

DAC Clinical Trials Communication Template

**A template to guide effective communication with
stakeholders throughout the lifecycle of a trial**

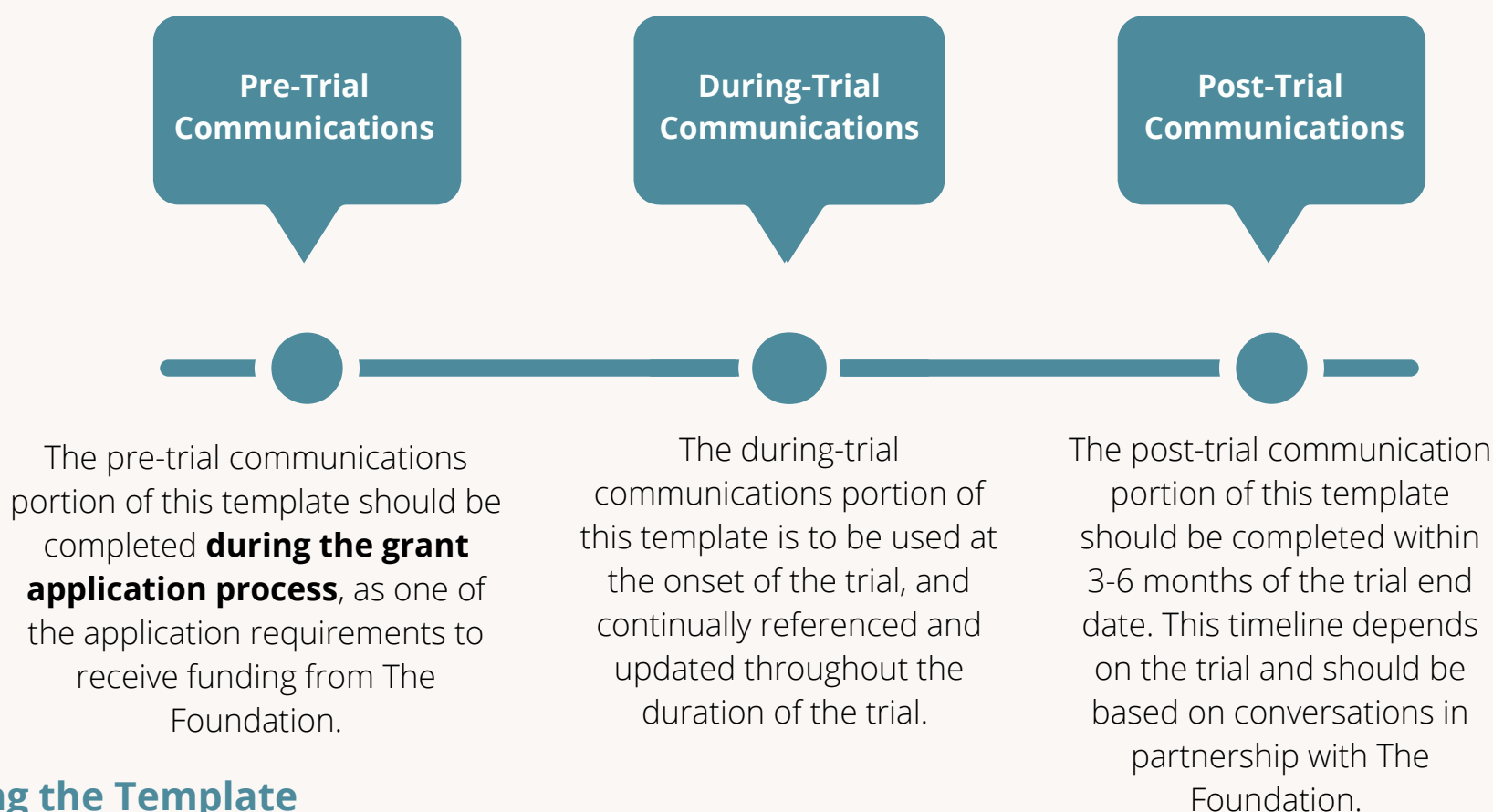
Who: This template was informed by a series of interviews with seven clinical trial experts who have vast experience designing and implementing trials all over the globe. We are grateful for their input and time. A special thank you to the experts who provided reviews and edits of this template: Alison Wiyeh, MD MSc, Duduzile Ndwandwe, PhD, Augustine Choko, PhD MSc, Innocent Valea, PhD MSc, Boghuma K Titanji, MD MSc DTM&H PhD.

What: The template is not meant to be an exhaustive guide for the wide variety of communications that take place around a clinical trial. This tool instead shares key principles to guide your own creative thinking for what will work best in your given context, with your identified priority stakeholder groups. These principles are meant to be adapted to fit the needs of the trial participants, community, and stakeholders impacted by your trial.

Why: This communication plan template was developed to support effective, inclusive communication to all stakeholders, including clinical trial participants and their broader community, before, during, and after a clinical trial.

How: This template and the guidance it provides was informed in part from a mixed-methods analysis examining publicly available clinical trial protocols for the role of communications with trial participants and their communities. This template includes a step-by-step process with targeted questions for users to fill in to develop a communication plan with the goal of guiding stakeholder and community engagement.

When: This communication template is divided into three phases - pre-trial communications, during-trial communications, and post-trial communications. **The pre-trial communications portion of this tool should be used by all grantees when applying for funding from The Bill & Melinda Gates Foundation.** The graphic below outlines when to complete each portion of the communication template throughout the trial. With these parameters in mind, it is important to note this tool is intended to be a living document and users are encouraged to re-visit all phases of the tool as the trial evolves, stakeholder groups are better understood, and communications are tested and refined.



Using the Template

This template Includes a series of prompting questions in each section wherein users must fill out their answers in the column next to the question. It is a fillable tool, allowing users to fill in answers to each question directly.

This template outlines a comprehensive overview of steps and best practices to consider when drafting a communication plan. As a result, we've created a **minimum set of acceptable standards** for each section of this template. Each question outlined in **black text** is a **required** question. Other questions outlined in **green text** are not required, however, they are intended to serve as a useful guide, and should be completed if relevant for trial at hand.

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Pre-Trial Communications



Pre- Trial Communications

Step 1: Understanding Priority Stakeholders



Before this Step:

- Work with trial organizers to understand the ideal trial participants.
- Perform a desk review. Determine if there are any studies done in or around the community you'll be working in or in similar communities about the disease area you will focus on in the trial.
- Develop a questionnaire or interview guide for stakeholders. The questions in step 1 and step 2 of this template will serve as a helpful guide to generate questions.
- If your budget allows, visit the community and meet face to face with select community leaders or representatives such as chiefs, religious leaders, women's groups, etc. Interview stakeholders about the disease area focused on in the clinical trial, and any concerns they have. Ask about any previous trials and how they went. Ask generally about their community, what they value, and how they consume information.
- Conduct a focus group to understand what kinds of benefits priority stakeholders would like to see from the trial. This will allow your team to hone in on what is useful for the community, without making assumptions about the kinds of benefits they are interested in receiving.

Pre-trial communication is vital as it sets the tone for the duration of the clinical trial. Step 1 begins with understanding your priority stakeholders and the context in which they live, serving as the foundation for the rest of your communication plan.

Type your answers in the right column for each question listed below.

Who are your trial participants? What are the demographics and other defining features to consider about the participants?	
What are the local cultural traditions, history, and customs of the community in which you are carrying out the trial? How may that impact how the trial is perceived?	
Beyond trial participants, whose opinions and decisions will impact your ability to implement the trial successfully and/or promote the application of findings?	
Who stands to gain or benefit from the trial and why? <i>Examples include: researchers, participants, families, etc.</i>	

What languages are spoken in the community? What are the literacy levels for trial participants and the community more broadly?	
What are current events or major issues that could impact your trial? <i>Examples include: elections, conflict, rainy season, etc.</i>	
Has the community hosted trials in the past? How were they received? Will you address any negative feelings or risk perceptions if they exist ?	
What are the existing and preferred communication channels used by priority stakeholders in the community?	

The Importance of Understanding Priority Stakeholders

The most effective communications are targeted. Targeted communication starts with identifying and understanding priority stakeholders, allowing for the grouping of stakeholders into subsets that share similar characteristics or needs for information.

Research on priority stakeholders is necessary for effective segmentation and prioritization. At a minimum, you should collect information to understand priority stakeholders' awareness, beliefs, and feelings about the issue you are researching; influencers or those they communicate with; what is most important to them; and preferred channels for communication. Part of this process includes analyzing the risk perception of your audience. Perhaps there is stigma around the disease being addressed and stakeholders are afraid to be associated with it; or they fear being part of the trial will make them a target in the community for favors or loans. Understanding these perceptions will help you create effective messages that can address concerns.

While planning your communication strategy for priority stakeholders, it's important to note what kinds of benefits they would like to see from the trial. Benefits sharing can take many forms, and while the most tangible is the the sharing of financial benefits from research, other benefit sharing categories include developing capacity and infrastructure, increasing skills and knowledge, better access to healthcare and/or improved health facilities, and enhancing career opportunities and attribution/recognition for stakeholders. It is essential to consider that individuals and their community may have a wide range of motivations for participating in research, and many have different priorities when it comes to the types of benefits anticipated as well as who will accrue them (see a recommendation for how to gather this insight in the *before this step* section above). We have deliberately added a column in Table 1 which asks you to consider how each priority stakeholder group benefits from the trial. This could be information that you know as a result of conversations with stakeholders, or it could be a list of potential benefits that you will discuss/adapt in partnership with participants as the trial evolves.

Identifying priority stakeholders also allows you to prioritize communication efforts. In addition to understanding priority stakeholders, it is critical to identify the most effective and trusted messengers to deliver communications. Once priority stakeholders are identified and prioritized, begin determining the contacts within those audiences and key considerations for communicating with them (see Table 1).

Pre- Trial Communications

Step 2: Priority Stakeholder Mapping



Before this Step:

- Review results of the desk review and interactions with community stakeholders to understand their concerns, risk perceptions, and values to help determine who will be most important to prioritize for communications.

Fill out **Table 1** with contact information to help you easily reach out to your stakeholder groups. *Note that not all of these groups will be your priority stakeholders. These are examples of some that may be on your list. Complete only those that are priorities for your communications. Feel free to add other groups that don't appear.*

Priority Stakeholder	Contact	Email/ phone	Who does this group communicate with?	How does this group benefit from the trial?	Other Considerations
Ministry of Health					
Regional Health Board					
Local Leaders (Village Elders)					
Religious Leaders					customs (dress), gender norms
Political Leaders					
Community Advisory Board					
Health Care Workers					
Policymakers					
Media Contacts					
Social media influencers					
Participants and Family					working hours, access to cell phones or Wi-Fi, literacy

Pre- Trial Communications

Step 3: Develop Communication Objectives and Key Messages



Before this Step:

- Work with trial organizers to understand key message they want to emphasize.
- Review results of the desk review and interactions with community stakeholders to understand their concerns, risk perceptions, and values and address them in the objectives and key messages.

Objectives should be designed to empower trial participants and the communities that surround them to understand the trial, building trust for the clinical research, and the institution or health facilities implementing clinical research. Craft communication objectives in partnership with your team and then draft key messages that will help you achieve these objectives. Key messages can address barriers you have identified to achieving your communication goals, risks, or misperceptions that your priority stakeholder group(s) may hold.

What are three communication objectives you want to achieve during this trial? Each objective will inform the messages you will design in the next column.

Objective 1:

Objective 2:

Objective 3:

What are three key messages you want to communicate to the trial participants and community regarding the trial? Connect each message to one of the objectives listed on the left.

Message 1:

Message 2:

Message 3:

Type your answers in the right column for each question listed below.

Who will serve as your communication spokespeople responsible for crisis communications?	
List (as many as you can) the kinds of crises that could impact your trial. <i>Examples include: pandemics, safety concerns, allegations of exploitation, a data breach, negative attention from in-country stakeholders, organizations in other countries, or by the media.</i>	
What communication channels will you use to communicate with media, employees, core constituents, advocacy groups, opinion leaders, stakeholders, and policymakers in a highly charged crisis atmosphere?	

Pre- Trial Communications

Step 4: Crisis Communication Planning

What is a crisis communication plan?

While clinical trial staff cannot predict a crisis, they can plan for one. Crisis communication plans outline the communications steps that trial staff and partners should follow at the local, national, and possibly global level when a situation or event threatens to negatively affect a clinical trial. While this template does not include an exhaustive crisis communications template, your plan should outline the policies and procedures for rapidly assessing and responding to an evolving crisis scenario. This plan should identify who must be involved in crisis response, at what time, and in what manner.

This template requires users to outline a benefits sharing plan for priority stakeholder groups in earlier steps. This is particularly important so that opportunities for benefits sharing are utilized even in the times of crisis. Taking a proactive approach to benefits sharing can ensure that the voices of global populations are heard regarding scientific advancements that directly and indirectly affect them, and that scientific teams are well positioned to ensure the promotion of equitable benefit sharing for all, especially during times of crisis.

Assembling a communications team:

A good communications team requires a diverse team of people to work together. Consider the following when assembling your communications team:

- Select and train spokespeople, giving them authority to respond to inquiries from officials, media, and the public. All trial spokespersons should be well informed about potential crises, and have a communication plan for how to respond in each scenario.
- Provide the chosen spokespeople with media training.
- If applicable, leverage members of the CAB to serve as spokespeople.
- Train several spokespeople so there is always someone prepared to speak to stakeholders when necessary.

Pre- Trial Communications

Step 5: Determine Communication Channels

 Before this Step:

- Review results of your interactions with stakeholders to determine which channels are best suited to deliver your messages.
- In order to ensure that your key messages reach your priority stakeholder groups, you must decide on the best mix of communication channels as well as the ideal frequency of those communications. You do not have to utilize all of the channels listed below, however, you should be using multiple channels of communication to amplify your message.

Fill out your answers for each communication channel in order to ensure key messages reach priority stakeholder groups identified in Table 1: priority stakeholder contact information.

Channel	Which priority stakeholder group does this reach?	During which phase of the trial will you use this channel? Please indicate whether it's <i>pre-trial</i> , <i>during trial</i> , or <i>post trial</i>
Flyers		
Radio		
Whatsapp		

Text/Phone Call		
Email		
Social Media		
News Media		
Religious Institutions		
Village Meetings and Social Groups		
Community Drama		
Word of Mouth		

Pre- Trial Communications

Step 6: Consent and Expectation Setting

A communication plan should take into consideration the ethics of participant consent and community assent. Individuals must independently decide if they want to participate in research based on effective communication about the study’s purpose, what the research activities consist of, what risks are involved, and how they might benefit from the research. The information should be well understood by not only the participants, but also by their families and the broader community, as well as by the research team delivering the message(s).

Type your answers in the right column below. Required question are in **black text**.

How will you assess informed consent for clinical trial participants?	
How will you address any risk perceptions identified among your priority stakeholders?	
How will you ensure there is no therapeutic misconception?*	

** Therapeutic misconception is when participants assume that enrollment in the research trial guarantees them a cure or a positive outcome in relation to their health condition.*

Pre- Trial Communications

Step 7: Consider a Community Advisory Board (CAB)

 Before this Step:

- Review results of the desk review and interactions with community stakeholders.
- Review your list of priority stakeholder groups and their representatives.
- Speak to your priority stakeholder representatives and ask for their suggestions or opinions on potential CAB members.

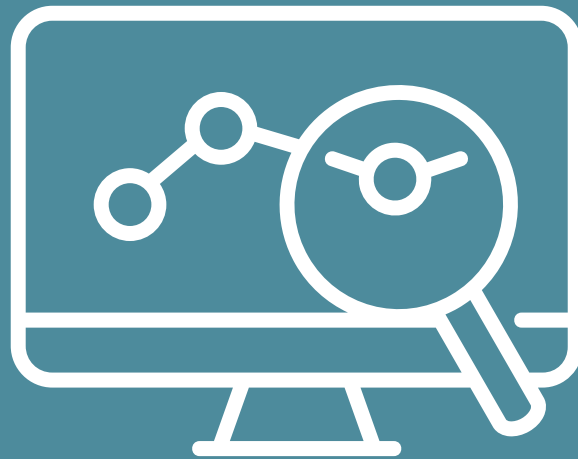
Many trials use Community Advisory Boards (CABs). They can act as a consistent conduit of information both from and to the community around your trial. They can be instrumental in understanding cultural norms and social values that can influence your communication plan (and even trial design). Establishing a CAB is labor and time intensive and once established, it must be nurtured throughout the trial. There are a number of useful resources on establishing a CAB that are available on The Global Health Network DAC trials knowledge hub. Be sure to visit them [here](#).

Fill out your answers to the following questions in the right column in order to plan for the design of your CAB. **All of the following questions are optional, as their use depends on whether or not your trial is utilizing a CAB.**

What will be the role of the CAB in this particular trial?	
How will you recruit members of the community to serve on the CAB in a fair and equitable way?	
What groups do you need representation from in order to create a diverse CAB?	

How often will the CAB meet?	
Where will the CAB meet?	
Research shows that compensating the CAB for their time is a best practice. What is your budget for CAB compensation? How and when will this be provided to them?	
Will food, transportation, and childcare be provided for CAB meetings?	
How will the CAB play a role in disseminating the trial information prior to, during, and after the trial? How will they help share the results with the community?	

During Trial Communications



Communication Implementation Plan

In the pre-trial communications section, you identified priority stakeholders, created communication objectives, and developed key messages. Before you begin the monitoring and evaluation phase, you must create a communication implementation plan which details your communication activities. .

For each priority stakeholder group you identified in the pre-trial communications plan, fill out **table 2** below to indicate your communication activities for each stakeholder group.

Priority Stakeholder Group	Key Message	Channel or Activity	Frequency	Timing	Cost

The Role of Infographics

Infographics are a powerful tool to convey messages surrounding the trial in an engaging way, increasing retention and promoting a more rapid understanding of the key objectives. Infographics may be used in all phases of the trial and should be translated and/or culturally adapted as needed depending on the priority stakeholder group you are seeking to reach with the infographic. Consider the following when planning for and designing infographics as a part of your communication implementation plan:

- Infographics about the trial itself should explain intended outcomes of the trial, the patient journey, and potential side effects.
- Infographics which are targeted for trial participants should emphasize the individual clinical trial participant's contribution to the broader research question, making it clear how their participation directly impacts the study.
- Infographics should be tailored to each priority stakeholder group outlined in the pre-trial plan. Infographics can and should be used before, during, and after a trial.
- At the highest level, an infographic can be created to summarize the overall communication plan so that the PI team can socialize “the big picture” to different stakeholders in trainings and other forums.
- Infographics should be translated into local language(s) and in coordination with the CAB (if relevant) and priority stakeholder groups to ensure they are culturally relevant and resonate with the target audience.

Monitoring and Evaluation

A key component of your communication plan should detail how you will monitor process and quality of communication. In addition, you should evaluate the outcome and impacts of your communications on a consistent basis. Monitoring should take place throughout the life of the trial, beginning implementation monitoring, and ending with evaluation.

Fill out your answers in the right column below. Questions in **black text** are required.

Retention rates: how will you monitor retention rates throughout the trial and how will they inform your understanding of how the trial is being received in the community?	
Pulse checks: How often will you conduct “pulse checks” with trial participants and their families? What are some questions you might ask beyond the clinical profile to gauge how they and their community are feeling about the trial?	
Measure impact: How will you know if your communication strategy is successful? How will you determine if promotional activities are getting the word out?	

Feedback loops: What stakeholders will you seek to build informal feedback loops with to ensure you are receiving input on communication materials and activities? How will you solicit and receive feedback (i.e. phone calls, email, SMS) on trial communication activities?	
How will you leverage the CAB to provide essential feedback about the ongoing attitudes and perceptions of the trial?	
How will you ensure participants understand their rights and obligations on an ongoing basis? <i>*A bill of rights and responsibility should be provided to all participants at screening and enrollment, especially their right to exit the study at any time without any impact to their expected standard of care.</i>	
How will you measure if communities are receiving the shared benefits you identified in pre-trial research? Use the benefits sharing column of <i>table 1 on page 9 for reference.</i>	

Common Challenges & Tactics to Address Them

While it is impossible to predict the kinds of challenges that will emerge when it comes to trial communications, below are a number of common issues and associated mitigation strategies drawn from our research and interview process. This is by no means an exhaustive list. The intention of this information is to encourage users to be proactive, anticipating challenges in order to get ahead of them.

Common Challenges	Mitigation Strategies
Rumors, misconceptions, spread of misinformation (i.e., WhatsApp groups where friends and family send videos with misinformation)	• Build up autonomic responses to disinformation and misinformation through awareness campaigns and tech-enabled nudging (if feasible in the context). • Ensure your communication team is monitoring local media (print, radio, and TV) as well as social media to flag and address any rumors or misinformation immediately. • Train your communication spokespeople on the best way to correct false claims and fact check (i.e., do not repeat the misinformation to avoid unintentionally reinforcing the “stickiness” or believability of false information). Instead, reference the incorrect information in a vague manner from a credible, trusted source and focus on articulating the correct information. Explain in a world-affirming way that resonates with the audience's preconceived notions and beliefs.
High rates of illiteracy in the community	• Create infographics that can depict objectives and key messages with few words. • Use local radio, community theater, and other auditory forms of communication to get out key messages.

Gender roles/ cultural norms (i.e., when not culturally appropriate to speak to a man or woman, dress, etc.)	• Seek local insight on cultural norms before the trial and implement culturally appropriate communication using the right messages, through acceptable channels and messengers, in observance of correct cultural norms such as dress, etc. • Work with the CAB (if you have one) to help you better understand gender and cultural norms
Local language: not using a local community member to navigate the community context	• Engage a full-time translator and community expert before the trial. This person(s) should not just speak the language but should understand the culture and context from living in the community themselves.
Decay in communication over the course of a study, especially for longer studies	• Reinforce messages by conducting events and focus groups with participants. • Train and incentivize research lab staff to speak with participants on a consistent and specific cadence. Incentives could be financial if possible, but could also be realized through “peer influence” campaigns by creating a culture of accountability for this practice. • Engage in marketing efforts (where appropriate) to engage and excite external audiences about the importance of the study as well as the intended outcomes. This will reinforce the need to capture individual patient stories. If budgets don’t allow for external marketing, engage local media for stories during the life of the trial.

More focus on communication during recruitment than at the end of a trial	• Structure grants in such a way that there is adequate time and resources to engage in a robust post-trial communication strategy. • Emphasize and communicate research that demonstrates the value of post-trial communication as a tool to build trust in communities and surrounding areas (who may not have been involved in the trial), creating future opportunities for follow-on research, and reinforcing a positive perception of researchers.
Failing to approach important community leaders first	• Engage with community leaders early and often, ensuring they feel like they are a part of the communication strategy design process and have a say in who else is consulted as a part of the process. • Ensure community leaders are represented on the CAB.
Using a poor choice of communication pathways, breaking trust and causing confusion before the trial even begins	• Build enough time in the grant for a comprehensive discovery phase which allows the research team to identify the correct communication pathways. • Be transparent about the compensation given out to participants and the purpose of the compensation. The amount should be reasonable enough not to serve as an inducement. Inducement refers to undue influence. • The communication plan should provide information on alternative resources to those who may not be eligible in the study, outlining where they can access other health services that align with their needs.

Post Trial Communications



Post-Trial Findings

Sharing trial results with the public is not only a best communication practice, but also a researcher's ethical duty. Even if a trial proves unsuccessful or uninformative, participants and communities should be informed when the trial is over. This demonstrates appreciation for their contribution and that it is valued regardless of the result. In addition, it is important to consider how the data is shared with the wider public to avoid negative or stigmatizing attention both for individual participants and the broader community, ensuring the community as a whole is not attributed with harmful labels.

As done throughout the trial, assess the best channels to use to communicate study findings. Meet with local leaders and health officials to discuss findings and implications. Local radio shows can be extremely effective and engage communities beyond where the study took place. Community meetings can be effective in spreading messages about study findings to large groups. Mail, email, or phone calls may be appropriate if resources are available. Consider sharing positive examples of research outcomes from trials in "trial fatigued communities" to rebuild trust for future work, even if there is no immediate plan to conduct trials in this community.

Regardless of the medium used, post trial messaging should be simple and clear, avoiding highly scientific language or jargon. Ideally, messaging would make the results practical for the lives of participants and communities. Sharing post-trial results should happen as quickly as possible, and as close to the release of study findings as possible. Communication with trial stakeholders about the outcome of the research shows respect and acts to encourage the broader community to participate in research in the future.

Post-trial communication is often the weakest part of a communication plan. Deliberate communication activities can be conducted with trial participants and communities to ensure that stakeholders conclude their trial experience positively and support and/or participate in clinical trials in the future.

Fill out your answers to the following questions in the right column. Questions in **black text** are required. Depending on the length of the trial, this information should be filled out 3-6 months in advance of the trial end date.

How will you inform participants of the transition plan post trial? The transition plan refers to how the trial will end, how participants will be phased off of medication/interventions, and outlines whether participants will have access to treatment and resources post trial .	
How will you understand and document ongoing concerns from participants, their families, or caregivers?	
How will you thank participants and communities for the time and energy they have devoted to the trial? If relevant, how will you formally and publicly thank the CAB?	
Did the benefits outlined for each stakeholder group in pre-trial communication come to fruition? If not, how will you identify and share what needs to change in order for stakeholders to receive the benefit in the future?	

If applicable, how will you explain the benefits gained from the trial to the community (including equipment, staff, education, and capacity building)?	
How will you avoid community level stigma and harm from reporting? What could be the negative or stigmatizing effects of reporting results and how will you address that?	
What channels will you use to communicate the post-trial findings? How will you ensure these channels are engaging and accessible for participants?	
How will you communicate the post-trial results in a way that is engaging, avoids medical jargon, and builds trust with the community?	
Who will you meet with to discuss findings? (local leaders, health officials, etc)	
How will the research from this trial reduce inequality, contribute to socio economic goals, and support policy making solutions?	

Thank you for using the DAC Clinical Trials Communication template.

Our intention is for this template to be a living document, and we encourage users to re-visit and revise it throughout the trial duration as the context shifts and new learnings emerge.