TREAT TB | Technology, Research, Education and Technical Assistance for Tuberculosis

PRACTICAL RECOMMENDATIONS
FROM THE STREAM CLINICAL TRIAL

Community Engagement

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About this guide

STREAM is a multi-country clinical trial evaluating shorter, more tolerable multidrug-resistant tuberculosis (MDR-TB) regimens, carried out over more than 10 years.

The trial offered an exceptional opportunity to evaluate key issues related to community engagement (CE) and this guide presents eight practical recommendations designed to improve CE in future clinical trials.

Companion documents covering implementing clinical trials and pharmacy and clinical supplies can be found here.

LEFT

Chennai CAB Coordinator, Sister Mary Josephinal Francis (left) at the Street Theater event in Northern Chennai (September, 2020)

Background

STREAM is the first large-scale, multi-country clinical trial to examine shortened regimens for MDR-TB. It is also the first phase III trial to test the efficacy and safety of bedaquiline in a shorter regimen. The trial recruited more than 1,000 participants at sites in Ethiopia, Georgia, India, Moldova, Mongolia, South Africa, Uganda, and Vietnam, making STREAM the world's largest recruited clinical trial for MDR-TB.

STREAM Stage 1 compared a 9–11-month MDR-TB regimen to the locally-used regimen in line with guidance of the World Health Organization (WHO) (approx. 20 months). Results from Stage 1 were published in the *New England Journal of Medicine* and demonstrated that favorable outcomes for participants on the control (20–24-month regimen) and intervention (9–11-month) regimens were very similar under trial conditions. The STREAM Stage 1 results, which also showed that the shorter regimen can reduce costs to the health system and patients, played a key role in the development of the WHO recommendations on the use of shorter regimens to treat MDR-TB.

STREAM Stage 2, which is ongoing, is evaluating an all oral, bedaquiline-containing regimen that is potentially as effective as and more tolerable than the injectable-containing regimens currently in use. It is also evaluating the comparative cost of the two regimens, for both the patient and the health system. Stage 2 is expected to contribute important evidence for future policy decisions about injectable-free MDR-TB regimens. Recruitment to Stage 2 of the trial closed in January 2020 and results are expected in 2022.

A comprehensive program of CE was supported by the STREAM clinical trial at all Stage 2 sites.

- Community advisory boards (CABs) comprised of representatives from non-governmental and community-based organizations, TB survivors, and other community representatives were established and supported as coordinating mechanisms for CE at all 13 trial sites.
- Local CAB coordinators were chosen from CAB members, with the support of the trial team.
- A community liaison/engagement officer was appointed at each site to act as a bridge between CAB members and the study site/team.
- Funding was provided for CE activities developed by the CABs, including feedback to and from the study team regarding STREAM, stakeholder meetings, CAB member training and capacity building, attendance at health policy meetings, community outreach, psychosocial support for STREAM participants, and cross-site experience sharing.
- Technical assistance and CE coordination were provided to CABs by Vital Strategies and partners, including REDE-TB and Wits Health Consortium.

"When Stage 2 began, a CE Plan was developed to harmonize the trial's initiatives for including communities in the study. The CE plan was piloted and initially implemented in Mongolia (2015) and later in Ethiopia, Uganda, new S. African sites, Georgia, Moldova, and finally the three Indian sites. Implementation was sometimes challenging because community participation in TB research was unprecedented at some STREAM sites."

STREAM CE COORDINATOR,
REDE-TB

Community Engagement

Community engagement is an ethical obligation and an integral part of all tuberculosis (TB) research. It cannot be an afterthought but should be a fundamental part of how the research is conceived, designed, implemented and used by policy makers. Done well, CE improves trial implementation and participant outcomes by building a relationship of trust between affected communities and trial implementers. It also allows affected communities to participate in all stages of the research cycle – from setting the research agenda, to the design of clinical trials, through to evidence-based policy change based on research results. STREAM's significant commitment to CE yielded important successes, but also highlighted areas for improvement to achieve meaningful and lasting impact from CE.

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Commitment to Key Principles

Key stakeholders must understand and commit to the principles underlying CE to achieve its benefits

The Good Participatory Practice (GPP) guidelines for TB Drug Trials 2012 represent an important set of CE principles developed by a working group whose members included the World Health Organization, the United States Food and Drug Administration and the National Institutes of Health. As such, they are an excellent, agreed starting point for defining the minimum standards required for effective CE. The GPPs confirm that the benefits of CE – mutual understanding, complementarity and efficiency – require a genuine commitment to six guiding principles – respect, fairness, integrity, transparency, accountability, and autonomy.

STREAM's commitment to these principles yielded important and long-term successes, including the development of highly productive working relationships between STREAM CABs and study teams, as well as creative stakeholder collaborations on complementary activities – for example, STREAM CABs supporting national TB programs with community outreach. Careful implementation by the Sponsor also ensured CABs had the freedom to act independently as the voice of the community throughout the trial.

Nevertheless, the STREAM experience highlighted areas of focus for future trials. Although the GPPs indicate their intended audience includes trial funders, sponsors, and research teams, many STREAM study teams were unaware of the GPPs at the start of the trial, and study team buy-in to the GPP principles was quite variable. Awareness and understanding of the GPPs by CAB members was also variable. This highlights the need, at the start of every trial, to discuss and agree with both the study team and CAB members the incorporation of the underlying GPP principles into an agreed CE plan.

At some sites, the study team's commitment to information sharing – a key prerequisite to transparency – required development over time. In addition, cultural norms sometimes led CAB and community members to be reticent about sharing their views, and study team members being less likely to acknowledge and respond to CAB and community feedback. Overcoming these barriers required a structured program of study team/CAB member interactions, active intervention from the Sponsor/CE Technical Advisor/Coordinator where stakeholder expectations did not align, and a targeted training program for CAB members aimed at increasing their capacity for meaningful participation in trials.

"[Our biggest CE successes were d]evelopment of an effective Community Engagement structure in a new site where there was no prior research and forming a regional and even international CE structure that addresses the needs of all communities involved."

STREAM STUDY TEAM MEMBER

RECOMMENDED BEST PRACTICES

Build in understanding and adherence to GPP principles as a requirement of the trial through the following measures:

- Donors should require researchers to build-in CE and to fund CE/CABs meaningfully from the beginning of trial planning and design, through to dissemination of results
- Particularly where there is limited experience with CE, the sponsor should arrange for appropriate technical assistance for CABs
- The GPP guidelines should be clearly referenced in the trial protocol
- The choice of sites should, in part, be based on experience with and support for CE
- Sponsors should plan to fund a significant FTE for a Community Liaison Officer/Community Engagement Officer (CLO/CEO) in the study team to support CE
- All trial sites should appoint a CLO/CEO that fully commits to CE
- The CLO/CEO should be empowered to work independently with the trial CAB (or other established CE mechanism)
- Site initiation should include training in GPPs for study team members and ongoing GPP training should be offered throughout the trial

Agreed Roles and Responsibilities

Roles and responsibilities of all stakeholders must be agreed by all key stakeholders

Structured CE was a new practice for most sites involved in the STREAM clinical trial. At all but one Stage 2 site, a new CE coordinating mechanism (in all cases, a CAB) was established around the time the trial began at the site. This meant there were no pre-agreed roles and responsibilities for key stakeholders related to CE. And, clearly defining and documenting the roles and responsibilities for CE in STREAM was not always prioritized at sites prior to initiation.

Despite this, STREAM CABs and study teams worked hard to build understanding of how their knowledge and skills were complementary and could be employed to improve trial results. In most cases, this meant involving CAB members as trusted partners for community outreach and (at some sites) participant support (financial and/or psychosocial). For CAB members, study teams invested in training CAB members to maximize their ability to participate as full partners throughout the clinical research cycle.

Despite the overwhelmingly positive experience of STREAM, there were a few areas of misunderstanding that arose from ill-defined roles. One example relates to contact between trial participants and CAB members. Although the benefits of peer support for MDR-TB patients are well-accepted, there is no consensus regarding the role (if any) CAB members should play in providing psychosocial support to trial participants. The confidentiality of research participants in trials is paramount, and therefore some sites elected not to support CAB member/participant contact. On the other hand, CAB members were often drawn from NGOs and CBOs whose role in other contexts is to support people with TB and they were therefore expecting to play the same role in the trial. At study sites where this issue was not clearly addressed and agreed by stakeholders, diverging expectations had to be resolved.

A second example relates to the role of CAB members in recruitment. Trial sites are often under pressure to meet recruitment targets agreed with the trial sponsor and, in that context, it can be tempting to rely on CAB members (who often have deep roots in the community) to boost recruitment. On the other hand, the GPPs emphasize that the objectives of CE and recruitment activities are different, and that CAB members should not participate in participant recruitment. Differences in the expectations of STREAM study teams and CABs regarding their roles in recruitment required further engagement and discussion, although this improved over time.

"Lack of previous experience in [our country] of community involvement in clinical research and lack of understanding by the research team of the clear role of the community in research [were challenging]. It required building relationships and understanding aspects of clinical research management to delineate areas of common interest to provide added value."

STREAM CAB MEMBER

RECOMMENDED BEST PRACTICES

Clearly define and document roles and responsibilities of the study team and the CAB with respect to CE through the following measures:

- Before site initiation, the sponsor should convene all stakeholders (CABs, CLO/CEO, PI) to agree roles and responsibilities with respect to CE
- Ensure roles and responsibilities of all stakeholders with respect to CE are formalized and documented, ideally, in the trial protocol
- Produce Terms of References for CAB members and the CLO/CEO (signed by PI and CAB members)
- The sponsor should monitor CE activities carefully and intervene (where necessary) if stakeholders depart from agreed roles and responsibilities
- The sponsor should act as a "mediator" if sites and CABs are unable to agree roles/responsibilities in connection with the trial

Open and Honest Communication

Meaningful CE requires regular, open and honest communication between CABs and PIs/Sponsor

In any clinical trial, researchers have important knowledge and information that the community stakeholders do not, and the same is equally true for community stakeholders. Researchers understand the disease and the trial, but community stakeholders understand whether communities and participants think the trial is relevant and acceptable to the community. Therefore, to optimize trial implementation and impact, there must be regular and open two-way communication between the study team and the community. This will also build trust between researchers and community members, which will have important long-term benefits for future research.

Ensuring regular and open communication is not always easy, particularly if stakeholder roles and responsibilities are unclear. In addition, variations in cultures and norms across sites and countries add complexity to establishing a uniform trial communication plan. For study team members, who are already very busy, informing community members about trial progress is sometimes seen as a burden, without obvious benefits. As well, researchers can be concerned about sharing confidential information with CABs and community members.

In STREAM, all sites held regular (usually semi-annual) general CE meetings as a mechanism to update key stakeholders, including STREAM CABs, about trial progress. However, a number of CABs preferred more frequent updates, which sometimes did not occur. In addition, the scope of information PIs were willing to share was sometimes circumscribed. For example, at one site, the protocol for the trial was not shared with the CAB due to confidentiality concerns, even though it was publicly available.

In addition, quarterly meetings between CABs and the study team took place at most sites. It was hoped those meetings would be a forum for study teams to learn from CAB members about community suggestions for improving trial implementation and acceptability. Our experience, however, was that CAB/community input was both solicited and given less frequently than we would have liked. It is likely this resulted from limited study team buy-in to community involvement, limited community experience with clinical trials, and cultural norms.

"Knowledge and literacy about community engagement in research increased among medical staff and TB people. Trust [on] both sides was increased."

STREAM CAB MEMBER

RECOMMENDED BEST PRACTICES

Build institutions and processes that ensure regular and open two-way communications between researchers and CAB/community members through the following measures:

- Before the trial begins, a communications plan should be developed and agreed by the sponsor, PI, and CAB setting out how and when trial information will be shared
- The sponsor should encourage study teams to seek out CAB input on trial implementation challenges and protocol amendments
- The sponsor should ensure sites implement at least quarterly meetings between study teams and CABs
- CAB coordinators should be regularly informed of study progress and invited to the annual investigators' meetings and other sponsor/researcher meetings where important design/implementation decisions are made. CABs are a key stakeholder entitled to trial updates whose input is needed
- The sponsor should provide clear guidance to PIs regarding which trial documents can (and should) be shared with CAB members

Input throughout Research Cycle

Research will be more relevant and acceptable if CABs/community members have input throughout the research cycle

Ethical research must be both relevant and acceptable to the community where it is conducted. Community stakeholders are uniquely placed to comment on whether a proposed trial addresses a question that is important to the community, whether the trial design and implementation plan conform to cultural norms, and how best to communicate trial results to ensure policy change. Therefore, it is important for sponsors to consult CABs (as community representatives) before, during, and after a trial to ensure the trial addresses the health priorities of the community; trial documentation and procedures are culturally appropriate; and community members are equipped to advocate for better programs and policies.

In common with many other regulatory trials, STREAM faced significant challenges involving CABs/community members at the design phase. Although input from the global TB CAB was solicited and incorporated, input from community members at trial sites could not be sought before the sponsor finalized the trial design with the US Food and Drug Administration (FDA). This is because US FDA interactions occurred before sites were selected and site initiation (including CE) began. There will be different challenges related to donor funding cycles and priorities at the other end of the research cycle – translation of results into improved programs and policies. Advocacy and policy change based on STREAM results will continue long after results are available and donor funding ends. As a consequence, community-led advocacy at STREAM locations – for example, to amend national guidelines to incorporate shortened regimens and ensure availability of bedaquiline at reasonable prices – can only take place if STREAM CABs/CAB members continue to operate independently after STREAM funding ends.

"Even when the clinical trial has ended, CE still continues and paves the way for other studies. CABs have experience in advocacy and can influence policy change, assist improving the lives of participants, show how research can be done in our community, and [eliminate] stigma"

STREAM CAB MEMBER

RECOMMENDED BEST PRACTICES

Foster CAB involvement and sustainability across the research cycle through the following measures:

- Invite CAB members to be part of local institutions involved in research agenda-setting
- Invite CAB members to be members of research ethics committees
- Donors should fund CE before a trial begins so that local community input can be sought as part of trial design
- The sponsor should seek input from existing CABs as part of the design/protocol writing process. At a minimum, invite Global TB CAB input on the relevance and design of multisite TB trials before finalization with central regulators (e.g., the FDA or EMA)
- A results dissemination plan should be developed by the sponsor, PIs, and CABs to ensure trial results are accessible to participants and community members
- Develop capacity for advocacy by CABs
- Develop capacity of CABs to receive and manage non-trial funding to enable CE activities to continue "between" trials

Representative CABs

Research will be more responsive to community needs if CAB membership is representative

Good research is relevant and acceptable to the community where it is conducted, and CE mechanisms – like CABs – are an effective way to ensure researchers hear and understand the views of the local community and those affected by the research. However, this will only be true when CAB membership is representative of the community where a study takes place. CAB members should therefore be drawn from and chosen by the community they represent.

At all but one site (where a CAB already existed before STREAM began), STREAM supported the establishment of representative CABs through the following process. The trial's CE Technical Advisor/Coordinator – worked with the trial site to identify (or "map") community-based organizations, faith-based organizations, NGOs, patient support groups, activists, advocates, government officials/offices, and other civil society and government organizations that were likely to be key stakeholders in the trial's CE activities. The initial stakeholder mapping was completed in-person at STREAM research sites. Once a preliminary list of stakeholders was developed, the trial's CE Advisor often held one-on-one meetings with pivotal potential CAB members to confirm the output from the initial mapping exercise.

A workshop for potential CAB members was then held, with the goal of establishing a representative CAB with members chosen from the workshop participants. These workshops were designed to be inclusive (often involving 50+ participants) and participant-led in the local language to enhance the CAB's legitimacy within the community. Following the workshop, a final stakeholder meeting was held to introduce the CAB to the research team and other key stakeholders with the aim of ensuring the CAB was recognized as a legitimate participant in the STREAM research process.

In general, the STREAM process was very effective to ensure representative STREAM CABs at inception. However, ensuring CABs remain representative throughout the trial requires active intervention. CAB members are volunteers, and competing personal and professional priorities can lead to turnover. In addition, in comparison to HIV, a TB survivor may become less engaged in the CAB over time because TB (and TB treatment) are not lifelong.

"Since the CAB is multidisciplinary and diverse, ... the CAB was the eyes and ears of the community."

STREAM CAB MEMBER

RECOMMENDED BEST PRACTICES

Invest the time and resources to ensure CABs are and remain representative through the following measures:

- When forming a new CAB, systematically map stakeholders to ensure CAB make up is representative of the community, legitimate and supported by its constituency
- Ensure formation of a CAB takes place through a community-led process
- Encourage CABs to review membership on an annual basis and to fill membership gaps from key community stakeholders

Capacity Building for CABs

It is essential to increase CAB knowledge about research, TB and CE

CAB members are not typically TB researchers, and therefore may have limited knowledge about research or clinical management of TB. In addition, CAB members may have limited experience with CE in countries where CE for TB clinical trials is new. However, CAB members do need to be familiar with fundamental concepts about research, TB and CE in order to make meaningful contributions to trial design and implementation. It is therefore incumbent on sponsors and researchers to ensure CAB members have access to the capacity building opportunities required to develop their knowledge of research, TB and CE.

Capacity building activities for STREAM CAB members were multi-faceted, and had both locally- and centrally-led components. Study teams used regular quarterly and general CAB meetings to train CAB members on key trial documents, including the protocol and informed consent. During each CAB's annual work planning and budgeting process, CABs were encouraged to incorporate local training sessions – for example, training on advocacy or building basic computer skills – to be funded by the Sponsor.

The most important aspect of centrally-led CAB capacity building was a cross-site webinar series organized by the trial's CE Technical Advisor/Coordinator to cover topics suggested by STREAM CABs. The series extended over two years and eventually included nine sessions on topics ranging from the WHO guideline development process to the role of community members in ethics committees. Expert presenters from organizations including the WHO, Makerere University and Wits Health Consortium were invited to lead the webinars. The Sponsor also supported CAB participation in international conferences, such as the Union World Conference on Lung Health, and cross-site experience sharing visits by CABs to other research sites.

In addition to making STREAM CAB members better partners for local study teams, this investment in capacity building translated into excellent community outreach work by the STREAM CABs, where information about the study and TB treatments were shared with communities.

> *"The community representatives did not ha[ve] a positive attitude to research in general and specifically to a clinical trial before they were a member of the CAB and involved in the activities of CE. Attending as a CAB member helps them to have a basic knowledge on what research is, its benefit and risk, who shall attend and the benefit... from [participating] in studies."*
>
> STREAM CLO/CEO

RECOMMENDED BEST PRACTICES

Ensure CABs are equipped to make meaningful contributions to trial design and implementation by building capacity through the following measures:

- Early in the trial, develop and agree on a mandatory training curriculum for CAB members to be delivered by the research team. Modules should include (at a minimum):
  - Study protocol
  - Study informed consent
  - Participant confidentiality
  - Basic principles of Good Clinical Practice
  - GPPs
- Support locally-led training in CAB work plans and budgets
- Regularly map CAB training priorities and adjust centrally-led capacity building programs accordingly
- Establish mechanisms for cross-site learning and experience sharing
- Create space for CAB members to discuss health policies, local health institutions and international TB guidelines
- Use lower-cost, virtual meetings to expand centrally-led training opportunities

Autonomous CABs

CE processes must empower CABs to act autonomously and share community views

The ultimate objective of CE is to foster independent input into the research process by the community where it is conducted. However, CAB autonomy can be hard to achieve because reliance on the Sponsor for funding and on researchers for information and training can contribute to a significant imbalance of power that is difficult for CABs to overcome. This is especially true in locations with no or limited experience with CE in clinical trials and/or a hierarchical social structure where civil society participation is not a regular practice.

Of the 13 STREAM sites, 11 had no or limited experience with CE in a TB trial and no pre-existing CAB. As a consequence, Sponsor involvement in CAB formation, CAB work planning and budgeting, and CAB capacity building was necessarily significant. This involvement likely reduced CAB independence and autonomy; however, the Sponsor concluded this was necessary to ensure CE activities were implemented, given the inexperience of some trial sites. In addition, in all but one case, funding for CE activities was funneled to CABs via the trial site, increasing CAB reliance on the study team. This was necessary because most CABs/CAB members were not separate legal entities or able to manage external donor funding.

To mitigate the impact of significant sponsor involvement, an intensive CAB capacity building program was implemented, and CABs had significant freedom to choose and implement CE activities that responded to their local priorities and conditions. In addition, during the last year of CE activities, the sponsor held a cross-site training series focused on longer-term CAB sustainability covering topics such as CAB integration into existing research structures and post-trial funding opportunities. Therefore, we are hopeful that STREAM's investment in capacity and institution building will benefit future TB trials.

"A strategic starting point for [our CAB] was transcending the institutional subjection of the project [becoming autonomous from the research institute]. Starting with 2018, we can undoubtedly call [our CAB] a community initiative, independent from the Research Team and [Research] Institute."

STREAM CAB MEMBER

RECOMMENDED BEST PRACTICES

Foster autonomous CABs through the following measures:

- The sponsor should always empower CAB members to communicate openly and honestly with the study team (even if their views are unpopular)
- The sponsor should ensure CAB representatives participate in key trial stakeholder events and given "space" to present the community's perspective
- In addition to capacity building related to research, TB and CE, the sponsor should invest in capacity building related to finance, program management and other topics to strengthen long-term sustainability
- Where possible, the sponsor should make CE grants directly to CABs (or CAB members), rather than to research sites. This will enhance CAB independence from the trial site
- The sponsor and researchers should invest in long-term CAB sustainability

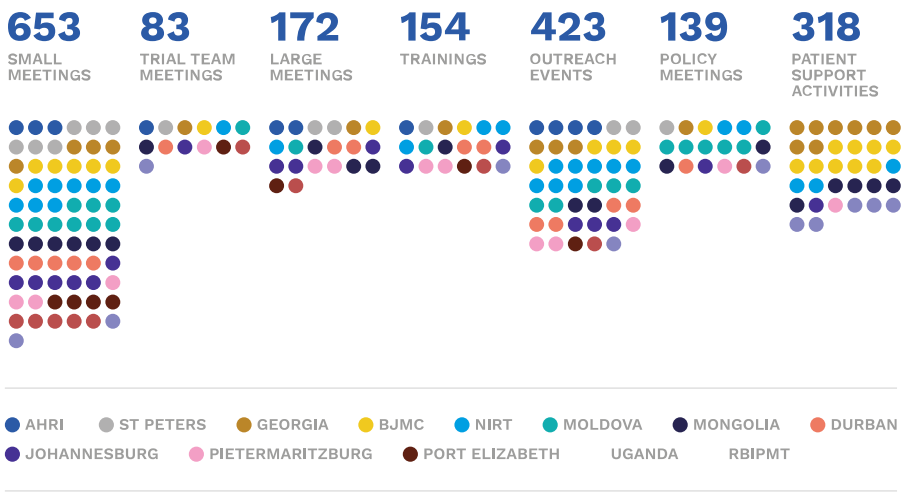
Evaluation of Impact

Sponsors should monitor and evaluate the impact of CE to demonstrate its value to research

There is limited evidence regarding the impact of CE, as it is a relatively recent part of TB clinical research. This makes it difficult to convince donors and other stakeholders that meaningful CE is worth the time and investment. In addition, there is no widely accepted best practice on how to assess the desired impact of CE activities, which is a prerequisite for any impact evaluation.

The Sponsor began collecting STREAM CE monitoring data in 2016 and sharing a monitoring dashboard with CABs in 2018. The dashboard tracked activities by site and over time, as well as highlighting CE successes and challenges. In 2019 and 2020, a theory of change – which identified and incorporated the desired impact of STREAM CE – was developed in a participatory process involving all STREAM CABs. A logic model provided a useful framework for identifying evaluation questions; however, it would have been more useful to develop the CE logic model at the start of the trial to guide monitoring and evaluation throughout the trial.

Summary of community engagement activities for STREAM Stage 2



1–14 activities = 1 dot 15–24 activities = 2 dots 25–34 activities = 3 dots etc.

"Donor support for CE in STREAM was substantial, in part because we were able to provide information on its impact from regularly collected monitoring data."

STREAM SPONSOR

RECOMMENDED BEST PRACTICES

Build in monitoring and evaluation of CE impact through the following measures:

- Donors and sponsors should commit appropriate resources to monitoring and evaluating CE
- Early in a trial, a logic model should be developed through a participatory process involving CAB members
- The sponsor should develop and implement a monitoring and evaluation plan for CE, based on the agreed logic model
- Where possible, the sponsor should evaluate the impact of CE using an experimental or quasi-experimental design (and, where useful, qualitative methods)

CASE STUDY

Community engagement in Chennai, India: Building bridges to improve clinical trials

In 2017, when the STREAM clinical trial began at the National Institute for TB Research (NIRT) in Chennai, India, active CE in trials wasn't common. It wasn't obvious to researchers how community members should be involved in the research process, and there was no community advisory board (CAB) to act as a bridge between researchers and the communities where STREAM was implemented. Today, the STREAM CAB is a valued partner for Chennai's TB researchers and the NTP. This remarkable journey was possible only because key partners invested in building bridges based on trust.

For STREAM, it was important to build bridges among all CE partners. The study team needed to trust that the CAB is a unique and valuable partner in the trial and the CAB needed to trust that the study team would consider the views of the CAB and the community related to the trial.

"We recommend the CAB to be a part of every research as far as TB is concerned because [the] CAB's mission is very much aligned to the vision of National TB Program."

STATE TB OFFICER

The trust-building exercise began on day one. It was essential to ensure the CAB had the diverse and representative membership required to be a legitimate voice of the community. The STREAM CAB included people affected by TB, members from community-based organizations, and members from non-governmental organizations with many years of experience in TB. Their geographic reach covered a large region around Chennai. They worked at a grassroots level and they were experts in how TB can impact patients, with strong community ties.

Once the CAB was formed, it was important for the CAB and the study team to clearly define their roles related to CE for the trial. There was no "road map" for this, and like all relationships, it developed over time and relied upon building trust. The study team ensured the CAB understood the trial – things like the different treatment regimens and the main terms of the informed consent – and the CAB highlighted how they could support the trial through things like community outreach (to raise awareness of the trial) and psychosocial support for trial participants.

Concrete opportunities for collaboration between the CAB and the study team quickly arose. Through their outreach, CAB members helped raise awareness of the trial, which made it easier for the national TB program to refer patients from the program to the trial. The CAB held events in vulnerable communities that had never heard about research, improving the community's understanding of TB and research, and helping to reduce stigma. The CAB talked to TB patients about TB, patient-centered care and infection control, empowering them to seek care and manage their illness. The success of these events was an important contributor to the respect and trust that now exist between the CAB and NIRT.

As the value of CE became more apparent, the study team continued to invest in capacity building for CAB members around research and TB concepts to improve the CAB's ability to participate as equal partners in the trial. Webinars and trainings arranged by the Sponsor covering topics including the ethics of research and the WHO TB guidelines development process empowered CAB members to provide the study team with important input. And regular meetings between the CAB and the study team created a structured environment for sharing community input.

"Although it is treatable and curable, the reason that we are not able to end TB for so many centuries is because there is no commitment and comprehensive effort by the whole society. We are all trying to do it with our bits and pieces. When there is a concerted effort, we will succeed."

SISTER MARY JOSEPHINAL FRANCIS, CHENNAI CAB COORDINATOR

The STREAM experience has demonstrated to both researchers and communities that CE improves trial implementation and participant outcomes by building a relationship of trust. And the experience has just begun. Recently, NIRT has invited the CAB to consult on new studies being implemented at the Institute. In addition, the CAB is documenting its experience; extending the reach of its work by helping to establish an all-India CAB; and working with the NTP to improve the diagnosis and management of TB in Chennai. CAB members continue to draw on the international network of CE advocates they met through STREAM for technical and moral support. By working on research beyond STREAM and extending its community engagement partnerships and networks, the CAB hopes it will have an important impact well beyond STREAM.

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