

New TB Tools:

Is ending TB (finally) within sight?

Side event of the United Nations High-Level Meeting on TB

Tuesday, 19 September 2023

MEETING REPORT



Sponsored by:



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MINISTRY OF HEALTH
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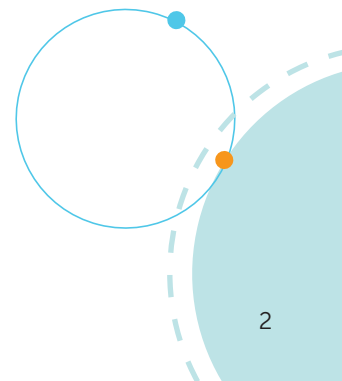
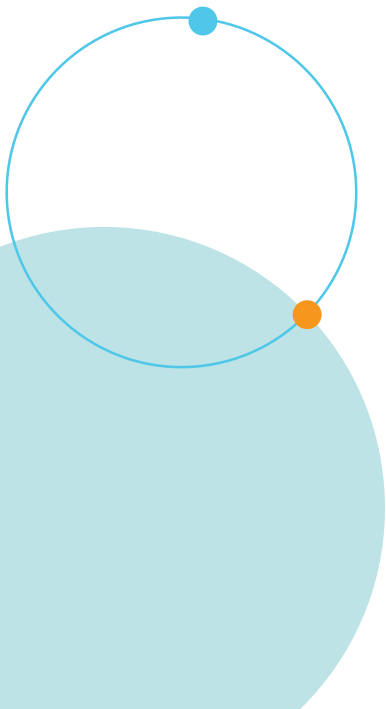


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In association with RESULTS US, Stop TB Partnership, and Treatment Action Group

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Speaker list

Emcee

- Priyanka Aiyer, Communications Specialist, TB HLM 2023 Affected Communities & Civil Society Coordination Hub

Setting the scene for new TB tools

Opening remarks

- Louie Zepeda-Teng, TB survivor and Founder, TB People Philippines
- Pascalle Grotenhuis, Director General International Cooperation, Government of the Netherlands

High-level remarks

- Sandra Gallina, Directorate General for Health and Food Safety, DG Santé, European Commission

A quick look at new TB tools

Framing remarks

- Dr. Tereza Kasaeva, Director, Global TB Programme, WHO

New tools presenters

- Dr. Kavindhran Velen, Senior Scientist, FIND
- Dr. Mel Spigelman, President & CEO, TB Alliance
- Dr. Lewis Schragger, Senior Leader, Tuberculosis Impact Area, IAVI

Moderator

- Mike Frick, TB Program Co-Director, Treatment Action Group

Panel discussion

Framing remarks

- Dr. Suvanand Sahu, Deputy Executive Director, Stop TB Partnership

Panelists

- Dr. dr. Maxi Rein Rondonuwu, Director General of Disease Control and Prevention, Ministry of Health, Republic of Indonesia
- Prof. Norbert Ndjeka, Chief Director, TB Control & Management, National Department of Health, Republic of South Africa
- Janet Ginnard, Director, Strategy, Unitaid
- Lord Nick Herbert, Founder and Global Co-Chair, Global TB Caucus

Closing

Reflections

- H.E. Katarzyna Drążek-Laskowska, Director, International Cooperation Bureau, Ministry of Health, Republic of Poland

Closing remarks

- H.E. Pak Budi Gunadi Sadikin, Minister of Health, Republic of Indonesia

Abbreviations

BPaL/M – Bedaquiline, pretomanid, linezolid, moxifloxacin

DG SANTE – Directorate General for Health and Food Safety, European Commission

LAM – Lipoarabinomannan

M.tb – Mycobacterium tuberculosis

NAAT – Nucleic acid amplification test

PDPs – Product Development Partnerships

POC – Point-of-care

R&D – Research and development

SDGs – Sustainable Development Goals

TAG – Treatment Action Group

TB – Tuberculosis

UNHLM – United Nations High-Level Meeting

WHO – World Health Organization



Executive Summary

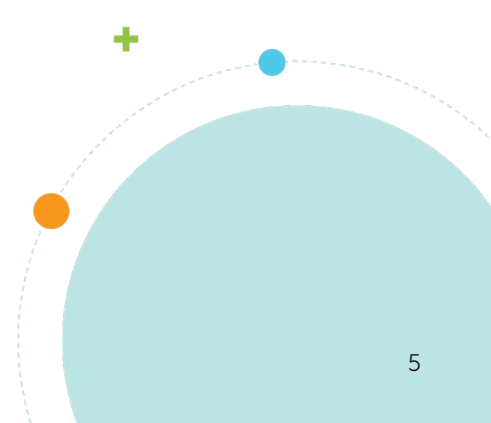
Achieving the end of the global (tuberculosis) TB epidemic is only possible with innovation in research and development (R&D). Recent developments in TB diagnostics, treatment and vaccines hold significant promise in improving effective diagnosis, management, and prevention of TB. To realize this potential, member states urgently need to support the development and delivery systems of new TB tools and ensure that there is demand for and equitable access to these innovations. The second United Nations High-Level Meeting (UNHLM) on TB on Friday 22 September 2023 provided a crucial platform to discuss and address the challenges faced in combating this deadly disease, revisit previous commitments and progress, and renew the focus to eliminate TB.

The meeting “**New TB Tools: Is ending TB (finally) within sight?**” was held on 19 September 2023, as a side event to the 2023 UNHLM on Tuberculosis in New York City. The meeting was convened by FIND, TB Alliance, and IAVI, in association with RESULTS US, The Stop TB Partnership and TAG (Treatment Action Group). This meeting brought together key stakeholders to discuss current and future breakthroughs in TB diagnostics, vaccines, and treatments that are urgently needed to improve TB care and control in high-burden countries. The event aimed to promote collaborations and partnerships among stakeholders to foster the development and implementation of new TB tools.

New TB tools are critical to meet the Sustainable Development Goals (SDGs) targets to [end TB by 2030](#). Innovations in TB diagnostics, treatment and vaccines hold significant promise in improving the early detection, accurate diagnosis, effective management, and prevention of TB. New diagnostics – including rapid non-sputum tests, rapid drug resistance testing and sequencing – are a critical component of finding the many “missing” millions of people with TB who are not diagnosed or properly treated. Major breakthroughs in TB therapy for both latent and active TB are also bringing us closer to having a sustainable pipeline of drug regimens to effectively treat every person with TB. This is also a historic time for TB vaccine development, with more vaccines in development than ever before and several promising candidates in Phase 2/3 efficacy trials.

Greatly increased funding is urgently needed to support the development and delivery of these innovations and realize the goal to end TB by 2030. Member states must now invest US\$5 billion in TB R&D each year, as outlined in the [Global Plan to End TB 2023–2030](#). Funding and focus are also needed to ensure that there is demand for and equitable access to these new tools once available. This will require strong primary health systems and engagement with affected communities, so the tools can be delivered where people seek care.

As a global disease, ending TB requires global solutions, driven by joint funding and innovative partnerships. Member states must support a whole-system approach, where innovation is fully resourced, and new tools are implemented across the continuum of care for effective TB prevention, diagnosis and treatment. Now is the time to ensure that the commitments endorsed by member states in the [2023 political declaration](#) are turned into action. Investing in and developing new TB tools is truly a shared responsibility. Only together can we end TB as a public health threat by 2030.



Setting the scene for new TB tools

“Every country can and should contribute to a global TB response centred around the needs of people...we must make sure that all TB tools are equitable, accessible and available to all in need.”

Director General Pascale Grotenhuis, Ministry of Foreign Affairs of the Netherlands

Innovations in TB diagnostics, treatment and vaccines hold significant promise in improving the early detection, accurate diagnosis, effective management, and prevention of TB. Greatly increased investments are needed to advance the development and delivery of these tools and to ensure equitable access once available.

The last five years have seen the TB space change dramatically, not only through the devastating impact of COVID-19 on TB, but also with welcome advancements in the development of new TB diagnostics, treatments, and vaccines. And while TB targets have largely not been met, significant progress has still been made, with some countries achieving notable declines in the incidence of TB and TB-related mortality.

New TB tools are urgently needed to meet the 2030 End TB targets. The World Health Organization (WHO) is supporting initiatives to make this possible, including support to facilitate rapid uptake of the new six-month BPaL/M (bedaquiline, pretomanid, linezolid, moxifloxacin) regimen. In addition, the WHO recently launched the [TB Vaccine Accelerator Council](#), to facilitate the development, testing, authorization, and use of new TB vaccines.

Product Development Partnerships (PDPs) like FIND, IAVI, and TB Alliance are particularly well placed to develop these innovative tools, bringing together stakeholders from the public and private sectors. Equitable access, central to the PDP mission, and strong health systems will be key to realizing the potential of these innovations and maximizing their impact on the growing global crisis of antimicrobial resistance. This potential, however, can only be reached through sustained public sector support. Such support has been critical to the success of the PDP model to date, including by countries like the Netherlands, the session co-sponsor.

To realize the potential of new TB tools, we must leverage the momentum of the 2023 UNHLM on TB and work together in close collaboration to optimize the global TB response. We must continue to demand equitable access to new TB tools and prioritize and advocate for comprehensive research in collaboration with the TB community. We must keep advancing innovations in TB tools, while also working to implement existing tools so that as many people as possible have access to the TB diagnostics, treatments and vaccines that they need.



Louie Zepeda-Teng delivering her opening remarks.

“TB is a global challenge that requires global solutions”

*Director General Sandra Gallina,
Directorate General for Health and Food Safety (DG SANTE), European Commission*

A quick look at new TB tools

Innovations in TB diagnostics

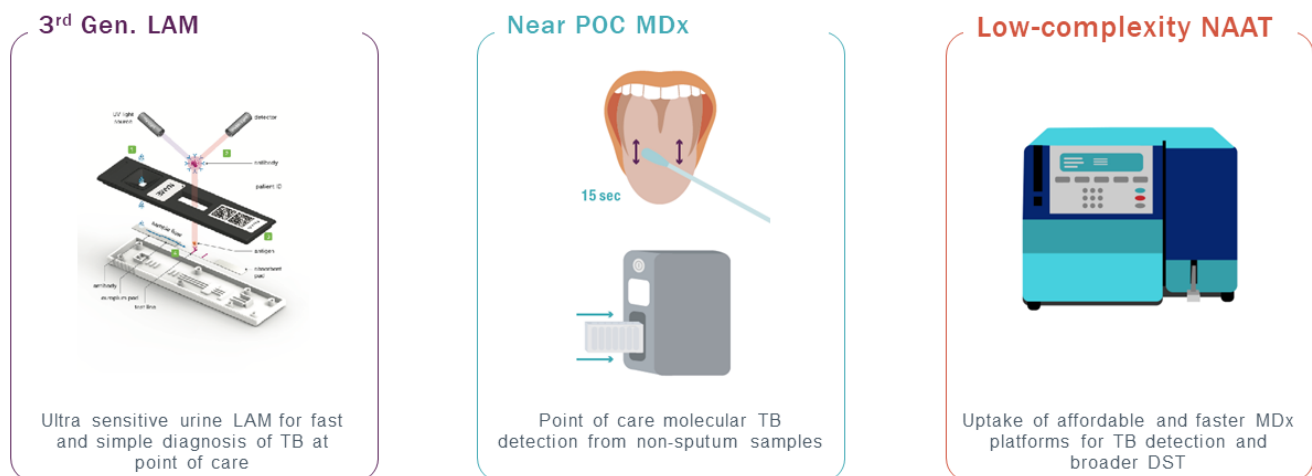
Kavindhran Velen, FIND

New diagnostics are a critical component of finding the many “missing” millions of people with TB who are not diagnosed or properly treated. While the technology landscape for TB has advanced greatly in recent years, there is still a trade-off between the performance, multiplexing capacity, and operational characteristics of TB diagnostics. In particular, there is a need to broaden access to testing in locations that are convenient for patients (e.g., in the community and primary healthcare).

Diversifying the multi-pathogen platforms that are available in district hospitals and other Level 2 facilities will also be important to enable testing for other diseases alongside TB. Newer diagnostics are also needed to fill critical gaps across different healthcare settings, as no one TB diagnostic can meet all use cases. While complex testing systems that can identify multiple diseases currently tend to require specialist, well-resourced laboratories, the COVID-19 pandemic has spurred a pipeline of multi-pathogen molecular tests that are simple enough to be used in primary care clinics.

Promising innovations are on the horizon. The [DriveDx4TB](#) package, developed by FIND with support from Unitaid is supporting the development of three classes of disruptive diagnostic technologies for TB. These are 1) third generation lipoarabinomannan-based rapid tests; 2) portable, rapid near-point-of-care molecular diagnostics using non-sputum-based samples; and 3) low-complexity nucleic acid amplification tests that can provide broader drug susceptibility testing. In an important step forward, targeted next-generation sequencing has recently been recommended by WHO for the detection of drug-resistant TB.¹ Sequencing will be important to support the use of newer drugs that are not currently captured by molecular testing methods.

Figure 1. Three classes of disruptive diagnostic technologies supported by DriveDx4TB



LAM, lipoarabinomannan; **POC**, point-of-care; **NAAT**, nucleic acid amplification test.

Source. Presentation by Kavindhran Velen, Senior Scientist, FIND

¹ World Health Organization. Use of targeted next-generation sequencing to detect drug-resistant tuberculosis rapid communication, July 2023. Available from: <https://www.who.int/publications/i/item/9789240076372> (accessed 25 September 2023).

Advances in TB treatment

Mel Spigelman, TB Alliance

Recent years have seen major breakthroughs in therapy for both latent and active TB. This includes regulatory approvals, new guidelines, and the roll-out of highly effective, six-month, all-oral treatment for drug-resistant TB. Other key breakthroughs include guidelines and momentum for four-month treatment of drug-sensitive TB, as well as the availability of one-month treatment to prevent active TB. There have also been notable advancements in the treatment of drug-resistant TB, particularly with the approval of pretomanid in 2019 as part of the all-oral, six-month BPaL regimen for the treatment of highly drug-resistant TB. With modern treatments, the treatment of drug-resistant TB should not be more difficult than drug-sensitive TB, but the major impediment for both is a lack of funding.

However, innovation has to be applied to ensure that drugs reach people who need them, as well as for R&D. At present, pretomanid is approved in 17 of the 30 countries with the highest burden of drug-resistant TB, and approved in 11 other geographies. Access to pretomanid has been catalysed through WHO guidelines endorsing the regimen and through access initiatives led by the TB Alliance.

Moving forward, a priority for 2023–2024 is to dramatically increase access to the BPaL and BPaL/M regimens through a range of measures. This includes programmatic roll-out and scale-up in key countries, and expansion of access to other priority countries through technical assistance and experience sharing. More broadly, other priorities for the treatment of TB are the development of shorter and simpler regimens, and the development of a “universal” regimen for active TB. Another important area is the use of long-acting injectables for latent and active TB, which could one day make it possible to test and treat patients in the same visit.

Figure 2. Regulatory status of pretomanid

Top 30 High DR-TB burden countries (17 approvals, 6 pending)

Angola	DPR Korea	Kyrgyzstan	Nigeria	Moldova	Ukraine
Azerbaijan	DR Congo	Mongolia	Pakistan	Russia	Uzbekistan
Bangladesh	India	Mozambique	PNG	Somalia	Vietnam
Belarus	Indonesia	Myanmar	Peru	South Africa	Zambia
China	Kazakhstan	Nepal	Philippines	Tajikistan	Zimbabwe

Other geographies (11 approvals, 4 pending)

Cambodia	Georgia	South Korea	USA	Namibia
EMA	Hong Kong	Thailand	WHO-PQ	Tanzania
Ethiopia	Moldova	Turkmenistan	Kenya	Uganda

Approved Filed

Source. Presentation by Mel Spigelman, TB Alliance

Delivering new vaccines this decade to end TB

Lewis Schrager, IAVI

This is a historic time for TB vaccine development, with more vaccines in development than ever before and several promising candidates in Phase 2/3 trials. New TB vaccines are predicted to have a major socioeconomic and public health impact. A recent WHO-commissioned investment case for new TB vaccines demonstrated that every US\$ 1 invested in the delivery of a 50% effective TB vaccine for adults and adolescents could generate an economic return of US\$ 7 in terms of averted health costs and increased productivity over 25 years.² Over the same period, new TB vaccines are estimated to avert up to 76 million new TB cases and 8.5 million deaths. TB vaccines will also play an essential role in preventing drug-resistant TB disease and thus an important role in the global response to antimicrobial resistance.

The 16 TB vaccine candidates in [the pipeline](#) employ a range of vaccine strategies, improving the chances of identifying a successful TB vaccine this decade. Three such candidates are currently in advanced development: VMP1002 (recombinant BCG vaccine), M72:AS01E (adjuvanted subunit vaccine), and MTBVAC (live, attenuated Mycobacterium tuberculosis [M.tb] vaccine).

For TB, the cost of inaction is high and will surpass cost of action, in terms of lives, livelihoods, and economies. However, the burden of funding for TB vaccine clinical trials largely falls on philanthropists, meaning it can take longer to raise funds to conduct a Phase 2 trial, than to conduct the trial. Support by governments and other sources is needed to accelerate the TB vaccine development.

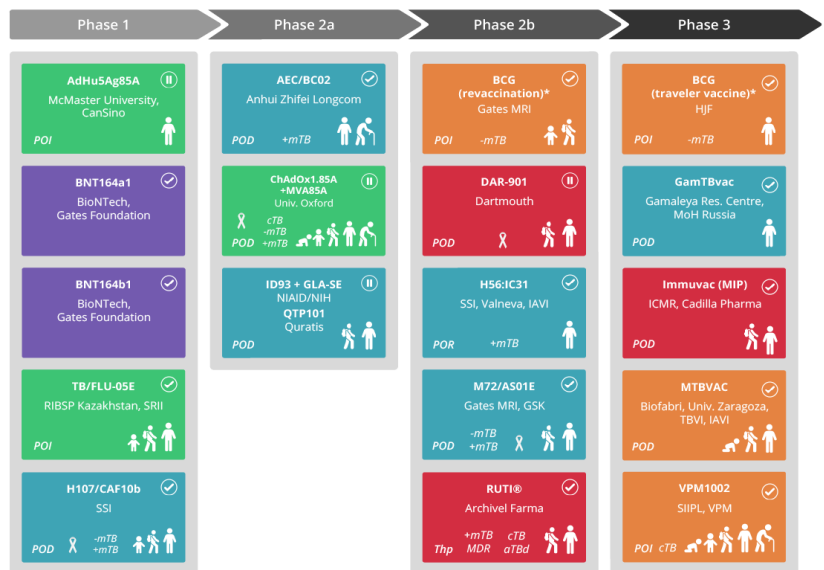
Figure 3. The TB Vaccine Clinical Pipeline

TB Vaccine Pipeline

Vaccine candidates under clinical development

There are 17 vaccine candidates in the pipeline as of November 2023, of which 13 are in active trials. The candidates are placed under the phase which corresponds to the most advanced ongoing or completed trial.

Platform	Trial status
■ Mycobacterial - Live attenuated	✔ Active trials
■ Mycobacterial - Inactivated	⏸ No active trials
■ Viral vector	
■ Protein/Adjuvant	
■ DNA/RNA	
Candidate target population	Primary candidate indication
Elderly	<i>POI</i> Prevention of Infection
Adults	<i>POD</i> Prevention of Disease
Adolescents	<i>POR</i> Prevention of Recurrence
Children	<i>Thp</i> Therapeutic
Infants	
People living with HIV	
<i>-mTB</i> People without mTB infection	
<i>+mTB</i> People with mTB infection	
<i>aTBd</i> People with active TB disease	
<i>MDR</i> People with MDR-TB	
<i>cTB</i> People cured of active TB	



*BCG appears twice in the pipeline to distinguish between the investigation of its use in BCG-naïve individuals (traveler vaccination) and in individuals who have previously been vaccinated with BCG (revaccination).



Information reported by vaccine sponsors or found in clinical trial registries or other public sources. For the full list of completed trials for each candidate, visit www.newtbvaccines.org/tb-vaccine-pipeline/

Last update: 30 November 2023

Source. The Working Group on New TB Vaccines

² World Health Organization. An investment case for new tuberculosis vaccines. Available from: <https://www.who.int/publications/i/item/9789240064690> (accessed 26 September 2023).

Insights from the moderated Q&A and panel

The moderated Q&A session and panel discussion provided a space for the panel and audience members to discuss key issues around new TB tools and outline next steps for the TB community to ensure innovations are available to everyone affected by TB.

Funding for new TB tools

Funding is critical to take advantage of the promise in the pipelines for TB diagnostics, treatments and vaccines. The COVID-19 pandemic was a real-life example of what it takes to rapidly develop diagnostics, drugs and vaccines, but the funding provided for COVID-19 was exponentially higher than anything available today for TB. For rapid progress, funding in the order of US\$ 100 billion over a couple of years is needed, as was provided for COVID 19. US\$ 5 billion dollars alone is needed for basic TB research and research into new diagnostics, treatments and vaccines per year. However, current TB funding is a fifth of that.

There is a strong economic argument for investment: investing US\$ 1 in TB produces a return of US\$ 40. On the contrary, if we do not invest in tools to tackle TB, the cost of inaction could exceed US\$ 1 trillion. With COVID-19, we saw that this was possible, with vaccines developed within a year, and diagnostics scaled up with 1-2 months. To make this possible, the TB community needs to think about creating an enabling environment for TB vaccines ahead of launch. Collaborations between organizations can help maximize the resources available to further TB tools within the next few years.

Attention also needs to be given to reasonably ensure that all components of TB control are funded and that funds are distributed equitably across the TB continuum of care. Funding is also needed to support access initiatives, which will be critical to ensure that everyone has access to new tools once they are available. As a community, we also need to share accurate information on the return on investment for potential funders of new TB tools and initiatives, to encourage greater investment.

Ensuring equitable access to new tools

“New TB tools will not save lives by themselves, unless we develop new ways of delivery to enable access.”

Dr. Suvanand Sahu, Deputy Executive Director, Stop TB Partnership

Although there is now an exciting landscape of current and upcoming TB tools, the TB community needs to be prepared to scale-up access to these new tools, if they are reach the people who need them most. Today, newer TB tools are still not available in many settings and countries. A problem is that funding is disproportionately allocated for the development of new tools, rather than developing new ways of delivery, which is just as important.

Access has to be built in from the beginning, from research through to product development, with consideration of how tools will be deployed. We saw the power of creating demand for new tools at the community level for COVID-19, but the same system does not yet exist for TB. Consequently, there is a need to work with communities to develop awareness and demand for new tools. Research can sometimes feel distant to communities, and as such it is important to talk to communities about the science behind new innovations in TB, as it allows



H.E. Pak Budi
Gunadi Sadikin
delivering closing
remarks

them to ask informed questions, and drive demand. Strong and well-funded primary healthcare systems will also be vital to create an enabling environment for the introduction of vTB tools once available.

Initiatives are underway to drive demand for and access to new TB tools. The TB Alliance, IAVI and FIND are working with civil society organizations and communities around demand and access for new tools. There are also active access groups working on access for TB vaccine development. More broadly, Unitaid is dedicated to realizing equitable access for all tools in terms of innovation and availability. For innovation, this includes that the tool is designed fit for purpose, and that it responds to country priorities and needs as defined by communities themselves. In terms of availability, this means ensuring that tools are affordable, products are quality assured, and that tools can be deployed at scale, without supply and delivery vulnerabilities.

Insights from country experiences of introducing new tools can also be valuable. In South Africa, the adoption of the new BPaL regimen was made possible through collaboration between the National Department of Health and civil society organizations, the academic community, and other key partners. Efforts were also made to inform and engage healthcare workers well in advance of introducing new treatments like BPaL.

“This year’s political declaration will be critical to renew commitments, promote political visibility of key challenges in TB and mobilize funding and action to properly address them both at a domestic and international level.”

*H.E. Katarzyna Drązek-Laskowska, Director,
International Cooperation Bureau, Ministry of Health, Republic of Poland*

Translating the 2023 political declaration into action

A key question for the TB community is how to ensure that commitments in the 2023 political declaration are translated into action, when those from the 2018 declaration were not. A crucial part of this will be translating targets into specific actions that are meaningful for countries and ensuring accountability to these targets. TB caucuses will play a key role in this; however, they need tangible actions that can be taken to governments.



Panelists with session moderator, Mike Frick

Acknowledgements

The meeting was organized by FIND, IAVI, and TB Alliance in association with RESULTS US, the Stop TB Partnership and Treatment Action Group.

We extend our gratitude to the Ministry of Health, Republic of Indonesia and the Government of the Netherlands for sponsoring the meeting.

We thank all the speakers, presenters, and panelists for their thoughtful contributions and continued efforts in the the development and delivery of new TB tools.

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