Solidarity Trial Vaccines (STV)

Good Participatory Practice (GPP) with trial populations for the Solidarity Trial Vaccines (STV)

An international randomised trial of candidate vaccines against COVID-19

World Health Organization

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Contents

Abbreviations

CAB	Community Advisory Board
COVID-19	Coronavirus Disease 2019
GPP	Good Participatory Practice
PI	Principal Investigator
STV	Solidarity Trial Vaccines

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Introduction

Coronavirus Disease 2019 (COVID-19) continues to spread globally and vaccination remains a critical element in the world's response to the pandemic. A number of vaccines have already shown excellent results and are now being used in various countries - after the approval of national regulators.

However, we will still need many more vaccines to cover the world and to combat new variants of the virus.

Given this need, WHO has launched the Solidarity Trial Vaccines (STV), a randomised clinical trial to provide definitive evidence of the safety and effectiveness of the next phase of promising vaccine candidates.[1]

The design of the trial will allow researchers the flexibility to drop poorly performing candidates and insert new ones.

Population participation is at the heart of all successful research initiatives. Community members, who input, advise and sign up for trials, make a significant contribution to advancing new knowledge for collective gain. Engaging and involving affected populations in key aspects of the trial demonstrates core values of respect, fairness, integrity, transparency, accountability, responsiveness and autonomy, and can enhance trust.[2] Good Participatory Practice (GPP) is therefore a core element of the Solidarity Trial Vaccines. GPP benefits trials by helping to assess feasibility and acceptability in a given community, ensuring communication throughout and at the end of trials, and can improve uptake in policy and practice once a study is completed.

Best practice is achieved when GPP, outreach and engagement occur with a wide range of stakeholders who have an interest in the research being conducted, including potential research participants, enroled participants, wider publics, district leaders (civic, religious, cultural), health professionals, professional societies, researchers, scientists, trial teams, media, government, regulatory and other authorities. Overall responsibility for GPP and communications for the STV lies with the trial Principal Investigator (PI). Each trial site or network will also have a person nominated as a STV "engagement focal point" who will lead GPP at local level. A team at WHO headquarters and regional offices will work with engagement focal points to develop and implement their plans.

Throughout the trial, this handbook will be updated in response to the needs and learning from the study. This version includes additional materials and detail related to each step of planning engagement activities.

Aim of this document

This document is **written for engagement focal points and research teams as a step-by-step guide** to setting up and delivering GPP with trial populations for the Solidarity Trial Vaccines, led by WHO.

It includes information for engagement focal points at trial sites to detail and specify contextually relevant and feasible plans for GPP with local stakeholders and trial populations. It covers local engagement planning and includes some media and wider public engagement. It does not cover engagement with policy makers, sponsors, ethics committees, regulatory authorities etc., and is also not designed to steer a comprehensive communication plan for the trial.

The document provides guidance on (a) the role of engagement focal points, (b) the aims of GPP with trial populations for the vaccine trial, (c) key features of the vaccine trial, (d) definitions of communities of interest, (e) activities at different stages of trial set-up and delivery, and (f) an implementation plan with a list of resources available to support engagement focal points at every step.

Role of the engagement focal point

Engagement focal points are members of the vaccine trial teams who lead local engagement planning and activities with research populations. Engagement plans are developed and agreed jointly with all members of the research team, and strong communication within the team is key to their success.

Roles and responsibilities of the engagement focal point include, but are not limited to:

- Identifying stakeholders for engagement.
- Developing context-specific and feasible plans for engagement.
- Taking responsibility for conducting rapid engagement activities, acting as a dialogue facilitator, and creating a simple, clear, informative overview of the study by including graphics, finding or creating educational videos and engaging champions.
- Keeping clear records of the research, and also of engagement activities.
- Bringing practical recommendations to the research team that can improve the experience of those participating in the trial.
- Tracking questions raised by research participants and the community where the trial is situated and ensuring these are responded to.
- Communicating specific needs/challenges relevant to the context in which the trial is being implemented.

Objectives of engagement for the vaccine trial

Overall objective of engagement

To engage with local stakeholders' views and expertise in ensuring the Solidarity Trial Vaccines is planned and implemented in a way that is acceptable, feasible and relevant to potential participants. In this way, engagement activities seek to maximise poten tial for the trial to reach target recruitment and retention of participants and to generate timely high-quality evidence related to vaccine effectiveness.

Specific objectives

- To engage with individuals and groups whose support is necessary to perform the trial.
- To understand context-specific dimensions that inform communication and implementation of the STV.
- To understand the views, questions and concerns of local populations related to key aspects of the STV that inform implementation of the trial.
- To describe ways of conveying the potential benefits and risks that participation in the trial may confer, both to the individual, to wider society and to science in general.
- To demonstrate respect, build trust and partner with local stakeholders to ensure support, participation and prepare the foundations for later introduction of a COVID-19 vaccine or vaccines.

Key features of the vaccine trial that will inform engagement activities

Engagement activities will bring rapid insight into **contextual and socio-cultural considerations** for the trial team as they plan and implement the trial.

The research protocol for the trial sets out requirements for the trial to be conducted in a way that is scientifically robust. Key aspects of the trial design are driven by scientific judgements and cannot be altered. However, some aspects of how the trial is implemented, for example, recruitment strategies and ways in which consent is sought from trial participants, can be adjusted to ensure they are relevant and appropriate for those participating.

The goal of the trial is "to coordinate prompt, efficient, and reliable evaluation of the many preventive candidate SARS-CoV-2 vaccines under development, to assess their safety and efficacy and to identify those that are likely to be appropriate for deployment to influence the course of the pandemic".[1]

The trial design includes **adaptive features**, specifically:

- Choice of vaccines to be included (as trial interventions will change).
- Choice of success criteria.
- Choice of study population.
- The way efficacy will be monitored.
- Choice of control group.

A key message related to this novel trial design is that adaptability and change are built into the design of the trial to ensure responsiveness to new products, new epidemiology and new knowledge. Change is part of the design and informed by evidence not random or personal choice.

Aspects of the way in which the vaccine trial has been designed that cannot be altered

GPP activities will allow the trial team to gain insight into how local populations view these aspects of the trial design so that communication about them can be clear and contextually informed. Engagement activities will include identifying which aspects of the trial design (if any) give rise to confusion or concern among local populations so that these concerns can be addressed upfront or as early as possible.

Features related to the implementation of the trial which can be shaped by local population priorities, concerns and sensitivities to locally appropriate adaptations

- Public-facing communications for general information, e.g. press releases, posters, notices, announcements.
- Public-facing documents for research enrolment, e.g. information sheets, visual materials to explain the trial, Frequently Asked Questions.
- Group sessions for information exchange. These are an important opportunity for potential research participants to learn about the trial and for the trial team to build trust.
- Information about the use of novel technology for participant identification (iris scanning).
- Information and processes related to biological sampling (serology).
- Consent process and documentation.
- Where to set up clinics in communities; opening and closing times.

Definition of the communities we want to engage

The primary communities to be engaged are those from which research participants will be recruited. This will include members of lay society, civil society groups, such as community groups, women's groups, faith-based organisations, professional associations, advocacy groups etc. Further, those managing and working in facilities in which trials will be conducted, and those providing direct care to patients with COVID-19, will be additional groups for engagement.

Stakeholder and community mapping are key parts of developing local engagement plans. Resources are available to support this process where primary groups will be segmented. Secondary groups will also be identified as these can influence the perceptions of primary audiences.

Activities for setting up and conducting Global Solidarity Trial engagement

Engagement before the trial: Site(s) not yet selected

- ☐ Establish an internal engagement and communications group. This group will help you plan engagement activities for the trial – see Appendix 1 for information and a planning template.
- ☐ Become familiar with the location(s) and social context(s) of local populations where the trial will be hosted – see Appendix 2 for a template to guide context and environment scanning.
- ☐ Map stakeholders, develop and document tailored and specific plans for engagement based on what is contextually relevant and feasible: see Appendix 3 and use the template that takes you through the steps for planning engagement activities.
- ☐ Identify human and financial resources available and needed for engagement activities.
- ☐ Consider how you will work with a Community Advisory Board (CAB). Identify any active CABs you could engage with. If there is not a suitable pre-existing CAB, plan for how one would be rapidly set up with clear terms of reference: See Appendix 4 for information about setting up and working with a CAB.[3]
- ☐ Review the research protocol and plans of the trial team for implementation and anticipate concerns, clarifications or needs in the context in which you will be implementing the trial, e.g. technology, sampling, group information sessions. Discuss formally or informally with key informants the perceived main obstacles to the study and how to address these.
- ☐ Establish clear communication channels with the PI and project team, e.g. expectations regarding which meetings you will attend, how to feedback engagement activities, how to raise areas of concern.
- ☐ Establish reliable social media resources and media contacts where needed, to enable communication and contact (e.g. WhatsApp).
- ☐ Engage with global WHO coordination meetings to share solutions and be part of the global trial community.

Engagement before the trial: Site(s) selected but not yet open to recruitment

- [ ] Finalise and share engagement plans with the project team, including communication channels. See Appendix 3: completing the step-by-step planning and templates will result in an engagement plan.
- [ ] Include engagement plans in the trial protocol that is submitted for ethical approvals. See Appendix 3: the engagement plan can be included as an appendix in the ethics application to demonstrate your planning. Unless you are planning specific research activities as part of your plan, you do not need ethical approval before starting engagement.
- [ ] Engage a CAB. If a pre-existing group is not established, rapidly set up a CAB, including with clear terms of reference.[3] See Appendix 4 for information about setting up and working with a CAB.
- [ ] Review stakeholder mapping of groups to be engaged and consulted. Consider youth groups, women's groups, men's groups, patient groups, traditional and religious leaders, health workers, media. Consider power and gender dynamics. Consider engaging minority groups who might not be consulted because of, for example, age, religion, ethnicity, sexuality, and how to reach them safely and ethically.
- [ ] Plan and conduct activities with key groups, including community leaders, using a range of suitable methods such as focus group discussions, formal or informal key informant interviews, small group discussions.
- [ ] Develop tools and materials, including key messages, Frequently Asked Questions, public-facing leaflets, flip books.
- [ ] Based on the outcome of the consultations, review and refine key messages and communication materials for potential research participants, e.g. session planned for group information exchange, public-facing written and visual information materials, consent form etc.
- [ ] Based on the outcome of the consultations, review and refine study processes (where possible), e.g. recruitment process, community consent etc.
- [ ] Establish mechanism(s) for public information and communications, including, for example, responding to press enquiries.
- [ ] Troubleshoot challenges and share successes with the global trial community through the WHO coordination group.

Engagement during the trial: Site(s) open to recruitment

- [ ] Establish mechanism to ensure continuous input from local stakeholders throughout the trial, e.g. regular meetings with community leaders and/or community groups.
- [ ] Establish mechanisms for bi-directional informal and formal communication about the trial.
- [ ] Establish a system for monitoring anxieties, concerns, rumours related to vaccines and/or the trial.
- [ ] Proactively engage in activities to foster trust and transparency, e.g. video recording vaccine trial activity with participant permission to share locally, nationally and internationally. Provide alternatives for trial-related activities that can engender mistrust, e.g. offer video consent option in lieu of signatures.
- [ ] Troubleshoot challenges and share successes with the global trial community through the WHO coordination group.

Engagement after the trial: Site(s) closed to recruitment

- [ ] Prepare and communicate closure and exit strategies in advance.
- [ ] Obtain feedback from CAB and local champions for communication strategies to help manage expectations regarding study outcomes, follow-up, recommendations and implementation of trial findings, continued access to successful interventions and related resources.[4]
- [ ] Troubleshoot challenges and share successes with the global trial community through the WHO coordination group.
- [ ] Plan sufficient resources at the end of the trial for sharing findings with local stakeholders, collaborators and participants.

Implementation plan

Activity	Resources to support activity	Endpoints	Time	Responsible	Priority
Map the landscape of stakeholders, including district leaders, civic, religious, cultural, local communities, key civil society groups, local engagement and social mobilisation actors in the response, government representatives etc.	Template for stakeholder mapping	Map of key groups for engagement to help clearly define which are primary groups of interest and how other stakeholder groups might be engaged (e.g. Ministry of Health by trial team PI)	2 weeks	Trial team/ Engagement focal point	High
Develop and document tailored and specific plans for GPP based on what is contextually relevant and feasible	Template for GPP plans with local populations	Locally relevant and feasible plan for GPP	2 weeks	Engagement focal point	High
Before the trial starts					
Define composition and establish CAB	1) How to set up a CAB document 2) CAB terms of reference	CAB set up with clear role descriptions and understanding about remuneration	3 weeks	Engagement focal point	High
Organise and conduct meetings with district leaders (civic, religious, cultural) to understand key questions, concerns and information needs	1) Tools for community mapping to ensure inclusion 2) Example topic guide(s) or session planners for community discussions	Leadership engagement and mutual understanding Minutes of the meeting(s) that inform: 1) Draft key messages 2) Draft FAQs 3) List of words or explanations that should be avoided in communications 4) Recommendations to trial team	3 weeks	Trial team/ Engagement focal point	High
Conduct consultation(s), for example, via focus groups, interviews, small group discussions with community representing trial population to: (1) Understand key questions, concerns, general research literacy and information needs, (2) Identify appropriate practices for recruitment and informed consent, (3) Establish best ways to keep populations informed throughout the trial, and (4) Anticipate obstacles that could undermine trial success	1) Tools for community mapping to ensure inclusion 2) Example topic guide(s) or session planners for community discussions	Minutes of the meeting(s) that inform: 1) Draft key messages 2) Draft FAQs 3) List of words or explanations that should be avoided in communications 4) Recommendations to trial team	4 weeks	Engagement focal point	High

Activity	Resources to support activity	Endpoints	Time	Responsible	Priority
Pre-test and refine messages and explanations of key aspects of the trial and obtain feedback on public-facing documents	Study documents for pre-testing (session planner for group information exchange, public-facing information documents, consent form, consent process, comic flip books etc.)	Recommendations and amendments to trial documents and processes			High
Based on reports from community consultations, review and refine key messages and trial communication materials (e.g. fact sheets, FAQs, booklets)		1) Communication and recruitment materials developed 2) FAQs finalised 3) Draft press release 4) Content and wording of documents refined	4 weeks		High
During the trial					
Establish a mechanism for community partnerships throughout the trial to ensure continuous input and feedback from: 1) Trial participants 2) Community leaders 3) CAB	Catalogue of examples and ideas	1) Regular reporting to trial team to inform on community views 2) Real-time adjustments to communication and engagement plan and/ or trial procedures to optimise engagement		Engagement focal point	High
Establish and manage a mechanism for monitoring anxieties, concerns, rumours	1) Media analytics 2) Catalogue of examples and ideas	1) Regular reporting to trial team to inform on social media analytics 2) Real-time adjustments to communication and engagement plan and/ or trial procedures to optimise engagement		Engagement focal point	High
Keep a record of issues raised and how they were managed, including measures to improve trust	Catalogue of examples and ideas, e.g. videos, voice recordings, media success stories			Trial team	
Trial closure					
Prepare and communicate closure and exit strategies		Documented closure plan		Trial team	
Communicate trial results through two-way communication, aligned with vaccine deployment plans	Catalogues of examples and ideas of two-way communication of trial results	Documented materials on trial outcomes		Engagement focal point	

References

1. WHO: **An international randomised trial of candidate vaccines against COVID-19**. 2020.
2. WHO: **Good participatory practice guidelines for trials of emerging (and re-emerging) pathogens that are likely to cause severe outbreaks in the near future and for which few or no medical countermeasures exist (GPP-EP)**. 2016.
3. WHO COVID-19 Research Roadmap social science working group: **Working with Community Advisory Boards for COVID-19 related clinical studies**. 2020.
4. WHO COVID-19 Research Roadmap GPP working group: **Good Participatory Practice for COVID-19 clinical trials: a toolbox**. 2020.

Appendix I: Setting up an internal engagement and communications group: Information and planning template

What is an internal engagement and communications group?

The internal engagement and communications group works as a core part of the operations of the trial to plan and steer engagement and communications for the trial.

Composition of the group may comprise:

- Trial country/site PI or delegated senior trial staff member;
- Solidarity Trial Vaccines engagement focal point;
- Members of the engagement team;
- Research institution's head of communications;
- Other important stakeholders who are key to trial engagement/communications (e.g. media officer, policy engagement officer, social scientist).

What is the role of this group?

- **Meet on a regular basis** to co-plan engagement and communications activities, and to report back on implementation. This may be on a daily basis initially, but is likely to become weekly as engagement/communication activities proceed.
- **Act as a conduit of communication** between the trial team, stakeholders, participants and wider community/public. Laying the foundation for this is key to ensuring that public/stakeholder views/perceptions/insights are fed into trial implementation and ensure responsiveness.
- **Take responsibility for preparing engagement/communication tools.** This may involve modifying/translating generic tools for the local context, or developing new tools which will be used for engaging different individuals and groups.

Planning template:

	Team member	Role	What they bring to the team
1.			
2.			
3.			
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Appendix II: Template for context and environment scan

It is important that information about the location(s) and social context(s) of local populations where the trial will be hosted is available to your internal engagement and communications group. This can be done informally through gathering information from the trial team, local PIs and local team members. Together with the trial team, identify which populations will be included. Note key issues raised in community relationships with COVID-19 response teams; channels of communication and decision-making; socio-cultural norms, practices and traditions; language(s); and other elements relevant to the study.

Site(s) location 1: [text]

General description of location Describe the geographic location, approx. population size, if it is urban or rural, transport links, accessibility of health facilities, security.
Description of various communities and populations Describe variation in populations or communities in the geographic area where the trial will be hosted. What is known about vulnerable groups (e.g. low-resource settings, gender)? What are pressing social or political issues faced by these groups?
Perceptions, experiences, sentiments What are local or national perceptions about COVID-19? What are perceptions about vaccines in general? Perceptions related to a COVID-19 vaccine? Are there formative research activities that can give insight into this? Have these populations been exposed to other large trials, including vaccine trials historically? What impacts have been left through these experiences?
Information What is the information landscape? What is the main medium of communication accessed by populations (radio, TV, newspapers, social media channels, WhatsApp)?
Other COVID-19 trials Are there other COVID-19 trials (therapeutics or vaccines) in the location? What can be learned from their experience? What controversies have arisen through their operations? How have these been managed?

(Add additional locations as needed)

Appendix III: Template for developing local engagement plans

This planning tool is designed to guide planning for engagement for the Solidarity Trial Vaccines. The plan should be completed by the engagement focal point working with the internal engagement and communications team.

Introduction and objectives

Provide a short introduction to your local engagement plan that includes the main objectives.

Overall objective of engagement

To engage with local stakeholders' views and expertise in ensuring the STV is planned and implemented in a way that is acceptable, feasible and relevant to potential participants. In this way, engagement activities seek to maximise potential for the trial to reach target recruitment and retention of participants and to generate timely high-quality evidence related to vaccine effectiveness.

Specific objectives

- To engage with individuals and groups whose support is necessary to perform the trial.
- To understand context-specific dimensions that inform communication and implementation of the STV.
- To understand the views, questions and concerns of local populations related to key aspects of the STV that inform implementation of the trial.
- To describe ways of conveying the potential benefits and risks that participation in the trial may confer, both to the individual, to the wider society and to science in general.
- To demonstrate respect, build trust and partner with local stakeholders to ensure support, participation and prepare the foundations for later introduction of a COVID-19 vaccine or vaccines.

Priority stakeholders for engagement

Map and prioritise the different groups that your engagement plan will focus on. Environment and context scanning will help too. Note this planning can be informed by a more detailed stakeholder mapping exercise.

Consider key groups in the following stakeholder categories:

- Leaders/ managers of specific target recruitment audiences (e.g. factory manager, local police chief);
- Local influential politicians, community leaders including religious, cultural, sports leaders;
- Local health managers;
- Civil society organisations and relevant NGOs;
- Media --- to access the general public.

Key local stakeholders for engagement		
Individuals and organisations	How will you engage with them? (e.g. joining regular meetings, invite to information sessions, invite to visit research sites, phone call, email etc.)	What do you want to achieve from engagement? (e.g. raise awareness, advocate for public support, permissions, operational support etc.)

Engagement activities before, during and after the study

Describe key activities that will support engagement before the study opens. Recruitment of the first and last participants will be important milestones in trial operations. In this template, document key engagement activities that are doable in your setting before, during and after the trial opens to recruitment.

Before study opens to recruitment

List bullet points on engagement activities to achieve the following:

- Introduce the trial and dialogue with communities about key features of trial operations (general audience), e.g. meetings, webinars, information sharing (leaflet);
- Review and refine key messages, communication materials, enrolment processes, public-facing documents, including the readability and ease of understanding of information sheet(s) and consent form(s), e.g. through consultations with CAB, focus groups, informal information-gathering via meetings with key stakeholder groups;
- Set up two-way communications mechanisms so community members know how to contact engagement teams, e.g. dedicated study phone line or email.

During ongoing recruitment of participants to the trial

List bullet points engagement activities to achieve the following:

- Ensure continued partnership and dialogue with key communities about the trial, e.g. CAB, regular meetings, feedback from research participants;
- Monitor and respond to public narratives and sentiments revealing anxieties, concerns and rumours, e.g. via media monitoring, followed up by targeted communications activities;
- Monitor and respond to research participant anxieties, concerns, e.g. through two-way communication channels, routine engagement via technology platform;
- Conduct activities to foster trust and transparency, e.g. video recordings and testimonials;
- Provide information to the public about the trial, e.g. TV, radio, news interviews, social media messages, videos etc.;
- Prepare to communicate key milestones and transitions such as recruitment launch, times when Data Safety and Monitoring Board (DSMB) reviews are reported, or when the trial or arms of the trial are paused or stopped, e.g. through attendance at trial team meetings to identify and anticipate focused engagement and communication needs.

After the trial has closed to recruitment

List bullet points on engagement activities for when the trial has closed to achieve the following:

- How you will anticipate closure and exit strategies in advance, e.g. the team will develop plans with CAB to help manage expectations regarding study outcomes, follow-up, vaccine access etc.;
- Disseminate trial results, e.g. a dissemination plan will be developed together with national and local trial teams to feedback to local community stakeholder groups.

Keeping track of your plan

Describe how you will document and keep track of the activities in your plan, e.g. shared repository of all documents, list of recommendations for change that have been made to the trial team and how changes were taken up, engagement activity tracker, log of Frequently Asked Questions through engagement activities, minutes of trial meetings where engagement activities are fed back to the wider team.

Resources and budget

Develop a budget for planned engagement activities, including to fund core staff members working on engagement at local and national levels, to compensate CAB members for participation, costs to run meetings (venue hire, refreshments, travel costs if needed), costs to develop and print materials etc.

Appendix IV: Setting up and working with a Community Advisory Board (CAB): Information and planning template

This planning tool is designed to guide planning for engagement for the Solidarity Trial Vaccines. The plan should be completed by the engagement focal point working with the internal engagement and communications team.

Working with Community Advisory Boards (CABs) for COVID-19 clinical studies

What is a Community Advisory Board (CAB)?

A CAB is a group of lay representatives from the local communities where the STV will be hosted. As far as possible, the CAB should represent different perspectives from the local community. The CAB provides rapid feedback to the trial team related to key aspects of the trial throughout the life cycle of the trial. Having a CAB is an essential component of a clinical trial and, in some contexts, a key ethical requirement.

General considerations in establishing and working with CABs for the Global Solidarity Trial

The composition of the CAB should reflect key local communities of interest for the STV.

Identify who 'authentically' represents communities, e.g. whether CAB members speak on behalf of a particular community or are typical members of that community.

Include perspectives from vulnerable groups. To ensure the voices of the most vulnerable and marginalised are heard, consider adding specific groups to include their perspectives, e.g. the lowest-income groups, or people living with disabilities.

Facilitate appropriate motivation (intrinsic and extrinsic) of members. Compensation should cover direct and indirect costs. However, there should be additional motivation, achieved through non-monetary means to avoid undermining the independence of CAB members.

Ensure clarity in roles and adequate training to fulfil those roles. CAB members' ability to make meaningful contributions can be undermined by different understandings of CAB roles, as well as inadequate training in what research is and in basic research ethics principles. Power relations between members (and between members and researchers) can also undermine openness and action.

Identifying a CAB to work with

If possible, work with a CAB that is already in place, only setting up new CABs where necessary and possible. Established groups should already have some understanding of health research, of ethics principles in research, and of how advisory roles in health research work. It is important to begin working with these CABs using existing processes and agreements, so that they are not unintentionally undermined.

Where there are no existing CAB structures in place, consider whether alternative groups or networks can undertake aspects of CAB roles, such as patient/caregiver support groups, community health workers (CHWs), or frontline staff from local health organisations. In working with CHWs and frontline staff, particular care is needed to ensure that proposed CAB activities do not undermine their responses to the pandemic, or overburden them at a critical time. It should also be recognised that a potential advantage of working with these groups and networks is the relatively easy identification of members and explanation of the work; but a potential challenge may be their independence from the institution and inability to adequately 'represent' wider community members.

Where a new CAB is being started, it is important to establish how you will select (identify and approach) potential CAB members, and ensure roles, responsibilities and expectations are carefully discussed.

How to set up a CAB

1. Based on social context and environment scanning and stakeholder mapping, describe key groups that should be represented in the CAB that will guide group composition. Consider gender balance, representation of vulnerable groups, mix of socio-economic and cultural representation.

2. Develop terms of reference for the CAB and expectation related to numbers of meetings, length of time the group will be convened, expectations of roles and compensation.

3. Identify resources available to compensate CAB members and ways to ensure timely compensation

4. Identify ways to recruit CAB representatives, e.g. through engagement activities, public announcement etc.

5. Select candidates to create a group of 10-15 members as a starting number. Note that levels of engagement among CAB members will likely vary during the course of the trial and not all members will attend all meetings.

6. Facilitate training sessions, where CAB members learn about key aspects of the trial, including trial design, operational processes, the ethical review process, review by regulatory bodies, the role of DSMBs etc.

	Proposed CAB member	Why they are important and what perspective they bring
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Working with a CAB

Whether working with an existing or new CAB it is important to **clarify what all parties expect to get out of the interactions, discuss what is and is not feasible, and develop** ground rules regarding confidentiality, external messaging from the meetings, and how CAB advice will be documented and acted upon. A **clear and effective training** plan is essential, including information on research/the research institution, research ethics principles, COVID-19, specific study/studies being planned, and the role and functioning of the CAB. Training may have to be conducted using videos, animations and online presentations, and support such as data bundles may be needed. Once built, relationships between CAB members and researchers will need to be **protected over time**, including through giving feedback on discussion outcomes.

Tips for working with a CAB

- Ensure you have contact details for all participants with permission for holding these and for a communication mechanism, e.g. email list, WhatsApp group.
- At the first meeting with CAB members, discuss and agree terms of reference.
- Set up a regular meeting schedule and expectations regarding regularity of meetings etc.
- Set up two-way communication channel for any questions or feedback.
- Invite senior members of national/ local trial teams to attend meetings, present the trial and dialogue with CAB members.
- Anticipate and respond to power dynamics in group discussions in order to facilitate sharing and exchange of views, including via one-to-one follow-up as needed.

Specific challenges and how to overcome them

Additional challenges for COVID-19 studies include:

- Ensuring **interactions with CABs do not undermine, and ideally support, essential activities** of key local stakeholders working to respond to COVID-19, particularly Ministries of Health and leading health NGOs. CAB engagement will likely need to be followed or preceded by discussions with those key stakeholders, as part of a wider local engagement plan;
- Ensuring that bringing together CABs **does not cause any physical or social harms** through placing individuals at risk of infection, stigma, or inadvertently adding to unhelpful rumours or concerns. Interactions may not be able to be in-person, with alternative possibilities including Zoom, Skype or – more commonly for community groups in low-income settings – WhatsApp groups or telephone discussions. This may be more feasible for some types of communities, or particular members of those communities, than for others;
- Often **limited time to get studies up and running**.

Depending on the context, several types of CABs may be needed, together with wider stakeholder engagement, including:

- CABs composed of relatively well-known, confident, prominent and outspoken leaders speaking on behalf of their communities, such as religious elders, local chiefs or elders, or leaders of women's groups and other community-based or non-governmental organisations. For studies involving health workers, representatives may be team leaders or managers. These members are usually confident to voice their views and opinions, and their involvement may be reassuring to members of their communities;
- CABs made up of members more typical of their communities (such as representatives of an age group, illness, or a type of health worker), who potentially have better awareness of everyday issues and concerns than more outspoken leaders;
- CABs, perhaps differently constituted and organised, made up of relatively vulnerable and marginalised groups in relation to the research in that particular context (e.g. the elderly, people with disabilities, or out-of-school youths), who would otherwise find it difficult to voice their views and be heard.

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