally, TMEAD is a Platform technology that can be used for any illness that has long treatment duration.

How TMEAD is touching lives?

- The device has been used by more than 800 patients undergoing treatment for drug-sensitive and drug-resistant TB till date in Maharashtra & Gujarat.
- TMEAD's health technology assessment was completed by IIPHG, Gandhinagar, showing high levels of treatment adherence in the TMEAD intervention group (99%) as compared to the control group (90%). The results have been published in the scientific journal Frontiers in Public Health.
- The health technology assessment of TMEAD by Dept. of Health Research (DHR) revealed that treatment adherence is high with TMEAD compared to standard therapy of care for DS-TB patients and the intervention is cost-effective with an incremental cost-effectiveness ratio INR 11,599 (USD 146), which shows that the intervention is highly cost-effective. The results have led the device being recommended to the Central TB Division (CTD) for use in the NTEP. Based on DHR's presentation to CTD, TMEAD will be required to be integrated in the Nikshay platform, which will allow reporting of patient treatment adherence on the platform and supplement TB case notification and monitoring efforts. Based on these positive outcomes, TMEAD is currently being recommended by CTD to the states.



It has become a part of the family:

A photostory on how TMEAD is supporting patients adhere to long and arduous TB treatments

Located underneath the Memco bridge, in one of Ahmedabad's most populated neighbourhoods, is Meghaninagar Urban Primary Health Centre (UPHC). One room in the centre is given to the National TB Elimination Programme. The room has a large window that opens into a courtyard and serves as a counter for dispensing medicines.



Meet 41-year-old Gaurang Vaghela, TB Health Visitor in charge of 169 patients. *“Meghaninagar has a large population living in slums, where an infectious disease like TB can spread rapidly. Our job is to detect cases early and make sure they are treated,”* he says.

Many patients have multidrug-resistant (MDR) TB, which is harder to treat and needs as many as 12 pills a day for months and adherence is a problem, with patients forgetting to take their pills or stopping their drug regimen once they feel better, which leads to drug resistance.



Sanjay Bhavsar, 55, Senior TB Treatment Supervisor says *“Treatment was a very difficult process for TB patients in the past. They had to come three times a week and queue up to collect their pills from the centres, leaving their work, their home. Things have now become easier, thanks to new technologies.”*



TMEAD is essentially a smart pill dispenser, powered by a rechargeable battery and fitted with an alarm that alerts patients when it's time to take their medicine.



TMEAD helps healthcare workers to monitor patients' regimen through an App, which provides easy-to-read colour-coded dashboard, that classifies patients into high, medium and low adherence categories.



Meet Kiransingh Khair. As he poses on his bike, it is hard to imagine the 31-year-old was so enfeebled by MDR-TB that he could barely stand. His weight fell to 42 kg and he was bedridden for two months. *“It was so bad for a while that I thought I wouldn't make it. I had to take 15 pills a day for many months till I started feeling better”.*



Kiran is single and lives in a joint family. It is his spirited sister-in-law Geeta who took charge and ensured Kiran took his medicines. In this, she was aided by TMEAD. *“The TMEAD device became like a family member. We became used to the sound of its alarm going off to remind us to give Kiran his medicine,”* she says. Kiran is now much better and his pills have been reduced to 7.

Kiran is one of the hundreds of TB patients that benefitted from TMEAD under the pilots in Thane, Nashik and Ahmedabad. Since, the device has got approval from Ministry of Health and Family Welfare and has been recommended to be part of the national TB care programme.



5. Cutting down cattle to human transmission of TB

Bovine TB, an infectious disease of cattle, is the seventh largest disease threat to humans transmitted from animals. Currently, it takes a veterinary doctor nearly four days and two visits to diagnose bovine TB, making diagnosis an expensive and time-consuming process, which increases the ease of spread to humans.

To tackle this problem, IHF engaged with CisGEN Biotech Discoveries Private Limited to develop, validate and manufacture an accurate, rapid (under 10 minutes) and



affordable (INR 50 per animal) bovine TB test kit that uses a unique combination of antigen proteins that can differentiate whether the bacterial infection

is from TB-causing bacteria or from another environmental mycobacterium. First of its kind, the kit is truly a “One Health product” which looks at the interconnectedness between humans, animals, and the environment. Moreover, the Cisgen kit is deployable in farms with minimally trained manpower and does not need any bio-containment facility.

How Cisgen is making an impact?

- The in-lab validation for Cisgen kit was conducted on samples from India, UK, Ethiopia that showed 95% sensitivity and 100% specificity, making it superior to



existing kits and facilitating its adoption by the dairy industry – public and private.

- Field testing and adoption discussions are underway with National Dairy Development Board (NDDB), Bharatiya Agro Industries Foundation (BAIF) and IIPHG, Gandhinagar.

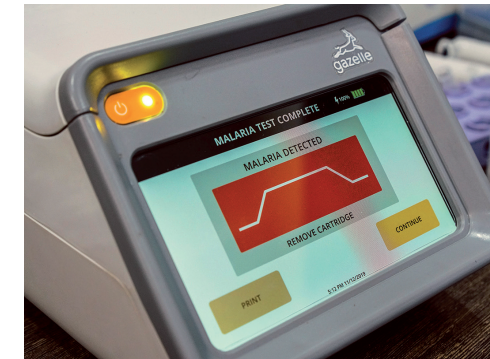
6. A 1-minute \$2 point-of-care differential diagnosis of Malaria

India is home to 3% of the 241 million world’s malaria cases and 2% of the 627,000 global malaria deaths with Plasmodium falciparum (Pf) and Plasmodium vivax (Pv) being the most common types found in the Indian population. Pv infections are becoming increasingly prevalent in India, however, these infections tend to have low parasite counts and are therefore often missed by conventional diagnostics.

Among the existing range of diagnostic tests, while PCR and LAMP molecular tests are very sensitive, they are also very expensive. On the other hand, microscopy-based diagnosis is

a challenge in peripheral settings due to the need for highly skilled microscopists. Moreover, microscopy has accuracy limits in detecting low parasite counts associated with Pv infections.

The lack of an accurate, affordable and quick diagnostic test for malaria detection and species identification in primary healthcare setting often delays treatment initiation and contributes to mortality. Differential diagnosis of Pv and Pf



Malaria is crucial for early and accurate initiation of treatment.

To address this gap, IHF engaged with Hemex Health to develop Gazelle – a one-minute, highly

sensitive and accurate, point-of-care, rapid diagnostic test for malaria, which simply detects Hemozoin, a metabolic byproduct of malaria infections. Using a single blood sample at the patients’ doorstep, the device can detect the presence of both Pf and Pv parasites in just one minute. Gazelle enables automated data acquisition and transmission of case-patient details to the malaria surveillance system resulting in real-time reporting. Targeted at cost of \$2 per test, Gazelle also supports



multiplexing by testing for other diseases such as sickle cell disease, beta thalassemia, that often occur in the same area as malaria.

7. The world’s first point-of-care biomarker-based test to enable rapid and low-cost triage of potential TB patients

Currently, India spends large resources testing 20-25 million TB suspects annually to identify the confirmed cases, which are much lower. 7-10 presumptive TB suspects have to be tested to identify one TB patient. Conventional methods for diagnosing TB are prone to nearly 50% error rates and can take 6-8 weeks to produce results. On the other hand, accurate culture and molecular TB confirmatory tests are time-consuming, expensive, require extensive training and cannot be used for screening all suspected TB patients. Also, the available diagnostic tools can fail to identify patients with low bacterial burden and result in nearly four million cases being missed.



Towards helping find these missing millions with an affordable, accurate and fast

trriage solution, IHF engaged with Stellar Diagnostics India Pvt. Limited. The TB triage test with a target cost of under 200 INR per test has the potential to enable rapid triage (within 20 minutes at point of care) of potential TB patients, speeding up diagnosis and linkage to treatment and narrowing the number of TB suspects that need to be referred for confirmatory testing. Moreover, the test requires no laboratory infrastructure and requires minimal training of health care workers. This innovation holds the potential to dramatically reduce the financial burden on the TB control program.



How is Stellar's triage test is gearing for impact?

1) Alignment with MoHFW:

As the test meets an urgent national priority and holds the potential to dramatically reduce the financial burden on the national TB control programme, the Ministry of Health and Family Welfare, Government of India, is closely following developments in the project and WHO and CTD have requested to fast-track development.



2) Linkages for manufacturing at scale: Stellar Diagnostics has already set up a joint venture with Molbio Diagnostics, who have committed to support production and manufacturing after the ICMR validation has been accomplished.

8. OmiX: A low-cost multiplex platform to detect and distinguish respiratory ailments COVID-19, influenza and TB

India reported 2.7 million cases of TB. Influenza burden is estimated at 0.6 -1 million while COVID-19 cases reached more than 25 million so far in India. Diseases like TB, influenza and COVID-19 manifest similar disease symptoms making diagnosis difficult for healthcare practitioners. Moreover, patients would need to take multiple (numbering 10-12), costly and time-consuming tests that could increase the risk of the patient's condition deteriorating. Current test prices: Price per test per disease ~₹1200-₹5000. Combined tests could range from ~₹3000-₹15000.

IHF funded OmiX Laboratories to develop Omi XiAMP, a platform trio test that uses Loop-mediated Isothermal Amplification (LAMP) technology to detect COVID-19, TB and Influenza. The point-of-care, automated platform is designed for use in low-resource settings, with simplified sample extraction and visual readout to facilitate diagnosis, which reduces the need for a skilled workforce to interpret test results while making the test error-free. Moreover, the platform can potentially report 10x more tests in the same time at 1/10th the combined cost of RT-PCR tests (Test price 1000 - 1500 INR for 3 diseases), making vast scale adoption more feasible.



Early diagnosis will not only improve patient outcomes by fast initiation of right treatment but also reduce the risk of spread of undetected infection. With higher specificity, better throughput and ease of use, the platform overcomes the limitations of current molecular diagnostics and could be made available to patients in areas with low testing load.

9. Autogene TB: An automated one-stop shop for TB diagnosis

The Indian government has chalked out an ambitious plan to eliminate TB by 2025, however with present infrastructure it is able to notify only 58% of TB patients. A person infected with TB, if left undiagnosed, can infect on an average 10 to 15 healthy individuals in a single year.



To reduce the gap between TB incidence and the notified cases, IHF engaged with Valetude Primus Healthcare to develop Autogene. A one-stop shop for TB diagnosis, Autogene enables safe collection of sputum samples from patients in specially designed capture bottles, which protect the healthcare workers from exposure to highly contagious TB bacteria. Furthermore, it provides rapid (TB diagnosis within 1 hour), accurate and affordable TB diagnosis without the need for skilled technicians at primary health level. The device includes a battery-operated RT-PCR diagnosis capability with an automatic gene detection feature that can be used for a broad range of automated applications including DNA isolation & extraction, enabling faster and error-free detection and allows for usage with minimal training of healthcare workers. It is a one-stop end-to-end detection solution - from sample collection, processing to report generation – that provides a holistic report to clinicians



on disease confirmation as well as persisting bacterial resistance. Moreover, Autogene is integrated with National TB program and sends results for

surveillance and reporting directly. Finally, it can also be used for the diagnosis of several bacterial and viral diseases including TB, COVID-19, Typhoid and Sepsis.

How is Autogene's device is gearing up for impact?

Autogene's in-lab validation has been completed with 800 samples and the device is ready for clinical validation.

10. A breakthrough RT-PCR test to speed the detection of drug resistance in TB patients from 4 months to 2 weeks

The standard first-line TB treatment typically lasts for approximately 6 to 9 months. However, some patients do not respond to this first-line of treatment as the TB bacteria have become drug resistant. In the last two years, about 1.15 lakh people were detected with drug resistant TB (DR-TB) with fatalities accounting for about 20% of the detected patients. The 'low responders' to standard first-line TB treatment have a high chance of severe consequences, like organ failure, high probability of catching multiple drug resistance and, even, death. It also leads to increased risk of community transmission of DR-TB. In these drug-resistant cases, the patient must be switched to second-line treatment as soon as possible. Rapid diagnosis of drug resistance is a key step to make this happen. As per the current protocols, the effectiveness of TB treatment and thus presence of DR-TB is realised about four months following treatment initiation. Patients have to undergo multiple tests to determine drug resistance that leads to delay in administration of 2nd line drug therapy and fatality linked to the disease. Diagnosing drug sensitivity needs intensive tools like culture preparation, LPA and cost ~ INR 6000. Often, this leads to late diagnosis and is one of the key reasons for the increase in incidence of DR-TB and fatality linked to the disease.



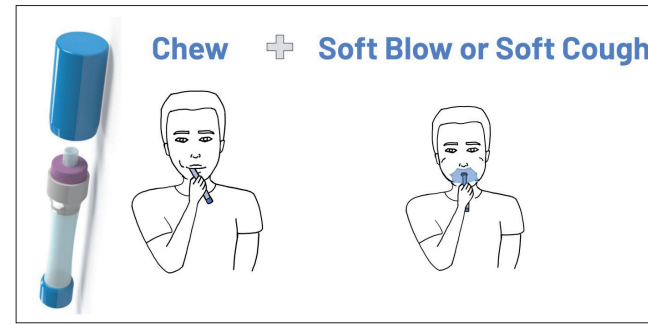
To shrink these timelines for diagnosis of DR-TB, IHF engaged HealSeq Precision Medicine Private Limited. HealSeq's host RNA biomarker-based blood test can accurately detect drug resistance from TB patients as early as two weeks after treatment initiation. The abundance of these RNA signature genes can help physicians to classify patients as good-, intermediate- or poor-responders to the treatment. Intermediate- or poor-responders, diagnosed as DR-TB patients, can be immediately shifted to second-line therapies. This is a breakthrough in the diagnosis and treatment of DR-TB as it has the potential to significantly speed up diagnosis, guide fast clinical decision of shifting to 2nd-line therapies, treatment initiation and thus curtail the spread of the disease. This easy-to-administer test, once developed, will be available at ₹1000 per test, which is 1/6th the cumulative cost of the multiple tests that need to be taken during the TB treatment course. The test itself takes 12-24 hours turnaround time vs. current methods that take 4-6 weeks. Moreover, the technology is a platform solution and can also be used to detect Sepsis, extra pulmonary TB and Cancer. HealSeq has completed product development and the test is being currently evaluated using TB patient samples from five tertiary hospitals in Karnataka.

11. Specially designed non-invasive device to aid sputum sample collection in children to improve diagnosis of paediatric TB

Every year, 1-1.15 lakh children get affected by TB in India. Of these, 96% of deaths, among paediatric TB patients, are due to a lack of bacteriologic confirmation and early treatment.

These missed cases not only contribute to higher mortality but also increased transmission of infection in communities. Exacerbating this, are current sample collection methods, which are time-consuming, painful and inconvenient for children and often need the expertise of healthcare workers. There is

absence effective, convenient, and child-friendly sputum collection methods which can be used in conjunction with existing diagnostic platforms.



Addressing this unmet need and keeping children at the heart of the innovation, IHF engaged with 221B Biomedical to pave the development and clinical validation of 221B Biomedical's simulated method: a first-of-its-kind specially designed non-invasive sputum collection device for testing tuberculosis (TB) among children. 'Blow-Pop', the flavoured low-cost device will require children to simply chew and blow or cough for easy and safe sample collection of oral fluids. The innovation will make testing simpler and will increase testing and treatment rates, lower mortality and infection transmission due to TB. Owing

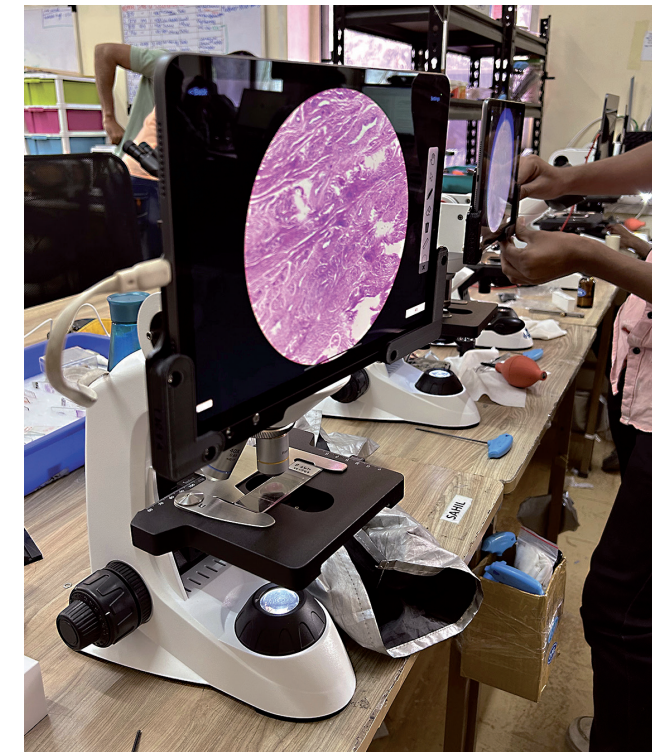
to its simplicity, the tool will be ideal for low-resource settings, including primary healthcare setups. While this tool will be developed initially keeping children in mind, a similar product can be used among adults too. Moreover, the device can also be used as sample collection tool for other diseases where sputum sample is required. Targeted at a test price: 80 INR (~ \$1), the device helps in obtaining specimen with improved quality, enhanced quantity, and viability suitable for processing within <10 min.

12. Artificial Intelligence-based detection, parasitic load calculation and species differentiation for faster and accurate diagnosis of malaria

India was home to more than 1.6 lakh malaria cases in 2021. While malaria-related deaths have been dropping recently, the

case numbers continue to be high. Evidence shows that conventional microscopy-based detection misses about 25% malaria cases in India; this problem is further exacerbated in hard-to-reach remote areas.

Analog microscopy as a diagnostic tool for malaria has



evolved very little since its first use. Even though the basic principles of optics remain constant, the subjectivity that comes with dependence on skills and training of officials who use the microscopes can result in wide variation in disease interpretation. These limitations in traditional microscopy-based detection result in underdiagnosis and poor surveillance of malaria and other diseases.

IHF engaged with Medprime Technologies for faster, more cost-effective and more accurate microscopy for disease diagnosis. Medprime's artificial intelligence algorithm, locally trained by machine learning,

automatically detects, identifies and differentiates between malarial parasites (*P. falciparum* and *P. vivax*). This tool will be particularly useful in identifying infections with low-parasite loads, which are commonly missed by conventional microscopy.

The algorithm is microscope, disease (communicable and non-communicable) and sample (blood, urine, stool, pus) agnostic and will slash- by third- the time taken for slide viewing, image processing and result reporting. The algorithm will also overcome the need for trained manpower and will prove important for training and research for medical, paramedical and allied health staff that need remote collaboration and interoperability. IHF's support to Medprime will enable the development and pilot testing of this AI/Machine Learning (ML)-led multiplex diagnosis software. The platform algorithm



can be used beyond malaria in WBC differentiation, histopathology and cytopathology for cancer, sickle cell disease etc. and can run samples like blood, urine, stool, pus.

13. A fever panel to detect dengue, chikungunya, and malaria

Mosquito-borne diseases are rampant in India with an observed rise in dengue and chikungunya cases between 2015 and 2021. While malaria prevalence has reduced over the last 20 years, absolute numbers stand high. These illnesses often present similar symptoms at an early stage, which can lead to a misdiagnosis or even delayed diagnosis. Thus, there is an immediate need for a rapid diagnostic test (RDT) that is real-time, easy-to-use, affordable, user-friendly and equipment free.



Addressing these need gaps, Ameliorate developed an accurate, multiplexed RDT for differential detection of dengue, chikungunya and malaria (with malaria falciparum and vivax differentiation). The single test kit uses a single blood sample and can be easily used by minimally trained workforce at primary level. The process eliminates the need of serum/plasma samples, is instantaneous, doesn't need cold chain facility/

biosafety lab; ensures minimal medical waste generation. The funding from IHF will enable prospective, multicentric performance and cost-effectiveness evaluation of the RDT, to be made available at a discounted price of INR 200/pc to the public health system for government procurements. This is far less than existing fever panel priced at INR 3000-4000.

14. Non-invasive patient-friendly AI-led platform that can detect active TB cases in minutes on mobile phones by reading cough signatures

Active case finding (ACF) is an established measure for the systematic screening of infectious diseases like TB in high-risk populations by frontline health workers, who are the first point of contact for under-served communities. In 2021, out of 22.3 million patients screened for TB through government programs, 73,772 patients were identified through ACF.

However, there has been a lack of affordable, rapid response and sensitive screening tools that can help find the millions of active TB cases that often go undiagnosed. Currently used ACF methods are visual inspection, patient questionnaires, and assessing exposure to TB-infected individuals, but these have limited



clinical application due to the subjectivity in understanding patients' symptoms and systematically deducing test results for identification and differentiation of different lung infections. This leads to about 64% of symptomatic TB patients going undiagnosed.

Addressing this need, India Health Fund and ACT For Health co-funded the development of Swaasa® - an AI Platform by Salcit Technologies that records cough sounds from patients using a phone's microphone and analyzes them to decode unique cough signatures to detect the possible presence of pulmonary tuberculosis using a proprietary AI algorithm and gives a report in just a few seconds.



Salcit's non-invasive innovation can run on any smartphone, requires no additional equipment/consumables and offers the key advantage of being used by patients themselves in the confines of their households, reducing the risk of infection spread or the need for trained staff. It can also be easily used by frontline health workers in low-resource and remote settings and thus, promises to be easily scalable to enable early detection of the disease.

Funding by IHF and ACT For Health will aid Salcit Technologies in the technical validation of Swaasa®'s AI algorithm. The project will include the collection of cough

“This past year, India Health Fund and ACT Grants aligned to support development and adoption of science and tech innovations to address unmet public health needs. The association holds the potential to be a catalytic instrument to advance healthcare accessibility and affordability in India and beyond. We have been very impressed with the panel of experts IHF has been able to corral and we learnt a lot from the round tables.”

Neetha Joy, Director, Health, ACT Grants

sounds from about 5700 subjects (TB and Non-TB), the technical validation of the platform across 6 public health centers and the enhancement of the platform to reach an accuracy of 90% for detecting the likely presence of TB.

Unlike other cough screening algorithms coming to the market, Swaasa® is a multi-focus platform that can be used for screening of various lung ailments including COVID-19, for which it is currently undergoing clinical trials. Swaasa® is also registered with CDSCO, is HIPAA and ISO27001 certified and has two granted patents and three publications backing its technology and use.

Salcit's proprietary combination of audiometric analysis and AI technology will undergo two more development phases post the review of the first phase by an external panel of technical experts representing Central TB Division, ICMR and WHO-India, among others.

The project is co-funded by IHF and the non-profit venture philanthropy platform ACT for Health.



Partnerships – Stronger Together

Partnerships amplify everything we do – from technical experts who help us identify problem statements and develop use cases; to business experts who guide us on feasibility of projects; from implementers on the ground who help us gather evidence for projects; to scale-up partners (public and private) who drive the last mile impact with us. Every partnership we nurture – for co-funding, co-developing, co-deploying – is a cog in the wheel that accelerates our journey from idea to impact.

TATA TRUSTS



Stop TB Partnership



United Way Bengaluru





**INDIA
HEALTH
FUND**

A TATA TRUSTS INITIATIVE