



COMMUNITY ENGAGEMENT LESSONS LEARNED: A COMMUNITY PERSPECTIVE

STREAM CLINICAL TRIAL



Summary

STREAM is the first large-scale, multi-country clinical trial to investigate shortened regimens for multidrug-resistant tuberculosis (MDR-TB), and the first phase III trial to test the efficacy and safety of Bedaquiline, a new drug with a novel mechanism of action, within a shortened treatment regimen. The trial established a Community Engagement (CE) Plan. The CE program was implemented at thirteen research sites within the STREAM trial, in seven countries. This paper sets out a summary of the experiences of CABs in connection with the STREAM clinical trial. It underlines relevant aspects that may be useful when planning and/or engaging communities in research. In conclusion, the experiences gained during STREAM, lead to both growing confidence in CE as a valuable process and community participation in advocacy.

Key Words

Multidrug-resistant tuberculosis

STREAM Clinical Trial

Community Engagement

Community Advisory Boards

CE Best Practices

CE Challenges

CE Lessons Learned

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Abbreviations

CAB	Community advisory board
CE	Community Engagement
GCP	Good Clinical Practices
GPP	Good Participatory Practices
ICF	Informed Consent Form
MDR-TB	Multi-drug Resistant Tuberculosis
NGO	Non-governmental Organizations
PI	Principal Investigator
R&D	Research and Development
SOP	Standard Operating Procedures
TB	Tuberculosis
WHO	World Health Organization

I. INTRODUCTION

The STREAM clinical trial is the largest recruited MDR-TB trial to date. It aims to generate evidence regarding the efficacy, safety, and cost-effectiveness of more tolerable multi-drug resistant tuberculosis (MDR-TB) regimens, including a 9-month, Bedaquiline-containing, all-oral regimen. Recruitment to Stage 2 of the trial began in 2016 and ended in January 2020, with 588 participants randomized to all arms of the study.

STREAM incorporated a robust program of community engagement (CE). Although there are many models, CE refers broadly to community participation in research. The Good Participatory Practices (GPP) in TB research - are the core foundations of STREAM CE. Community advisory boards (CABs) operating at all STREAM Stage 2 trial sites play a crucial role in the trial by communicating community input and participating in the updates and results dissemination. The CABs are located at 13 sites in seven countries: Ethiopia, Georgia, India, Moldova, Mongolia, South Africa and Uganda. Before the CABs were established, a careful mapping of potential community stakeholders to compose the core CABs took place. This was one of the fundamental steps, especially for the sites, with no history of CE in research to ensure a broad profile of community representatives interested in engaging in the STREAM study and in its research process. The primary purpose of the mapping exercise was to identify the countries' key stakeholders – TB managers, governmental representatives, NGOs and other institutions. The secondary benefit was raising awareness about the trial. This engagement process helped the partners support and sustain the STREAM CE initiative in the country's health system functioning and institutional relations.

Aim of the document

This document aims to set out a summary of the experiences of the STREAM CABs in connection with the STREAM clinical trial, as well as enhance and sustain community engagement within country - and culture-specific settings. It also gives an overview of STREAM CABs' practices and underlines relevant aspects that may be helpful to consider when planning and/or engaging communities in research.

Methodology

The methodology underlying this document includes data collection, which contains qualitative data gathered from a consultation organized in collaboration with all the 13 STREAM CABs in the seven countries, which answered dedicated questions developed for this purpose on the Survey Monkey platform and data analysis of quarterly CABs reports, trainings and All-STREAM CABs'webinars notes.

Data limitation

The overall review of practices, challenges and lessons learned is given in this document from a civil society and community perspective. The individual responses by CABs may represent a limited view. However, when evaluated collectively, given the broadly similar approaches to STREAM CE and the experiences from the All-STREAM CABs' Webinars, organized regularly within the network, it provides a general overview for all CABs. This paper was elaborated to document the CABs experiences related to this particular CE in research and development.

II. BEST PRACTICES

This section summarizes the best practices identified from the STREAM CE experience.

A. Broad-based membership of CABs

The diversity and multidisciplinary nature of CAB members are significant assets. A CAB comprised of members from different age groups, genders, professions, educational levels and experiences provides opportunities to incorporate different perspectives, leading to a pluralistic approach within STREAM CABs' activity.

The composition of STREAM CABs varies from site to site – ranging from people affected by the disease, members of grass-roots, community organizations, religious or opinion leaders, to national or international NGOs, which include medical doctors and lawyers. There are members who have research literacy, others who have not. In that way, STREAM CABs reflect the diversity of community stakeholder interests, needs, and cultures. The regular CE activities, including CAB meetings with the research team, contributed to communication, information sharing and transparency among all stakeholders about the ongoing clinical research. The CAB members share common objectives and an ultimate commitment to inform society, contribute to the local study, and understand the national policy-making process. Inexorably, CE functions in the context of the respective country's health system (or health structure) and its management depends on the dynamics between state institutions, civil society and communities.

Box 1. Multidisciplinary backgrounds of CABs' members

“Since the CAB is multidisciplinary and diverse, community engagement and community access was the most important and through CAB as the eyes and ears of the community.”

B. CABs as mechanisms for increased treatment and research literacy for communities

STREAM CABs worked according to a written work plan, approved and overseen by the CE program coordinators. The first work plan was developed at each site inaugural CE workshop. After that, every year, each CAB revises its work plan, which has activities supported by STREAM funding. Once CABs work plans were finalized and approved, every CAB delivered several trainings to their CAB members in order to increase their TB treatment and research literacy, CE and policy advocacy skills.

The CABs different experiences on contributing to capacity building, awareness-raising, cross-CAB collaboration and experience sharing emphasized the roles of the CABS in increasing treatment and research literacy for communities.

Box 2. TB Awareness Education

“TB has become a regular agenda in community meetings where CAB members are involved. The awareness of the community about TB and research has increased because of the activities undertaken by the CAB. This is likely to have a positive impact on TB activities at the community level.”

In short, to improve education, widening expertise and strengthening networking, there were three fronts STREAM CABs have worked on: training for CAB members, capacity building for communities and cross-site learning, especially by means of the All-STREAM CABs’ Webinars. These activities were encompassed within the concept of a logic model, helping to create ownership of the process, to improve planning and internal organization, aiming to reach the expected results. Although the development of the logic model was most important for work planning, it had a great secondary benefit for capacity building of the CAB members.

The program’s emphasis on cross-site learning development generated a “shared vision” of CE and widened the treatment and research literacy among all members. This contributed to strengthen efficient advocacy and capacities to effectively influence policy change.

I. All-STREAM CABs' Webinars

Since early 2019, the All-STREAM CABs' Webinars have enabled regular cross-site sharing of CABs experiences, understanding the differences in approaches, values and cultural references, in a complex multi-cultural scenario. Held quarterly, the webinars approach a variety of topics ranging from TB and research awareness to tools for advocacy and policy change. The themes are chosen according to a list of capacity building priorities established by the CABs. During each webinar specialists and experts ranging from the CAB teams to international figures (such as WHO) were invited to speak upon topics relevant to STREAM CE. As a core element for ensuring CABs sustainability, a practical exercise was also added to the agendas of the All-STREAM CABs' Webinars in the last STREAM year.

II. Logic Model

In order to help CABs to plan and implement their activities according to an agreed set of objectives, CE coordinators facilitated a workshop for representatives of all STREAM CABs in the 2019, in Hyderabad, India. It allowed CAB members to interact directly, discuss common perspectives and develop a theory of change (or Logic Model) for CE. It started with the overall desired impact, leading to long and short-term objectives and concluding with listing activities designed to achieve the objectives.

Moreover, the LM exercise helped as a visual tool for the project management, generating a framework for monitoring and evaluation.

The workshop identified "Ownership of clinical research by all stakeholders" as the overall objective of CE.

C. Building partnerships and trust

One of CE's overall objectives is to support policy change in countries to adopt the best evidence generated by research, thereby improving access, quality and equity in care for people affected by TB. CE in research contributes to this objective in several ways, such as bridging communities and researchers, generating ownership and legitimacy of the studies, creating and strengthening a culture of community participation in research. However, CE can only contribute effectively if there is trust and buy-in of CE's advantages and values by all stakeholders. Building partnerships was the main strategy to achieving a meaningful and sustainable support in the STREAM CE experience. At the same time, helping medical staff and TB people to progressively understand the aims of CE in research contributed to building trust. Developing meaningful relationships by regular common activities, and efficiently engaging research teams and TB advocates in networking, generated ownership among them. This positive environment has strengthened the capacity and the legitimacy of CAB members to engage in policy discussion with programs at different levels.

Box 3. Building partnerships

“One thing worked best in STREAM CAB is building close partnership with STREAM study team, the State TB Cell, the district TB program officers, the local NTEP members, technical consultants of WHO and the General CAB members, sharing a common vision and connecting the research with the community. The updates on the STREAM study and CAB, strengthens this partnership and creates a sense of ownership in these stakeholders.”

D. Focus on Ownership and Sustainability

Since their formation and throughout its development, STREAM CABs worked in a collaborative, inclusive and transparent way. This included observation of local norms and ethical principles. This spirit generated ownership of the study both in the community and national level and fostered accountability of the research process by all stakeholders. The result was a highly appreciative acknowledgement from diverse research and governmental institutions of the CABs role by the end of the TREAT TB grant.

The sustainability of the STREAM CABs was carefully strategized over its last year of USAID funding. Steps were taken to ensure STREAM CABs would remain connected and continue to work together through to dissemination of results, and beyond. Besides working to strengthen the capacities built throughout the STREAM study development, the focus on sustainability of CABs intended to guarantee a more significant participation of community representatives in other research cycles, increasing the meaningful engagement of people affected in new studies, from design until the discussion of implementation of best study results.

Box 4. Stakeholder Education

“CE has opened lot of ways to connect and communicate with all stakeholders and participant care is at heart. It proved that even when the clinical trial has ended CE still continues and paves away for other trial studies. CAB have experience in advocacy and can influence policy change, assist improving life of participant, show how research can be done in our community and kill stigma.”

III. CHALLENGES**A. Limited opportunity for input at start and end of the research cycle**

One of the objectives of a CAB is to bridge research and the communities where research takes place. *“Engagement with communities is needed from all TB scientists at each step of the R&D process, particularly in the pre-trial and post-trial phases” (A. DeLuca et al, 2014).* Moreover, it is assumed that CAB members, as legitimate community representatives, will directly contribute to research design providing civil society’s perspectives and enabling communities to have a greater understanding of research and its benefits. This

concept leads to the understanding of the imperative importance of the early engagement of community representatives since study design and develop a CE Program within the clinical study throughout the dissemination of study results and implementation of its best findings. While it is difficult to seek input from CABs at the start of a multisite trial, STREAM CABs believe that sponsors need to look for creative ways to seek meaningful community input – particularly to the protocol draft and instruments to be used with trial participants such as the informed consent form (ICF) – before the protocol is submitted for scientific, regulatory and ethical approval. This is particularly challenging, considering that in the preparation for a trial, often sites are chosen after the “central” or sponsors approval. One suggestion CABs brought was to pre-identifying at least one site that will participate in the trial and inviting community members to consult on the protocol and its instruments. However, at this stage, limited opportunities for input at the start and at the end of the research cycle (*pre-trial and post-trial phases*) remain ones of the most significant challenges for a CAB meaningful participation.

Box 5. Community input in the design

“It is important to have the involvement of the community from the moment of creating the concept of clinical research, including the contribution of the community to the development of the clinical protocol and the informed consent for trial participant.”

B. Limited understanding of GPP

The Good Participatory Practices Guidelines for TB Drug trials (GPP, 2012) link community participation in research with justice and fairness concepts. Although the Guidelines contemplate principles for community involvement, they do not explain how to operationalize that involvement. Despite providing a powerful framework for community involvement in research, there are varying levels of “buy-in” to the GPPs by researchers and limited awareness of the GPPs by community members. Therefore, two critical points need to be highlighted: (1) Researchers do not always “buy into” the need for community involvement as set out in the GPPs and (2) CAB members do not understand that the GPPs are an important source of the legitimacy of their involvement in research.

In STREAM CE, the insufficient understanding of these relevant points has led to limitations in the relationship among CAB members and trial participants, of community representatives and the researchers and research institutions, as well as other stakeholders. Because community members are not conversant enough with the GPPs, they miss real chances to use GPP as “leverage” to give input into the trial at key stages.

Box 6. Understanding GPP

“The site is trained on GCP and not GPP. Sometimes they don’t understand stakeholders’ anatomy and the importance of CE. Stakeholders need to have clear understanding of clinical trial in current and future plans

and better understanding of the life of communities. Research is a process with channels and guidelines to be followed. All these parties need to adhere to policies that protect lives."

C. Initial lack of buy-in by researchers

The initial process of CE at sites faced a certain initial discredit by researchers. Not all research team members completely bought-in the participation of communities following up the study development. Mainly this may be attributed to the uncertainty regarding the community capacity to contribute to good research development. Since cultural norms were quite hierarchical in many of the STREAM sites and CABs were a new concept, the introduction of CE in STREAM was challenging and required time and efforts to develop buy-in from PIs/study teams.

Box 7. Lack of buy in from Researches

"Lack of previous experience in 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."

D. Limited CAB involvement

A challenge referenced by some CABs related as well to the limited commitment by some CAB members. A few CABs reported issues with high turnover, while in some cases, the CAB members seemed to not always understand what participating in a CAB means. The implicit voluntary nature of CE could partially explain the time and commitment of CAB members. Due to that, it is difficult for CAB members in some CABs to make a relevant and long-lasting commitment to CE activities when they are contributing much of their time on a voluntary basis.

Box 8. Retention of CAB members

"It is difficult to retain sustainable activity because of the challenge in retaining CAB members and CAB coordinator."

Box 9. Community expectations

"In a poor community, the members have unrealistic expectations sometimes. They look at the opportunity to take part in CE as a gateway to welfare/empowerment yet the resources are not able to undertake such a task."

E. Culture and language

Cultural and religious values, beliefs and traditions are deeply rooted in any society and they necessarily influence effective CE in research. Although STREAM developed communication materials that were translated into local languages, still some CABs refer to the language as a practical barrier for CE. Considering those, access to relevant information and having materials/instruments in local languages by observing cultural particularities - is a key pillar.

Box 10. Language barriers

“Most of the reference materials about TB, research and CE are available in English; it has most likely created a gap and a limitation in understanding the content by CAB and community members due to language barriers.”

IV. LESSONS LEARNED

The lessons learned from STREAM CABs highlight that all lessons, either positive or negative, are opportunities of learning and for a better understanding CE in the context of the country realities. The STREAM CE experience has underlined the need to involve research participants and communities as partners, rather than merely subjects or users of the medical advances arising from the trial. It has also highlighted the important benefits to the trial and CE participants of a robust CE program. In light of the above-mentioned best practices and challenges of STREAM CE, and considering a series of perspectives expressed by the CABs in different opportunities, this document offers the community’s perspective on the following key aspects for consideration for CE in TB research:

1. **Map stakeholders to build diversity** within a CAB by developing a CE Plan based on a comprehensive mapping to identify (a) interested community representatives to participate in the CAB; (b) leadership for the group (eventually the coordinator) with good communication skills; (c) the stakeholders to support CE politically.
2. **Secure funding:** Although there is an expectation of community engagement being conducted at no cost or based principally on volunteer work, CE cannot take place without proper funding. Time and resources spent on the coordination of CE activities, managerial expenses of community organizations involved in CE, and the community activities themselves give rise to costs.
3. **Early involvement** of communities in **study design** (development of protocols and its instruments, such as ICF, questionnaires, etc.);
4. **Build PI buy-in for CE** by understanding that CE in TB research is still new in many settings, and therefore there may be a need to overcome initial lack of buy-in by researchers;

5. Donors should **encourage and support community representation** within scientific and policy-making fora in order to enable best participatory practices and contribution to the significant decisions;
6. Emphasis on **training and education of CAB members and research teams** on complementarity of their roles;
7. Enable spaces for **regular information and interaction with stakeholders** allowing understanding of research, the GPP Principles and the logic and value of community advocacy in health policies, including support to trial participants;
8. Establish an **SOP to guide scope of work for CAB members and coordination**; their relationship with researchers, donors, other stakeholders, and trial participants observing ethical and institutional aspects. A similar **SOP may also be relevant to researchers**.
9. **Reference materials** on implementation of CE, TB and Research activities and training manuals should be available **in local languages**. It will foster the meaningful CE and will create a better understanding by CAB members and community members of R&D processes;
10. **The training and constant education of community representatives** by means of CAB is vital to retain members and recruit new ones, ensuring a wider field of different backgrounds within the CAB in a long-term.

V. A WAY FORWARD

CE in STREAM Study Stage 2 could be seen as an unprecedented global exercise to scale up the stakeholders' engagement in a clinical trial. The experiences gained during STREAM lead both to growing confidence on the community participation in research, and to the general understanding of the importance of TB research advocacy. CAB members were invited to join international advocacy organizations; Sites with a limited history of advocacy are now actively participating with local health organizations to improve TB programs and policies. As results of the trial's sustainability support, some STREAM CABs transitioned to "institutional" CABs, in other words formally linking to the respective research centers; some CAB members invited to sit on local ethics committees; CABs formalized their organizational structure etc.

Hereby, find below some CABs achievements important to be acknowledged in the document:

- ✓ AHRI, Ethiopia - Establishment of a CAB with regular community involvement in research activities at the Armauer Hansen Research Institute (AHRI) for the first time after over 50 years of history.
- ✓ St. Peter's, Ethiopia - Increased representativeness of the CAB achieved through the collaboration between community members with diverse backgrounds, thus incorporating and providing a pluralistic and multidisciplinary array of perspectives.

- ✓ Georgia - Signature of a memorandum of cooperation between three community-based organizations (New Vector, Georgia Patients Union and TB People), led by the STREAM Georgia CAB members and the National Center for Tuberculosis and Lung Diseases (NCTLD) with the purpose of engaging in the follow-up of other studies and also in helping people in treatment for TB to overcome challenges of adherence.
- ✓ Ahmedabad, India - Organization of multiple awareness programs in collaboration with local community-based organizations, religious entities, health authorities (Ahmedabad Municipal Corporation) and the B.J. Medical College and Civil Hospital (BJMC) to continue improving TB and research literacy and to providing nutritional support to STREAM trial participants.
- ✓ Chennai, India – Strong relationships with the National Institute for Research in Tuberculosis (NIRT), State TB Cell, District TB program officers, local NTEP members and WHO consultants, sharing a common vision of community contributions to future clinical studies in India.
- ✓ Delhi, India – Leadership of efforts to form a National TB CAB in India with colleagues from Ahmedabad and Chennai CABs and in close consultation with India’s National TB Elimination Program (NTEP) officials and the Indian Council of Medical Research (ICMR) with the vision of ensuring community representation and participation in other multicentric domestic and international trials.
- ✓ Moldova – Close collaboration with the National TB Program on the elaboration of the five-year National Strategic Plan (2021-2025) and inclusion of community representation in the TB Institute Ethics Committee. Moldova CAB Coordinator also joined the Global TB CAB.
- ✓ Mongolia – Unprecedented connections with relevant stakeholders through regular attendance at national high-level meetings and through the organization of inclusive General CAB Meetings involving community members, former TB patients, partner NGOs, heads of local health centers, clinicians, healthcare workers Ministry of Health officials, Parliament members and WHO representatives.
- ✓ Johannesburg, South Africa – Concrete opportunities for participation in parallel and future clinical trials made possible by consolidated CE work, which started before STREAM. A positive track record in involving communities in the research cycle, advocacy efforts and influence in policy change has opened many doors in terms of connecting, educating and communicating with multiple stakeholders surrounding the STREAM study.
- ✓ Pietermaritzburg, South Africa – Creation of a program for TB advocacy in which task teams among CAB members were formed to work on issues such as TB stigma, training of healthcare workers engaged in conducting TB screenings and tackling homelessness.
- ✓ Durban, South Africa – Active partnership in War Rooms, which are local community platforms supporting National and Provincial TB programs, exercising influence, disseminating research findings, and taking part in government accountability.

- ✓ Port Elizabeth, South Africa – As the first CAB at the Empilweni TB Hospital, it has already engaged in CE activities for other TB trials. Forming of great partnerships and strengthen those relationships by continues meetings – and using each other strengths throughout the process.
- ✓ Uganda – Increased institutionalization through proximity to the National TB Program and constant engagement in activities organized by the Ministry of Health to provide community perspectives with the potential of taking the lead in CE for other upcoming clinical trials.

VI ANNEXES

Annex 1 List of the STREAM CABs that provided information

	COUNTRY	CAB / ORGANIZATION	RESEARCH SITE
1	Ethiopia	Armauer Hansen Research Institute (AHRI)	Armauer Hansen Research Institute
2	Ethiopia	St. Peter's	St.Peter's Hospital
3	Georgia	Georgia	National Center for Tuberculosis and Lung Diseases (NCTLD)
4	India	Ahmedabad	B.J. Medical College and Civil Hospital
5	India	Chennai	National Institute for Research in Tuberculosis (NIRT)
6	India	Delhi	Rajan Babu Institute of Pulmonary Medicine and Tuberculosis (RBIPMT)
7	Moldova	Moldova/Society of Moldova against Tuberculosis (SMIT)	Institute of Phtysiopneumology Chiril Draganiuc
8	Mongolia	Mongolia/Mongolian Tuberculosis Coalition (MTC)	National Centre for Communicable Diseases
9	Uganda	Uganda	MRC/UVRI and LSHTM Research Unit
10	South Africa	Durban	KING Dinuzulu Hospital
11	South Africa	Johannesburg	Clinical HIV Research UNIT (CHRU) Johannesburg
12	South Africa	Pietermaritzburg/ THINK	THINK Doris Goodwin Clinical Trial Unit
13	South Africa	Port Elizabeth	Empilweni TB Hospital

Annex 2 Survey Monkey Consultation questionnaire

The Survey questionnaire below was developed to help collect data from the STREAM CABs with the primary purpose of assessing practices, challenges and lessons learned during community engagement in research and development.

STREAM CE Lessons Learned

Survey for STREAM CABs' Coordinators

Dear STREAM CABs:

In order to document our experience in STREAM Community Engagement (CE) and showcase our experience in other formats, we would like to survey your experience as the STREAM Community Advisory Boards (CABs). Before you answer the questions below, consider your STREAM CABs' overall trajectory since the beginning of the STREAM trial. What would you highlight as successes? What were the challenges and what would you do differently?

Please discuss all these aspects among your CAB members prior to submitting your responses in the following survey.

	Survey questions
1.	<i>Do you give consent for your answers to be used in a report or article?</i>
2.	<i>Name of the person submitting the answers</i>
3.	<i>Name of the STREAM CAB</i>
4.	<i>Since STREAM began, what would you say has worked best for CE at your site? Please list up to three best practices and provide details of why they were important to the success of CE.</i>
5.	<i>Since STREAM began, what would you say made it hard to do CE at your site? Please list up to three challenges and provide details of why they affected CE negatively.</i>
6.	<i>Considering your answers provided in Q4 above, what aspects of CE would you do the same for your next trial? Why? Please list up to three (positive) lessons learned.</i>
7.	<i>Considering your answers provided in Q5 above, what aspects of CE would you do differently for your next trial? Why? Please list up to three (negative) lessons learned.</i>

Annex 3 Best practices, challenges and lessons learned | Survey collected data

The following tables present original data provided by 13 CABs in 7 countries on practices, challenges and lessons learned during community engagement in research and development.

CAB 1

Best practices	<ol style="list-style-type: none"> 1. Strong collaboration with Country Coordinating Mechanism (CCM) members The study findings were shared with CCM routinely. This was very important in order to have support from the side of policymakers. 2. Strong collaboration with study team Study team was sharing the knowledge regarding TB with CE members, which helped community to understand TB disease better, to solve the problems erased during the study, and improve patients' treatment adherence. 3. Trial participants' psychosocial and educational support Peer to peer talks with trial participants is important to CE success because participants feel that they aren't alone fighting TB and this motivates them to go through the whole treatment process.
Challenges	<ol style="list-style-type: none"> 1. COVID 19 Everything done remotely, no more face-to-face meetings with participants.
Lessons learned	<ol style="list-style-type: none"> 1. Good communication Communication is important part in CE because it positively affects community engagement activities, raises CE importance in society and policy makers, and helps with advocacy and fundraising. 2. Prepared for crisis Next time through gained experience during COVID-19 crisis, we will be more prepared to deal with this kind of situations, faster and with improved skills.

CAB 2

Best practices	<ol style="list-style-type: none"> 1. Doing awareness programs at religious site with support from religious leaders helps spread awareness effectively and also find positive patient 2. Visiting patients at their place has shown lot of benefits for research as patients feel connected and explained us their real issues - like not being able to fetch nutritious food or receiving wrong behavior attitude from family & neighbors. 3. Visiting patients even helped a lot to spread awareness in its true form, as personal interaction at slums gathered other people living around to understand the real issue.
Challenges	<ol style="list-style-type: none"> 1. Some cases/people were quite reluctant to continue with medication for very odd reasons - like superstition, considering this very long or mistreated by people around them, convening such absconded was a challenge for CAB.
Lessons learned	<ol style="list-style-type: none"> 1. Due to ongoing COVID-19, there were issues with visiting patients and so we connected with them on phone and/or message, which should continue in the coming quarter or next trial study. 2. Study trial patients are not connected well. They tend to skip treatment even though they benefit from this.

CAB 3

Best practices	<ol style="list-style-type: none"> 1. Adopting CAB as a mechanism of Community Engagement in the clinical setting Adopting CAB as a mechanism of Community Engagement in the clinical setting became the focal point of reference. It serves as a sounding board to prepare the work plan for community involvement, execute the same according to the given Standard Operating Procedures, share experiences, best practices, and lessons learnt. According to its nature of opening the doors, it has bridged the community and the research, maximizing the horizon of STREAM Trial stage II. 2. Capacity building of the CAB members
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	<p>Capacity building of the CAB members on protocol, research, confidentiality, strategies on clinical trials, cross-site visits, and clinical research (STREAM Stage I, Stage II etc.), attending conferences etc. by the study team and the STREAM team have widened the knowledge and understanding of the CAB members to respect the nuances of STREAM Trial stage II, build professional relationship with the stakeholders and be accountable.</p> <p>3. Building sustainable partnerships</p> <p>One thing worked best in STREAM CAB is building close partnership with the study team at NIRT, the State TB Cell, the district TB program officers, the local NTEP members, technical consultants of WHO and the General CAB members, sharing a common vision and connecting the research with the community. The updates on the STREAM study and CAB strengthen this partnership and create a sense of ownership in these stakeholders.</p>
Challenges	<p>1. Unforeseen COVID 19 pandemic</p> <p>Unforeseen COVID 19 pandemic made CE hard at our site because it totally stumbled the work plan, although STREAM CE team worked out alternative activities that strengthened CE further. The outreach activities that connect the community with the research and maximize the research result were cut totally. Just when the positive speaking sessions for the trial participants began to get its attention, lockdown spread its wings and put a full stop.</p> <p>2. Delayed direct interaction with the trial participants</p> <p>Non-inclusion of CAB in the Protocol and Consent Form.</p>
Lessons learned	<p>1. Working out alternative in times of unforeseen events</p> <p>Contingencies are “part and parcel” of life and hence it requires to be prepared for it. When COVID 19 pandemic made CE hard at our sites, and CAB members were not able to carry on the regular planned activities, the global STREAM CE Coordination team came up with new initiatives - virtual meetings instead of physical meetings; Vital Strategies came up with various trainings. Similarly, work out alternatives.</p> <p>2. Respond to the newly emerged needs. Learnt that unforeseen events are part of any intervention.</p> <p>3. Start CAB when the research question is framed or at least while reviewing the protocol.</p> <p>CAB will have a legal footing in the research without being intruders. This will facilitate to consult with relevant stakeholders who will be able to ensure that the study is based on their perspectives and experiences, which in turn will result in improved health outcomes among disadvantaged groups.</p> <p>4. Involve CAB in the Consent Form. Representatives of the CAB should be part of the Ethics Committee.</p>

CAB 4

Best practices	<p>1. Establishment of the CAB unit for the Research Institute for the first time</p> <p>The Research Institute did not have a formal and dedicated CAB unit even though it accounts for more than 50 years activities on research service. So, this was a very important change and progress of the institute to consider and involve community in the main process of conducting a research.</p> <p>2. Improving the knowledge of CAB members on TB/MDR-TB and Research in general</p> <p>The community representatives did not have a positive attitude to research in general and specifically to a clinical trial before they become a member of CAB and involved in the activities of CE. Attending as CAB members, helps them have a basic knowledge on what is Research; its benefit and risks; who shall attend and the benefit got from attending trial studies.</p> <p>3. Conducting regular meeting and scheduled training for CAB members to exchange their experience and carry out their role in the community.</p>
Challenges	<p>1. The value and acceptance given by the researcher’s team to the CE members, the unit, and their voluntarism to involve them in the research process to have a role - was minimal.</p>

	<p>Most of the research staffs of the Institute were not voluntary to establish the CAB to their research project as they think that it did not add value to the conducting research and not motivate them to contribute their input in the outreach programs within the community where research was planned to be conducted.</p> <p>2. The representatives of the nominated organization were not committed to do timely the activities assigned to them and also they did not attend the regular meeting and scheduled training programs.</p>
Lessons learned	<p>1. The CE should have a dedicated employee and unit head to do CAB activities for each study, which require the involvement of the larger community.</p> <p>Without the involvement and active participation of Community and its representatives, a research cannot be conducted as planned and the research output may not be accepted by the community to be implemented in the future time.</p> <p>2. To recommend to the Institute to employee a full time professionals, to the CE unit activities, who will took the responsibility to do activities related to the community and have the capacity to do CE related activities in collaboration with different teams within the institute and stakeholders.</p> <p>The unit should have a responsible individual and to conduct CE activities timely by involving the representatives of Community actively in different aspects to create awareness on research in general and how research outputs are used to treat different diseases specifically.</p> <p>3. To involve those representatives from different government and non-government organizations who are committed to do CE related activities actively, young and fully understand the meaning of voluntarism in the service of community engagement. Youngster are very flexible, easy to educate them and committed to do voluntary services compared to those who are of old age groups.</p>

CAB 5

Best practices	<p>1. Home visit and meetings with participant's family It helps to understand how family is supporting the participant.</p> <p>2. Quarterly Meetings It helps to understand the progress of study and ensure community engagement in all the process.</p> <p>3. Community Advocacy It makes sure that people surrounding participant's house are aware about issue and the stigma and discrimination could be reduced.</p>
Challenges	<p>1. Consent and involvement of participant's Although for every process, the study team and CAB take consents from participants and make them understandable but still it is not enough. As participant forgot many times, when we ask to give this in written, they are afraid and think that people may misuse their signature.</p>
Lessons learned	<p>1. Community Engagement Itself big learning for us is that as normally trial happens with only ethical committee, which is one way process, where community engagement and its involvement is very important. It strengthens community, participants as well as study team.</p> <p>1. Consent through video and in their own language For greater involvement and better results, we should have consent in video format and all consent forms should be available in mother language, so that they can read and understand in better way.</p>

CAB 6

Best practices	<p>1. Ensure Community participation is reflected in country strategic documents.</p> <p>Due to community efforts, one of the objectives of the NSP for 2021-2025 is focused on the participation of community representatives in clinical and operational studies from identifying research needs to study implementation and results dissemination, including community-based research.</p>
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	<p>2. Ensure the presence/the inclusion of a Community representative/s as a member/s of the Institute Ethical Committee.</p> <p>We consider that a community representative placed among members of the Institute Ethical Committee is crucial for further engagement in clinical trials and operational studies. It is reasonable to assume that this kind of engagement will bring a community perspective in the decision-making process and can be a valuable tool for advocacy, including advocacy for people-centred clinical trials.</p> <p>3. Autonomy of CAB STREAM.</p> <p>Starting with 2018, we can undoubtedly call CAB STREAM a community initiative, independent from the Research Team and Phthiziopneumology Institute. Community and CSOs play a key role in fostering social cohesion by acting as a bridge between different segments of the population and governments. This is why we consider that CABs should be independent of institutional governments and cutting the institutional and financial linkages is nothing else but a best practice because encourages ownership of the process.</p> <p>4. Good communication and linkages among research team, CAB and communities regarding implementation of the TB activities, not only related to clinical trial aspects.</p> <p>5. Knowledge and literacy about community engagement in research increased among medical staff and TB people (including HIV and Harm Reduction Networks). Trust to both sides was increased. Other communities amplified voice of the TB people, as HIV people are active participants of the TB community engagement and involvement in the advocacy and dissemination of the clinical trial result.</p>
Challenges	<p>1. Absence of clear mechanism of interaction among CAB members and trial participants</p> <p>Research ethics protect trial participants' data and preserve the integrity of science. Due to the confidentiality regulations of the protocol, the CAB has no access to trial participants as for counselling / informational sessions neither for psychosocial support. The only way to occasionally contact a trial participant where regular hospital visits. We believe that respecting the confidentiality of trial participants is important, but in the same time, there should be opportunities for CABs to communicate with trial participants on a regular basis. Building safe and clear mechanisms for the CABs would be effective in recruiting and retaining study participants, of course in cases when participants would wish to.</p> <p>2. Lack of previous experience in CE in clinical research and lack of understanding by the research team of the clear role of the community</p> <p>It required building relationships and understanding aspects of clinical research management to delineate areas of common interest to provide added value.</p>
Lessons learned	<p>1. Ensure strong connection, partnership and trust</p> <p>This approach helps enhance mutual trust and creates a sense of collective ownership. In the same time mutual understanding between researchers and the community are critical to ensure that those representing the TB community understand and could meaningfully participate in the research. CAB is an equal and trusty partner for the National TB Program.</p> <p>2. No CE participation in the designing of the protocol</p> <p>It is important to have the involvement of the community from the moment of creating the concept of clinical research, including the contribution of the community to the development of the clinical protocol and the informed consent for trial participant. To take part in the whole process - from the beginning and to include the patient's opinion in this broad process, as - nothing for us without us.</p> <p>3. There are no negative lessons</p> <p>All the lessons are only for clarification and better understanding of the reality.</p>
Best practices	<p>1. A community advisory board (CAB) with a diverse background was successfully established.</p>

	<p>The CAB is composed of members with different age groups, gender, profession, educational level and experience. The representativeness of the CAB has ensured the engagement of the community in the conduct of the trial.</p> <p>2. TB has become a regular agenda in community meetings where CAB members are involved. The awareness of the community about TB and research has increased because of the activities undertaken by the CAB. This is likely to have a positive impact on TB control activities at the community level.</p>
Challenges	<p>1. Most of the reference materials about TB, research and community engagement are available in English. This has most likely created a gap and a limitation in understanding the content by CAB and community members due to language barrier.</p> <p>2. Clinical trials are at a young stage of development in the country and the understanding by the community and CAB members is variable. The study team as a result has received limited number of feedback on the trial processes.</p> <p>3. The involvement of some of the study team members in community engagement activities was limited. The contribution by every study team member can have a significant impact on the performance of the CAB and strengthen CE activities by bringing in new perspectives and experience.</p>
Lessons learned	<p>1. Community engagement should be given a serious consideration at all stages of a clinical trial. Community advisory board can be a useful means of ensuring the engagement of the community when it is properly organized and is representative of the community. CABs can play a vital role in linking research, programs and communities.</p> <p>2. Reference materials on implementation of CE activities and training manuals should be available in local languages. It creates a better understanding by CAB members and community members.</p> <p>3. The strong engagement of study team members in CE activities can help the CAB achieve its objectives and goals.</p>

CAB 8

Best practices	<p>1. We organized few general meeting very successfully with broad of stakeholders including decision makers, Ministry of Health, WHO, Head of local Health centers, NGOs, patients. CABs main propose is bridging stakeholders that is why General meeting is great event for engaging communities and decision makers. In our General meetings there are around 60-80 people attending. STREAM clinical trial is the very first clinical trial conducted in the country so all experiences are new to us.</p> <p>2. In 2018, was organized a High-Level meeting for the first time with the support of the Prime Minister. On that meeting, our CAB coordinator who is a former patient had a chance to give opening speech in front of Ministry of Health, WHO representative, Parliament members, and other stakeholders. It was the very first time when a patient shared her experience at such an event. This being an ice-breaking moment for patient to connect with decision makers as well as health care sector.</p> <p>3. Meeting with Minister of Health in Nov 2019. It opened great one time campaign funding opportunity to us.</p>
Challenges	<p>1. To retain CAB members and CAB coordinator It is difficult to retain sustainable activity because of this challenge.</p>
Lessons learned	<p>1. Successful General meeting To build connection between stakeholders</p> <p>2. Attending all High-Level meetings To connect with all stakeholders</p> <p>3. Meeting with possible funders To sustain future activities</p>

	<p>4. Train patients and other stakeholder who are interested in our activity</p> <p>Our CAB is considering that continues training and regular updates are very important to retain members.</p>
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CAB 9

Best practices	<p>1. Being a responsive CE team</p> <p>We endeavored to respond to the people that took the time to respond to us, as well as respond to what was affecting people in real time. We were always deeply engaged in the activities that Ministry of Health organized because they always invited us for various reasons but specifically to provide the community engagement perspective. We therefore became emotionally engaged in a positive way with the stakeholders that responded.</p> <p>2. Providing community members a platform to express themselves</p> <p>To keep the CAB together, we kept most members engaged by providing a platform that different people from the different “walks of life” could express their concerns from the constituencies they represent. Holding monthly meetings for the CAB whenever possible has been a big opportunity for this. We have also been conducting Radio talk shows that have availed the community with the opportunity to listen to what their representatives in the CAB say on their behalf and submit real time supplementation.</p> <p>3. Having a God parent in the National TB Program</p> <p>Our CAB was blessed by the fact that our first CLO later became the program manager for the National TB Program. This helped us get into the corridors of the NTP easily, and it was further augmented by the fact that some of the CAB members were also working within the NTP.</p>
Challenges	<p>1. Community expectations</p> <p>In a poor community, the members have unrealistic expectations sometimes. They look at the opportunity to take part in CE as a gateway to welfare/empowerment - yet the resources are not able to undertake such a task. People want to benefit financially or at least materially from our engagement with them. Sometimes the message about the health situation at hand may not get home with everyone when these expectations are not met.</p> <p>2. Competing priorities</p> <p>As a CE team, we have committed to certain projects and project deadlines with all the intention of fulfilling such a promise. However, competing/conflicting events intervene in various forms that have made deliverables seem distant sometimes. This inevitably pulls down our standard and moral in general.</p>
Lessons learned	<p>1. Being a responsive CE team</p> <p>Being responsive has earned the CE team mileage on a couple of fronts. We have had the opportunity to be invited for various national activities, we have been asked to participate in the set up of a structured framework under which CE can be done in the country, and we have been considered to take a lead in the CE of other upcoming trials through being institutionalized.</p> <p>2. Being flexible during service</p> <p>In order to respond to the emerging needs/issues of our communities, we need to exercise remarkable flexibility during our engagement and activity implementation. If we tie services to particular forms of deliverables and stick to that alone, we miss what the new/pressing issues in the community are.</p> <p>3. If it were possible, I would start with the community being part of the design of the trial to allow utmost ownership of the trial</p> <p>4. To engage policy makers regularly...maybe quarterly.</p> <p>We think this can translate into a reduction of unrealistic expectations if the policy makers in higher offices announce our presence.</p>

<p>Best practices</p>	<p>1. Department of Health, Provincial, Doctors working in TB settings having regular meetings When STREAM started, what worked well was meaningful collaboration that existed between the Health Department ranging from provincial, district up to site level and research team. This was done through regular meetings with all stakeholders and regular feedback. The first meetings created a stable opportunity for clinical trial moving forward into the future.</p> <p>2. Protocol Trainings Protocol Training especially for community educators and Community Advisory Boards (CAB). This practice assisted to do community education with confidence, research literacy programs and having CAB members as catalysts in participant recruitment. Protocol training also helped alleviate the misconceptions associated with the study. Protocol training also addressed the safety of the participants.</p> <p>3. Community entry strategy This included training of CAB members on different aspect of the study. The activities done to have facility nurses and TB focal nurses on board. Community groups, civil society individuals, political leaders, African traditional medicine practitioners were all necessary people needed to be contacted and to have their buy in for STREAM to survive in the community.</p>
<p>Challenges</p>	<p>1. Decentralization: Patients were referred back to their local clinics to start treatment This meant that for recruitment purposes, the trial site cannot easily recruit from the hospital since all TB patients were referred to hospital for further management. Now that there were no longer patients in the hospital, another strategy was needed to recruit from different local facilities. The local clinics would sometimes be unwilling to accommodate recruitment since they would say that have their own targets from the Department.</p> <p>2. Negativity towards clinical trial Negativity of some community people against the study had a negative impact on the community. It became difficult to recruit and do community outreach in those areas.</p> <p>3. COVID-19 pandemic Community Engagement came to a standstill in our communities where there is lack of technological expertise.</p>
<p>Lessons learned</p>	<p>1. Importance of regular feedback meetings Feedback meetings helps clarify expectations and helps people learn from their mistakes and confidence is built. The feedback meeting provided a platform to correct the wrongs and congratulate people who have done well. It is in these meetings that people are aware of things that still needs to be done.</p> <p>2. Importance of protocol training Protocol training will be a necessity even in our next trial. It also clarifies the inclusion and exclusion criteria, which is one of the fundamental question an ordinary person would ask. It provides guidance and it is like an action plan. It answers all the question an ordinary person on the street might have.</p> <p>3. Results dissemination Result dissemination in our community was received warmly, especially because it was obvious that the job was well done in conducting STREAM 1. People from all spheres of the community gathered in the hall to hear the good news. The results were accepted and that action alone built trust between the community and the study team.</p> <p>4. Issue of decentralisation Now that the patients are initiated at their local clinics, it means having relationships with local clinics, the relationship that we never had. The referral system from the clinics to the trial site needs to be done and implemented. Paper work involved in transferring a patient to the trial site should be uniform from all the clinics. Continuous update on the wellbeing of the participant should be communicated with the sister at the clinic.</p>

	<p>5. Negativity should be addressed by research literacy Until people understand the importance and benefits of being in a clinical trial they will always be negative. People should be aware of the importance of their contribution towards clinical trial.</p>
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CAB 11

Best practices	<p>1. Participation of a participant Research strives in protecting and preserving the lives of our fellow community members and find better ways to preserve, protect the communities in simpler, better, and affordable ways to have a better health.</p> <p>2. Stakeholder Education CE has opened lot of ways to connect and communicate with all stakeholders and participant care is at heart. It proved that even when the clinical trial has ended, CE still continues and paves away for other trial studies. CAB have more experience in advocacy, can influence policy change and assist in improving the life of participant and how research can be done in our community and kill stigma.</p>
Challenges	<p>1. Site to understand GPP The site is trained on GCP not GPP. Sometimes they don't understand stakeholders' anatomy and the importance of community engagement, stakeholders. It helps both parties to have clear understanding of clinical trial in current and future plans and to better the life of communities.</p> <p>2. Community understand that research takes time in terms of results findings Research is a process and there are channels and guidelines to be followed. All this parties need to adhere to policies that protect lives.</p>
Lessons learned	<p>1. Training It is important to provide training. It equips all stakeholder to be informed and decrease stigma</p> <p>2. Learning from previous study outcomes Feedback and having overview on how studies were done, knowing the outcome help in current times and builds trust and people see transparency regarding participant and their participation in the community. They appreciate the participation done by their loved ones.</p> <p>3. Research is good in the community with partners Community wants to be involved in participation. When CE will be done in a right way, show that the community will benefit and no harm can be done to expose participants' life and safety is at heart to protect life.</p> <p>4. Stigma Reducing stigma is important because it minimizes recruitment, causes retention to be bad, interns of loss to follow up. It gives bad results for the entire overview of the study.</p>

CAB 12

Best practices	<p>1. Multidisciplinary team in a CAB and Stakeholders Engagement Since the CAB is multidisciplinary and diverse community engagement and community access was the most important and through CAB as the eyes and ears of the community.</p> <p>2. Understanding research literacy Capacity building of CAB was the most success as we as CAB need to cascade knowledge of TB to support the clinical trials and the community at large.</p> <p>3. Autonomy CAB working independently on organizing TB relevant activities. CAB were capacitated to do the advocacy on patients and community issues</p>
Challenges	<p>1. Understanding the reason of conducting the research Cascading information to the community and families of trial patients that they are not the Guinea pigs. Through informed consent the patient involvement was mostly implemented, research was thoroughly explained to CAB and to the patients before joining the trial.</p>

Lessons learned	<ol style="list-style-type: none"> 1. Understanding the research and Good Participatory Practice Principles of research were implemented and the role of the CAB underlined. 2. TB Advocacy CAB were able to tackle all advocacy issues. 3. Adherence counselling Assisting patients to adhere to treatment. 4. From negative to positive by bringing science to a community level of understanding Community had the voice and was able to dialogue with the clinical teams to have best outcome.
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CAB 13

Best practices	<ol style="list-style-type: none"> 1. Transparency Being open and transparent has worked a great deal at our site. Stakeholders like to be kept in know as to what is going on with site. How are participants, our studies? 2. Forming of great partnerships and strengthen those relationships Strengthen partnership by continuous meetings. Being available with the resources that we might have and they are not having. Using each other strengths throughout the process.
Challenges	<ol style="list-style-type: none"> 1. Establishing a CAB Some stakeholders did not show interest at first. 2. Members not being committed to the meetings Members would indicate that they will come to meetings but when we first started to establish the CAB (we invited and went to different clinic inviting) at the day of meeting, only a few members came.
Lessons learned	<ol style="list-style-type: none"> 1. Transparency Being transparent and information sharing is the best in the experience we had with CE. Stakeholders want to be involved and want to know what is going on. 2. Network building Building great network partnership and being able to call each other when we are doing Community Engagement programs. 3. Lesson learnt - is to recruit more members Having a wider field of different professionals within the CAB. 4. Follow up Follow up with all stakeholders about the upcoming meetings. Sending out reminders of the meetings that will be happening.

