Closing the pre-approval access gap for people affected by TB with expanded drug-resistance

Meeting Report

November 11 2025

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Overview

This two-day hybrid meeting, held on October 22-23 in Washington, D.C., at the Bloomberg Center brought together a number of key stakeholders working on drug-resistant TB (DR-TB) to discuss pre-approval access (a term that encompasses numerous other terms, including compassionate use) to new TB drugs for people living with DR-TB who have limited treatment options. The meeting was sponsored by the Office of the Provost of Johns Hopkins University and Unitaid and co-convened by members of The BETTER (Building Experience Treating TB with Expanded Resistance) Project. It was part one of a two-part meeting on closing the global health research-to-access gap (part two will be held in spring of 2026).

This meeting report summarizes the key discussions and action items from the sessions. The sessions were recorded, and presentations are available on request. The group will also be drafting a paper for publication in a peer-reviewed journal (tentatively titled "Compassionate Use Support Programs for Drug-Resistant Tuberculosis: A Model for Accelerating Access Across the Drug Development Spectrum").

The meeting agenda and participant list are available in the annex to this report.

Day 1

The hosts opened the meeting by setting expectations and aspirations, emphasizing urgency, since there is a real concern that "resistance will outpace innovation." The group discussed how lessons learned from DR-TB are relevant across the spectrum of antimicrobial resistance work, and was charged with keeping three priorities in mind:

1.) access frameworks must be embedded as early as possible in research to avoid delays;

2.) early access must be equitable and transparent, and include vulnerable populations;

3.) all stakeholders have obligations and a shared responsibility for promoting access. The goal of our collective work was defined as "narrowing the distance between discovery and delivery."

The first technical session of the meeting sought to share experiences gained as part of previous pre-approval access for DR-TB, with more than a decade of experience for the drugs bedaquiline and delamanid. Participants reviewed these experiences as a foundation to launch new pre-approval access/compassionate use programs (PAPs/CU) for the new TB drugs in the pipeline.

The need for these new TB drugs (herein referred to as “novel investigational compounds” or “NICs”) was confirmed with data from South Africa. It is estimated that there are currently thousands of individuals globally who have strains of TB that have resistance patterns that might require the use of NICs. The following session presented the views of impacted communities, treating clinicians, TB programs, and civil society on the need for new drugs and the readiness to use them, based on prior experiences with PAPs. Presentations from South Africa, India, and Georgia demonstrated that multiple pathways exist through which NICs could be deployed. The needs are urgent, and there is strong political will and practical implementation knowledge that can be brought to bear to support the systemic use of NICs.

Discussions during this session focused on the current limitations of existing drugs when treating people with DR-TB that has expanded resistance, outcomes are poor, and the regimens often include daily intramuscular or intravenous injections and medications that must be delivered intravenously. There was also discussion about the delays in identifying expanded resistance and the need to advocate for better diagnostic methods so patients who need NICs can be recognized earlier. The need to engage impacted communities at all stages was a consistent theme, especially when it comes to informed consent and developing patient-facing information. Participants emphasized the need for specific action steps, noting that many countries and programs have mechanisms for managing NICs and have even used PAPs/CU to establish sustainable research and access programs.

The next session focused on sharing the experience of NIC developers, with Johnson & Johnson presenting details on their PAPs/CU program for bedaquiline. The program was started as soon as phase IIb data were available but prior to any level of regulatory approval. The PAP had criteria but was flexible, responding to mechanisms that would work for countries. It was later expanded to a larger global access program that included a pediatric component with support from USAID. Data from the PAPs/CU program contributed to knowledge on safety and ran alongside randomized controlled trials. Lessons learned included the need for political will, working with credible implementing partners, commitment to pharmacovigilant (PV) monitoring, and continued engagement with catalytic partners. Group discussion focused on how the program was a strong example that could be built upon for current NICs. They also stressed the need for incorporating knowledge about drug susceptibility testing to the NICs (not as a program prerequisite but as a knowledge-sharing platform). There was consensus that the experience built with PAPs/CU for bedaquiline was a real asset in the DR-TB space.

Key Points

- There is an urgent need for NICs to offer people with strains of TB that have expanded resistance potentially life-saving therapy;
- There is agreement from multiple stakeholders, including impacted communities, clinical providers, national TB programs, and civil society organizations on the need as well as substantial expertise in implementing these programs over the past decade;
- Novel Investigational Compound (NIC) developers are interested in helping make their products available as life-saving interventions prior to formal regulatory approval;
- The experience with bedaquiline can serve as an example for current and future NICs, with improvements made for vulnerable populations such as children and during pregnancy.

The next session focused on World Health Organization (WHO) and regulatory agency perspectives on PAPs/CU programs. WHO shared their documentation and operational guidance that has supported PAPs/CU since 2014. Presentations summarizing public positions from the United States Food and Drug Administration (FDA) and the South African Health Products Regulatory Agency (SAHPRA) also showed support for PAPs/CU programs and clear mechanisms for their application. The U.S. FDA even allows PAPs as early as when there are phase I data on a drug if the patient has a life-threatening medical condition and limited treatment options. The European Medicines Agency (EMA) shared their guidance on PAPs, emphasizing that while most of what is learned about and used to approve a medication comes from randomized trials, there is a framework for PAPs/CU in the European Union (EU). The presentation discussed some of the complications in the EU due to the fragmented systems there but shared that they are even able to provide input on PAPs/CU protocols (as they did for hepatitis C). While there was general agreement that access to a drug is best ensured through formal registration, there was clear guidance on PAPs/CU programs.

The presenters also discussed the important topic of whether PAPs/CU programs could impact drug registration, a reason commonly cited by NIC developers to delay PAPs/CU programs. There are no instances in the EMA of a PAPs/CU program negatively impacting drug registration, nor were there instances from the U.S. FDA. Data were cited in which a review was done of thousands of FDA applications for NICs, and in only two instances (<1%) were temporary holds placed on NICs due to safety concerns seen in PAPs/CU programs. The group also discussed the distinction between permissible regulatory frameworks which allow for PAPs/CU programs versus supportive regulatory frameworks that facilitate PAPs/CU programs. Attendees noted the need to help country actors identify and navigate their systems and the confusing terminology across

countries and systems that could use clarification. While universal terminology across systems may not be feasible, country-specific language should be considered when discussing PAPs/CU programs.

Key Points

- There is WHO support and operational guidance on PAPs/CU programs and WHO supports accessing NICs in this way (planned updated guidance will be coming);
- There is support for PAPs/CU programs from multiple stringent regulatory agencies, with experience navigating the complexities of PAPs/CU programs in their settings;
- PAPs/CU programs do not negatively impact drug registration.

The next session focused on presenting specific principles for PAPs, including principles defined by impacted communities/implementing agencies, as well as those determined by NIC developers. The session started with a presentation on a framework for PAPs/CU programs based on personal experience, review of the BETTER Project documents, and years of experience with the Global TB Community Advisory Board (TB-CAB). Five key pillars of the framework emerged, including:

1.) Prioritizing access, including free and equitable access to novel compounds, both as single agents and as part of regimens for all DR-TB forms, as soon as early efficacy and safety data are available;

2.) Ensuring all populations can access new drugs, with the new drug given for as long as it is deemed necessary, alongside informed consent, counselling, and socioeconomic support where feasible;

3.) Having an independent body review the clinical files and recommend optimal treatment regimens with common and jointly agreed pathways;

4.) Collecting and sharing data on the use of new drugs with relevant stakeholders; and

5.) Building pharmacovigilance requirements for new drugs upon past experiences and existing systems rather than creating new, developer-specific systems.

The next presentation was from a group of NIC developers, who came together exchange experiences and prepare the ground for a common framework to provide NICs for individual CU. They have defined ten guiding principles for inclusion of NICs in CU programs. These guiding principles are not legally binding, but are considered minimum requirements, which do not replace any individual NIC developer's standard

operating procedures. The aim of these principles is to try and harmonize approaches. Some NIC developers are still obtaining internal legal and compliance clearance for signing on to these principles. The principles include:

1.) Consideration of local health authority regulations in CU;

2.) Inclusion of an NIC in CU should be for individual use and as a last resort;

3.) Regimens will not be designed by NIC developers but rather by independent experts (through a Consilium or Consilia) who take into account the best available preclinical and clinical evidence, reviewed and approved on a case-by-case basis;

4.) An established TB "Consilium" that agrees to these guiding principles should serve as a common, impartial, CU assessment body;

5.) A minimum safety data set should be available on the NIC (such as phase 2 data);

6.) The CU Consilium should ensure DST results are available;

7.) A single CU agent should never be added to a failing regimen;

8.) The Consilium and the NIC developers shall execute carefully the benefit-risk assessment of adding an NIC to any combination of anti-TB drugs;

9.) The final decision to provide the NIC lies with the NIC developer; and

10.) CU participants must have access to relevant information, and an informed consent form must be signed by them or their legal representatives and maintained in records by the treating physician.

There was general discussion noting that overall, there was harmonization of both groups' guiding principles. The successive discussion included questions about the level of transparency in decision making and raised concerns about the term "last resort", as there needs to be an early enough introduction of an NIC so that there are sufficient agents to compose a regimen, and that waiting for action as a "last resort" could drive poor outcomes and drug resistance. Emphasis on balance—starting early enough to potentially benefit people but also not so early that the person has a real chance of being cured without an NIC—was an important discussion point. Participants also flagged concerns about how comprehensive the drug susceptibility testing (DST) needs to be to access NICs through CU programs, noting that full DST can take months, may not be available in most settings, and could be a problematic requirement. There was discussion on how this was managed with bedaquiline and delamanid and that the Consilium could consider documented or likely resistance. Some participants also suggested changing the word "Consilium" which can sound restrictive, to a more

supportive terminology, such as “Compassionate Use Support Program” or “CUSP”. Of note, a CUSP would have many more supportive components than just a clinical review committee. Some participants felt the word “Consilium” was reasonable to use when referring to the clinical review committee.

Key Points

- The principles of PAPs/CU programs presented by impacted communities/implementing organizations and by NIC developers are well-aligned overall, although there was some concern raised about the term “last resort” and limited access to DST in a timely manner;
- There is an urgent need for a process and infrastructure to support PAPs and help navigate some of the key clinical details and specifics that need to be developed around the general PAP principles, as well as to define some of the more general terms used in those principles;
- The CUSPs must include impacted communities and should not be dominated by experts from high-income, low-burden countries, but rather should include expertise from high-burden countries and relevant specialists. These CUSPs should acknowledge and collaborate with existing national groups to prevent duplication of work and efforts, and to provide rapid input into patient care;
- Transparency in decision making will be a vital element of the PAPs/CU program process, along with equity, moving beyond “exceptionalism” to make sure these PAPs/CU programs can be accessed by all.

The final session of Day One focused on sharing information about the NICs and planned trials for people with DR-TB that has expanded resistance. There was a very comprehensive review of all the NICs in the pipeline, including data on safety, efficacy, and possible cross-resistance. Most trials are focused on drug-susceptible TB or simpler versions of DR-TB. Three trials at various stages are underway for DR-TB with bedaquiline resistance (both with limited other resistance to group A drugs) that combine multiple NICs. EX-DR will be based in South Africa, Eswatini, and Belarus and is currently in the protocol development phase (aiming to start in 2026). CLOBbeR-TB is a planned trial that has received an excellent National Institutes of Health (NIH) score but was originally planned for South Africa, which will no longer be possible within the NIH funding framework (so they are now seeking alternate sites and funding mechanisms). The third trial, called TASP, is planned by European and Developing Countries Clinical Trial Partnership (EDCTP). Participants discussed that the inclusion criteria of many of these studies could preclude large numbers of individuals as well as specific groups of people (i.e. those who fall outside age criteria, those who have co-

morbid disease, those who are in poor clinical conditions). There was general agreement that the trials and CU/PAPs can and should co-exist and be complementary to one another.

Key Points

- There are multiple NICs in the pipeline—including with phase 2b data—that could be part of PAPs/CU programs;
- Although there are planned trials for people with DR-TB that have expanded resistance, they are still in the protocol development phase or lack funding;
- PAPs/CU programs and formal research programs can and should complement one another.

Day 2

The second day of the meeting primarily focused on action points and discussions. For inspiration, the day started with two presentations showing how research and PAPs/CU programs can complement and inform one another, building sustainable structures that can later be utilized to support and roll out innovation. The first presentation focused on PAPs/CU programs for bedaquiline in France that later expanded to Georgia and Armenia and informed the development of the endTB clinical trial. The second presentation was from Eswatini, focusing on their experience with bedaquiline and delamanid PAPs/CU programs and how these informed not only treatment programs in the country but also diagnostic programs and capacity building in the country. Eswatini has a troubling strain of M. tuberculosis with an I491F mutation that is missed by Xpert MTB/RIF testing, and which is also associated with resistance to bedaquiline and clofazimine. To address this, the country has rolled out targeted next-generation sequencing (tNGS) for all patients, and in this way, they have found several individuals with bedaquiline-resistant TB. Eswatini has established a collaborative clinical support committee, led by local physicians but with input from international collaborators. Participants had discussions during this session about the possibility of “randomizing” people to or within PAPs/CU programs. Some participants felt this was an important way to learn and that it was an honest way of acknowledging that there were no definitive data to recommend one drug or another. Other participants expressed serious doubts about this, noting that randomization is complex, takes away people’s agency and choices (which may be especially important for people facing difficult treatment options), and does not really “control” for all factors that impact treatment outcomes. Overall, participants felt randomizing people to or within PAPs/CU programs was not ideal.

Key points:

- Research and PAPs/CU programs have a history of complementing one another, offering newer options for patients and driving innovation, as shown in successful programs from France and Eswatini;
- As better diagnostics are rolled out, they need to be linked to expanded treatment options;
- The programs from France and Eswatini would be good models to build upon for current NIC access through PAPs/CU programs;
- While formal research may be the ideal way to learn about NICs for registration, PAPs/CU programs can offer important means for learning about populations often excluded from research (i.e., pregnancy, people with comorbidities, people with substance use disorder) and to allow for people with limited treatment options to have maximal agency, by selecting care pathways that most align with their values and needs.

The next session was a large group discussion to take a deeper dive into some of the clinical details on who might benefit from NICs through PAPs/CU programs. The goal of this was to illustrate some of the complexity of the clinical decision making (thus reinforcing the need for an independent clinical support group through a CUSP). Another goal was to help identify gaps where work and support might be needed. The session began with a perspective of how complex the stories and treatment journeys of many of the individuals were. The group was then encouraged to think about what "reasonable use" of NICs might be as opposed to "definitive use" (e.g., comprehensive and full DST with proven resistance to most currently available drugs versus high degree of clinical likelihood of resistance based on exposure history and response to therapy). Deeper dives were taken into discussions on duration of therapy, cross-resistance, need for full DST, and comorbidities. The following points of agreement were reached:

1. Unless it is likely to expect cumulative toxicity, longer durations beyond what was formally trialed with NICs could be considered on a patient-by-patient basis (especially important given that stopping bedaquiline after 6 months sometimes led to culture reversion);
2. Unless there are specific toxicities or drug-drug interactions to consider, populations should not be excluded from participation (including people with comorbidities, pregnant women, and children);
3. Requiring full DST for many of the drugs will limit access and delay treatment decisions, thus it might be reasonable to include people with strains of M. tb with

proven resistance or in whom resistance is highly likely based on exposure history and response to therapy—although this needs to be coupled with advocacy for better access to diagnostics and possible storage of surveillance cultures or use of international referral labs;

4. If there is known to be clinically meaningful cross-resistance (i.e., within a class), then the NIC may not be optimal to use; however, if there is potential for cross-resistance but the minimum inhibitory concentrations (MICs) are below the achievable drug concentrations, then the NIC could be considered;
5. Given all the complexities of these decisions, it is important to have knowledgeable clinical advisors as part of a CUSP, including among those who determine if an NIC is warranted (i.e., "the clinical review committee within the CUSP");
6. The element of shared decision making is especially important, given all the uncertainties.

The group agreed with the NIC developers' principles that PAPs/CU programs with NICs should be considered for individuals in whom a four-drug regimen cannot be constructed either due to resistance (known or likely) or intolerance (with intolerance defined by the clinical review committee within the CUSP). The overall goal is to maximize the number of effective drugs while minimizing toxicity, all while recognizing that there is still quite a notable amount of uncertainty about how these NICs might contribute to efficacy or toxicity.

The group emphasized the importance of shared decision making and developing information for participants of PAPs/CU programs. This needs to go beyond complex "informed consent" forms that are usually developed or required (for legal reasons) by NIC developers and should be developed with input from impacted communities. The BETTER Project is currently working on some tools for this. A model for "shared decision making" could be one of the deliverables from a PAPs/CU program. The group also discussed the importance of setting expectations (e.g., time from application to drug-in-person-with TB, relative effectiveness of these agents) with all stakeholders. The participants also emphasized the need for two-way communication between NIC developers and those using NICs through PAPs/CU programs.

Key Points

- Clinical decision making can be complex and is best done by people who are near-to-patient (i.e., impacted community in collaboration with clinicians) and supported by international experts—ideally through a collaborative CUSP;

- Quality of life and quality of care are important factors to be considered, and communication with people living with these forms of TB and with DR-TB survivors is essential;
- Narrow criteria can limit access, but a reasonable balance needs to be taken into account, which can be supported by elaboration of best clinical practices that promote inclusion unless there are specific concerns for a patient or population;
- Shared decision-making to promote person-centered care is essential, and models for doing this could be one important "work product" from PAPs/CU programs that could be deployed across the spectrum to improve access within a human-rights framework;
- Given the urgency of implementing PAPs/CU programs coupled with the fact that this relatively small number of individuals have very intense needs, PAPs/CU programs could be an ideal way to field test end-to-end access issues at very early stages of product development.

The final session of Day Two focused on identifying next steps and key actors in each step (see Figure 1). The session focused on three core actors: treating providers and the people with TB whom they are working with; NIC developers; and national regulatory authorities. The responsibilities of each group were discussed, including:

People with DR-TB seeking care and their providers:

- Liaise with the local Ethics Review Board to get approval to proceed to CU with a specific TB compound
- Responsible for filling a CU request form on behalf of the patient that includes key medical history data
- Agree to follow the CU protocol developed by a sponsor for a particular CU compound
- Agree to report within 48 hours any Serious Adverse Event, pregnancies and Adverse Drug Reactions (i.e., non-serious adverse events which are possibly, probably, or very likely related to the administration of the TB compound under CU)
- Collect sample(s) for microbiological test and/or provide DST results whenever available and required by sponsors
- Sign a physician agreement when required by sponsors

NIC Developers

- Provide the full treatment for a new compound to be used under CU
- Provide information on the pharmaceutical quality of the new compound to local regulatory authorities (Good Manufacturing Practices certificate, certificate of analysis, etc.)
- Provide all relevant clinical information to practitioners and via informed consent from patients
- Provide feedback on Serious Adverse Events with reference to regulatory authorities
- CU compound to be provided free of charge, including freight costs

National Regulatory Agencies Consulted by Both Groups

- Provide information regarding CU rules and importation procedures for medicines not yet registered locally

The key areas include advocacy; development of clinical and implementation support tools; procurement and distribution of quality drug supply (including of NICs and companion agents); pharmacovigilance; laboratory support and surveillance; training and capacity building; and data collection and sharing. All these areas will need to be supported by funders, both catalytic (i.e., external) and long-term (i.e., national contributions).

Logistics partners Clinton Healthcare Access Initiative (CHAI) and Stop TB Partnership's Global Drug Facility (GDF) are on board. CHAI emphasized how this aligned with their target access profile work and was especially interested to follow up with NIC developers on timelines and next steps. GDF discussed their work on providing non-registered products to countries, including for pediatric formulations of TB drugs and for research projects, and their vast experience with the rapid distribution of combination regimens. GDF was also a key implementing partner in the global bedaquiline implementation program and can build on that experience as well.

Key Points

- Core participants for PAPs/CU programs include people accessing care and the clinicians providing that care; country health authorities; and NIC developers;
- These core actors are supported by facilitators (including CUSP) and funders, who must be open and inclusive, especially during these challenging global health funding times;

- Core tasks of these groups include advocacy; development of clinical and implementation support tools; procurement and distribution of quality drug supply (including of NICs and companion agents); pharmacovigilance; laboratory support and surveillance; training and capacity building; and data collection and sharing;
- These activities can all fit within the scope of the NIC developers interacting with an umbrella CUSP, but funding must be secured for the umbrella CUSP work;
- Key implementing and logistical partners are on board with some of the discussed work—including CHAI and GDF—and are keen to follow up with NIC developers and implementers on next steps.

Conclusion

The meeting concluded around the theme that “access cannot be an afterthought.” The participants felt that the meeting had achieved its goal and that the “terms of reference” for the next steps had essentially been written. The group committed to acting rapidly given the urgent need and will reconnect informally in November around the Union World Conference on Lung Health (although many stakeholders will be unable to attend due to funding cuts). Work will also continue remotely. The meeting contributed to the development of a platform and plans for further refining systematic approaches for PAPs/CU programs for DR-TB strains with expanded resistance that can be accessible to all people impacted by these forms of TB. In doing so, it pairs the highly individualized considerations with a strongly systematic approach, providing a model for how end-to-end access can be implemented across the spectrum of services. A proposed framework for supporting PAPs/CU was presented that highlights desirable elements to ensure timely and safe provision of NICs (see Figure 2). This infrastructure would require considerable investment and coordination.

Figure 1: Compassionate Use Support Program (CUSP) Components

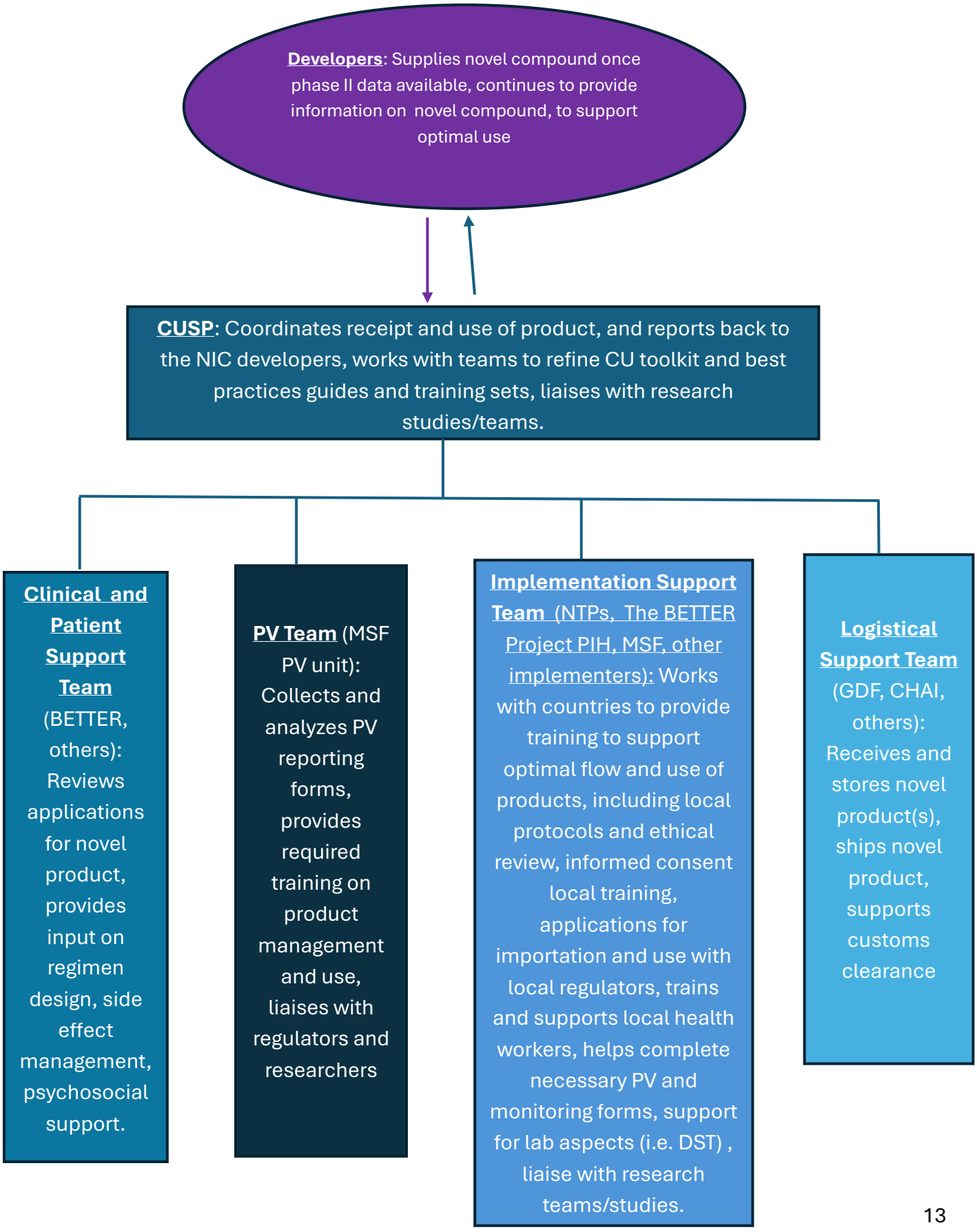
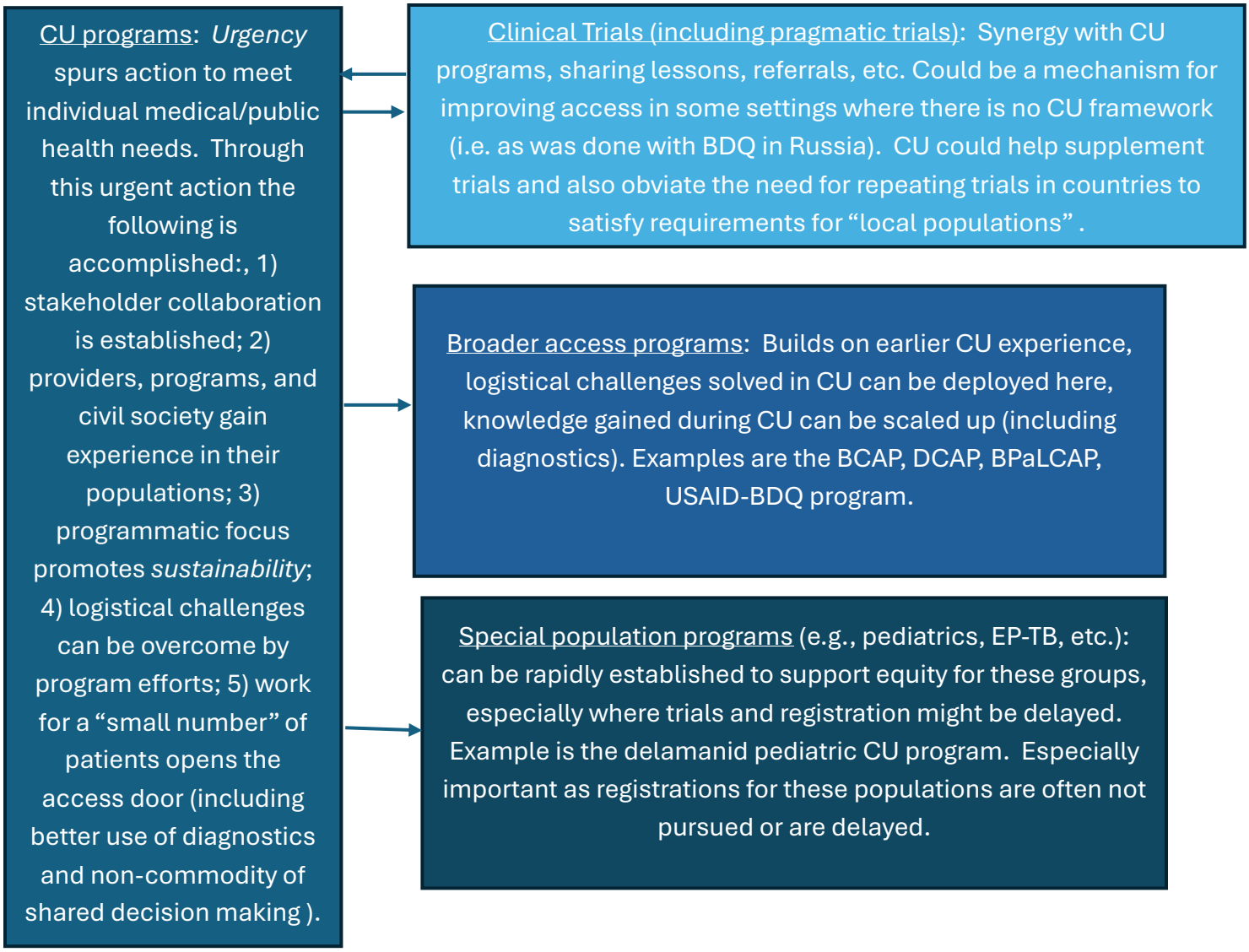


Figure 2: Compassionate Use as a Catalyst for End-to-End Access



Annex 1: Meeting Agenda

Closing the pre-approval access* gap for people affected by TB with expanded drug-resistance

📅 October 22, 2025, 7:30 a.m. – 2:30 p.m. EDT
October 23, 2025, 7:30 a.m. – 1:00 p.m. EDT
📍 Johns Hopkins University Bloomberg Center, 555 Pennsylvania Avenue, Washington, D.C.
💻 Hybrid format – Virtual participation available

Objectives

1. Apply a decade of experience in pre-approval access to new TB drugs, including bedaquiline and delamanid, to compounds currently in development
2. Identify new tools and/or resources needed to create sustainable mechanisms for supporting pre-approval access to new TB treatments in development
3. Develop core practices around challenging topics for pre-approval access
4. Identify roles and responsibilities of different actors and secure concrete commitments towards fulfilling them
5. Model for other disease areas a pre-approval access framework that can be adapted across various needs and settings

***Note on terminology**

This convening uses the term "pre-approval access" as a broad term that encompasses the varying ways countries, programs, innovators, and regulators think about compassionate use of new TB drugs for people with unmet medical needs. This includes, but is not limited to, compassionate use, expanded access programs, named-patient use, and other pathways that vary in name and regulatory thresholds at national or regional levels. Our objective is to draw up coordinated and feasible approaches to enable timely access to promising TB drugs for patients with limited treatment options. We intend to be inclusive of the terms that various stakeholders use while focusing on achieving concrete results for people living with TB.

Day 1 – Wednesday, October 22, 2025	***Schedule reflected in Eastern Daylight Time (EDT)***	
**7:15 – 7:30 a.m.*	*Registration and light snacks*	
7:30 – 7:45 a.m.	**Welcome and opening remarks** ▪ Inspiring collective purpose and emphasizing critical importance of advancing pre-approval access for drug resistant TB in the current political and scientific landscape. ▪ Setting objectives for the meeting.	Dr. Richard Chaisson *Johns Hopkins University* Dr. Cherise Scott *Unitaid*
7:45 – 8:05 a.m.	**Unlocking hope for pre-approval access** ▪ Framing pragmatic, solutions-oriented goals to achieve pre-approval access and expand knowledge. ▪ Coordinating pre-approval access pathways for novel TB compounds and recognizing that we have a successful track record in doing this work.	Dr. Jennifer Furin *The BETTER Project*
8:05 – 8:15 a.m.	**The timeliness of the moment** Presenting the current global needs for accessing new TB drugs from the epidemiologic perspective with a goal of aligning stakeholders on the need to act expeditiously.	Dr. Sean Wasserman *St. George's, University of London*
8:15 – 9:30 a.m.	**Learning from experience: pre-approval access precedents from the first new TB drugs in decades** Summarizing the experience with pre-approval access in the TB field from the individual, clinical, and program perspectives with a goal of sharing lessons that can be applied to new TB drugs. ▪ The survivor's experience: recapitulating testimony from one of the first recipients of BDQ + DLM in combination under pre-approval access in South Africa. ▪ The clinician's experience. ▪ The country's experience. ▪ How pre-approval access filled key research gaps and paved the way for uptake of new drugs.	Goodman Makanda *DR-TB survivor and advocate* Dr. Jigneshkumar Patel *P.D. Hinduja Hospital and Medical Research Center* Dr. Anja Reuter *Stellenbosch University* Dr. Zaza Avaliani *National TB Control Program, Georgia* Moderator: Wim Vandevelde *Global TB Community Advisory Board*

	▪ Implementation of early access to BDQ and DLM, highlighting community demand and research synergy, operational models, and policy innovation.	
9:30 – 9:45 a.m.	**Lessons learned from the sponsor's experience** Summarizing the experience with pre-approval access in the TB field from the sponsor and innovator perspectives, sharing lessons that can be applied to new TB drugs.	Dr. Ingrid Eshun-Wilsonova *Johnson & Johnson*
9:45 – 10:15 a.m.	*Coffee and breakfast*	
10:15 – 11:00 a.m.	**Regulatory and WHO perspectives** A companion session, summarizing the experience with TB pre-approval access from the WHO and regulators, sharing lessons that can be applied to new TB drugs.	Dr. Matteo Zignol *World Health Organization* *U.S. Food and Drug Administration* Dr. Marco Cavaleri *European Medicines Agency* *South Africa Health Products Regulation Authority (SAHPRA)* Moderator: Dr. Jonathan Stillo *Global TB Community Advisory Board*
11:00 a.m. – 12:20 p.m.	**Principles of pre-approval access and industry response** ▪ Sharing the perspectives of impacted communities and of innovators when it comes to establishing a framework for expanded access to new TB drugs. The goal will be to highlight areas of agreement and to navigate topics on which there are differing priorities and views. ▪ Reviewing the BETTER call to action. ▪ Discussion	Oxana Rucșineanu *Global TB Global TB Community Advisory Board and DR-TB survivor* On behalf of the New Investigational Compounds Developers – Dr. Nataša Lazarević and Dr. Masoud Dara *Otsuka Novel Products GmbH* Moderator: Dr. Carole Mitnick *Harvard Medical School*

12:20 – 1:15 p.m.	*Lunch break*	
1:15 – *2*:15 p.m.	**Research updates: New drugs and addressing potential cross-resistance** Scientific updates on the newer drugs, including planned/ongoing studies and data regarding efficacy/safety and possible cross-resistance with existing compounds. The goal will be to provide an open forum for all stakeholders to understand the science of the new TB drugs. ▪ Present current data on drugs in phase II or later stages of development. ▪ Present novel combos proposed for clinical trials focused on XDR-TB (EX-DR and CLOBBER-TB).	Dr. Ilaria Motta *Médecins Sans Frontières* Moderator: Dr. Sean Wasserman *St. George's, University of London*
2:15 – 2:30 p.m.	**Closing reflections**	Dr. Jennifer Furin *The BETTER Project*

Day 2 – Thursday, October 23, 2025	***Schedule reflected in Eastern Daylight Time (EDT)**	
**7:15 – 7:30 a.m.*	*Arrival and light snacks*	
7:30 – 7:45 a.m.	**Recap of Day 1**	Rekha Radhakrishnan *Johns Hopkins University*
7:45 – 8:20 a.m.	**How research and compassionate use complement each other** Showcasing how TB research and pre-approval access can complement one another and reach different populations. The goal will be to transform misunderstandings about pursuing "research instead of compassionate use" and developing a framework for maximizing benefits of both.	Dr. Lorenzo Guglielmetti *Médecins Sans Frontières* Dr. Tendai Nkomo *National TB Control Program, Eswatini*
8:20 – 10:20 a.m.	**Clinical scenarios for pre-approval access** Discussing the current clinical priorities for access to new TB drugs, both as single agents combined with existing TB drugs and as combinations of multiple new drugs and existing agents. The goal will be to identify populations to receive new TB drugs as part of pre-approval access in the next 6 months.	Dr. Jennifer Furin *The BETTER project* Dr. Animesh Sinha *Médecins Sans Frontières* Moderator: Dr. Jeffrey Tornheim *Johns Hopkins University*

	Building shared understanding on general clinical scenarios when pre-approval access is needed. 1. patients in whom a four-drug regimen can't be constructed based on resistance/intolerance; 2. as substitute for injectable and/or IV medicines because salvage regimens either require prolonged carbapenem or aminoglycoside use; 3. as holding regimen in people on BPaLM but not improving, don't yet have DST – countries, not innovators, need support in these areas. **Building shared understanding on general regimen development** This will include general principles for suitable regimens development, core agents for an optimized backbone, and when regimens can be constructed with only one new drug versus multiple new drugs.	
10:20 – 10:45 a.m.	*Coffee and breakfast*	
10:45 a.m. – 12:15 p.m.	**Mapping needs, responsibilities, and structures now and moving forward** Define concrete activities, responsibilities, and timelines for ensuring timely access to new drugs for TB. ▪ Countries ▪ Drug sponsors ▪ Funders ▪ Clinicians ▪ Pharmacovigilance ▪ Clinical review ▪ Data sharing **Next steps and closing commitments** Shared commitments and next steps for taking forward shared responsibility for pre-approval access.	Dr. Christophe Perrin *Médecins Sans Frontières* Dr. Jennifer Furin *The BETTER project* Dessislava Tarlton *Unitaid*
12:15 – 1:00 p.m.	*Lunch and departure*	

Annex 2: List of Participants

	NAME	ORGANIZATION
1	Richard Chaisson	Johns Hopkins University
2	Kelly Curran	Johns Hopkins University
3	Jennifer Furin	Harvard University
4	Rekha Radhakrishnan	Johns Hopkins University
5	Saloni Fruehauf	Johns Hopkins University
6	Christophe Perrin	Médecins Sans Frontières
7	Cherise Scott	Unitaid
8	Dessislava Tarlton	Unitaid
9	Carrie Tudor	Johns Hopkins University
10	Laurence Borand	Johns Hopkins University
11	Tejaswini (Teju) Dharmapuri Vachaspathi	Treatment Action Group (TAG)
12	Elizabeth Lovinger	Treatment Action Group (TAG)
13	Erin McConnell	Treatment Action Group (TAG)
14	Goodman Makanda	DR-TB survivor, one of the first to receive BDQ + DLM in combination
15	Ashna Ashesh	Lawyer, Public Health Professional, and MDR-TB survivor
16	Natasa Lazarevic	Otsuka Novel Products GmbH
17	Masoud Dara	Otsuka Novel Products GmbH
18	Norbert Heinrich	Ludwig Maximilian University of Munich
19	Simon Tiberi	GlaxoSmithKline
20	Ingrid Eshun-Wilsonova	Johnson & Johnson
21	Nyasha Bakare	Johnson & Johnson
22	Stephanie Seidel	TB Alliance
23	Jigneshkumar Patel	P.D. Hinduja Hospital and Medical Research Centre
24	Anja Reuter	Stellenbosch University
25	Julian Te Riele	Brooklyn Chest Hospital
26	Patrick Phillips	University of California San Francisco
27	Kelly Dooley	Vanderbilt University
28	Yuri van der Heijden	Vanderbilt University
29	Sean Wassermann	St. George's University of London
30	Jeffrey Tornheim	Johns Hopkins University
31	Pauline Howell	Sizwe Tropical Disease Hospital
32	Grant Theron	Stellenbosch University

33	Makaita Gombe	Aurum Institute
34	Gavin Churchyard	Aurum Institute
35	Lorenzo Guglielmetti	Médecins Sans Frontières
36	Ilaria Motta	Médecins Sans Frontières
37	Animesh Sinha	Médecins Sans Frontières
38	Anita Mesic	Institute of Tropical Medicine Antwerp / Médecins Sans Frontières
39	Olena Zarytska	MSF Access
40	Andrew Owen	University of Liverpool
41	Carole Mitnick	Harvard Medical School
42	Marco Cavaleri	European Medicines Agency (EMA)
43	Brian Kaiser	Global Drug Facility, Stop TB
44	Brenda Waning	Global Drug Facility, Stop TB
45	Matteo Zignol	World Health Organization
46	Marina Tadolini	ERS/WHO Tuberculosis Consilium
47	GB Migliori	ERS/WHO Tuberculosis Consilium
48	Claire Watkins	Clinton Health Access Initiative (CHAI)
49	Zaza Avaliani	National TB Program, Georgia
50	Nana Kiria	National TB Program, Georgia
51	Tendai Nkomo	National TB Program, Eswatini
52	Mansa Mbegna	KNCV Tuberculosis Foundation
53	Alexander Chu	Brigham and Women's Hospital
54	Jonathan Stillo	Global TB Community Advisory Board
55	Sneha Maru	Global TB Community Advisory Board
56	Wim Vandevelde	Global TB Community Advisory Board
57	Oxana Rucsineanu	Global TB Community Advisory Board
58	Sergiy Kondratyuk	Global TB Community Advisory Board
59	Joyce Ngetuny	Global TB Community Advisory Board
60	Blossom Makhubalo	Global TB Community Advisory Board
61	mlozano	Global TB Community Advisory Board
62	Patrick Agbassi	Global TB Community Advisory Board
63	Lusiana Aprilawati	Global TB Community Advisory Board
64	Ani Herna Sari	Global TB Community Advisory Board
65	Esther Mubiru	Global TB Community Advisory Board
66	Ganzorig Munkhjargal	Global TB Community Advisory Board
67	Ketho Angami	Global TB Community Advisory Board
68	Krystyna Rivera	Unitaid Communities Delegation
69	Ángela León Cáceres	Women4GlobalFund