By the time you are ready to start your trial, you should have an outline of your strategic communications plan—including details about internal and external communications, crisis management, and results dissemination (see Chapter 3 for details on creating your strategic communications plan). The outline will facilitate a successful launch for your trial and help you maintain good communication throughout the course of the trial.

This chapter describes how to put your communications plan into action. You will learn how to use your outline and adapt to emerging events so that you can maintain effective communication throughout the course of the study.

I     Announcing the start of your trial

There are no set rules for announcing the beginning of your trial. Every study is unique, and a decision on how best to introduce the study to relevant groups and individuals should be made on a case-by-case basis.

The approach you choose will depend on a number of factors, including the information obtained in your environmental scan (see Chapter 2). Some trials send press releases to international media and hold public events. Others choose to invite selected media, advocates, and other researchers to ribbon-cutting ceremonies at trial sites. Some trials simply start to enroll participants without any fanfare, limiting their announcement to an article in an organizational newsletter. The type of launch you select will depend on your study setting, timing, global and local context, budget, and the goals of your study (See Box 4.1 for a sample spreadsheet for a
Study launches often focus on government officials and local communities rather than the international scientific community. However, there may be instances where you will want to aim for a wider audience. For example, if the goal of your launch is to increase funding for the study by attracting attention from international donors, you might consider a high profile launch that seeks international media coverage.

**What kind of launch should you have?**

The following questions will help you determine the purpose of your launch and the activities that may be the most appropriate for your trial. Consider the following questions:

**What is the purpose of this launch? What are its objectives?** If the purpose is to garner the support of local opinion leaders, perhaps you should have a smaller launch, focusing on activities that acknowledge the value of their input and support. If you are seeking to increase dialogue about a certain health issue on a global level, you might consider a larger launch.

**Considering the goal of this launch, should you actively seek attention from local, national, or international media?** If you have existing relationships with journalists you trust, consider contacting them, if you choose to seek media attention. Regardless of whether you choose to seek media attention during your launch, you should prepare for it: Orient the study’s staff members and spokespersons as needed, and review your standard operating procedures (SOPs) for interactions with the news media (see chapters 2 and 9). Also, update your directory or contact list of stakeholders, including media contacts, once the trial begins.

**Do you have the staff you need?** If you are still sorting out the basics for your trial at the time you start enrolling participants, you may not want to have an event. Consider waiting to make a public announcement until you take care of the essentials.

**Will there be announcements from the government, the sponsor, or the funder? If so, when?** Coordinate with all partners, including the government and your sponsor, and time your announcement appropriately. Do not release anything before any official government announcements go out, and do not release an announcement before checking first with the study sponsor.

**Is this a multisite trial? If so, have you coordinated your strategy with the other sites and the headquarters staff?** Multisite trials require a lot of centralized coordination, because sites will often have different launch dates. If you are part of a multisite trial, you will likely work closely with the staff members at headquarters. They may provide you with a generic press release that can be adapted for your specific context. They may also work with each site to ensure that each site-specific launch is coordinated with the sponsor’s press release, if applicable.

**Are there upcoming conferences or other events that could provide an opportunity to release the news of your study’s launch?** You may want to consider timing your announcement around a scientific conference, since such events provide excellent access to the wider research community as well as news media interested in public health.

Use your judgment to determine the type of launch that would be best for your trial. Keep in mind your study’s setting, objectives, and budget.
Materials

The strategy for launching your trial publicly will determine the type of supportive materials that might be necessary. Basic materials you may need include a press release (see Chapter 9) and study backgrounders and Q&As (see Appendices 3.5 and 3.6).

In addition, large study launches often print additional promotional materials, such as brochures, posters, bags, and T-shirts. For more on developing materials, including pre-testing, see Chapter 3. For information about budgeting for these items, see Chapter 2. To read about incorporating key messages into materials, see Chapter 7.

Sample strategies for trial launches

Tailor your release to the needs of your trial. Be creative—draw on the ideas and suggestions of others. Here are some examples of trial announcements that were tailored to opportunities that arose during the planning phase.

Early government involvement. In Mazabuka, Zambia, the early involvement of the government helped to ensure successful communication during the launch of the Microbicides Development Programme’s (MDP) 301 study. The MDP 301 trial was a Phase III study that evaluated the safety and effectiveness of the vaginal microbicide PRO 2000 for reducing HIV infection in women. As they were planning the launch, MDP staff members called the office of the Minister of Health to invite him to participate in the public launch of the study. He agreed after the first call, and then met with the principal investigator to discuss the launch and the details of the trial. According to that study’s staff members, his presence at the launch was important for the public perception of the trial during the launch phase, especially since this was the first trial of its kind in Mazabuka. The fact that the Minister of Health was launching the trial led to a wide...
### Box 4.1. Sample spreadsheet for trial launch announcements

<table>
<thead>
<tr>
<th>Group</th>
<th>To be contacted</th>
<th>Activity</th>
<th>Date</th>
<th>Who will contact them</th>
<th>Materials needed</th>
</tr>
</thead>
<tbody>
<tr>
<td>Government officials</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Regulatory agencies</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Leadership of host institution</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Leadership of related trials</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Partners</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Donors</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Advocacy groups</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Community</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>News media</td>
<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>
representation of media—including journalists from government and private media sources—at the event. In the end, most coverage of the MDP 301 launch was positive.

**Tiered strategy.** For the multi-country VOICE (Vaginal and Oral Interventions to Control the Epidemic) study, the Microbicide Trials Network (MTN) developed a tiered announcement strategy, releasing information about the trial in waves. Such a strategy ensured that by the time the trial was under way, basic information about the trial had already been communicated—via public presentations at local, national, and international meetings—which gave news media, the scientific community, and civil society advocates access to accurate information. Although the VOICE team was not ready to officially announce the study until August 2009, the staff distributed a press release at the International AIDS Society Conference on HIV Pathogenesis, Treatment and Prevention in July 2009, stating that the trial would begin the following month. The MTN released a study backgrounder and a Q&A document at the same time. In September 2009, two further statements were released: one from the sponsor, the U.S. National Institute of Allergy and Infectious Diseases (NIAID), stating that the trial was under way, and another from MTN announcing that enrollment had begun at the Zimbabwe site. To launch the trial in Zimbabwe, site-level staff issued their own press release, a modified version of the larger MTN release. The other sites followed. In the end, MTN’s strategy—informing the international research community that the trial was coming, even years before the study began to enroll participants—paved the way for a smooth launch when the time came to release the official trial announcement.

**Box 4.2. Advantages and disadvantages of drawing attention to a study launch:**
“First South African-developed HIV vaccines begin testing in SA”

When the leadership of SAAVI 102/HVTN 073, a small Phase I vaccine study in South Africa, decided to organize a public launch for the study, their announcement attracted a lot of media attention. In general, Phase I trials do not seek much publicity (this trial would enroll only 36 participants). But there was something unique about the vaccine study: the candidate products were developed by local South African scientists. The study team decided to launch the trial publicly and invited high-profile speakers.

The launch received considerable, positive media coverage, especially as it coincided with the 2009 International AIDS Society Conference being held in Cape Town. It provided an important opportunity for the many stakeholders involved in the study to strengthen their connection to the study. Participants at the launch included government officials, researchers, leading advocates, and community stakeholders, as well as staff from the South African AIDS Vaccine Initiative (SAAVI), partners, and sponsors—the HIV Vaccine Trials Network (HVTN) and the U.S. National Institute of Allergy and Infectious Diseases (NIAID)—who were in town for the conference.

This type of public launch can have many benefits, but it also has potential drawbacks. Media attention can increase public pressure and heighten expectations for positive results from the trial—something that no study team can promise. Moreover, the larger and more prominent the event becomes, the more likely it is that stakeholders who were not invited will feel left out. In selecting a launch strategy, trial teams need to determine what is best for their studies, given the context, the timing, and other factors.
II Maintaining good communication

Courteous and respectful communication is an important element to ensuring the success of any trial. Another key element is continuous communication. Your team must develop ways to communicate openly and with appropriate frequency with stakeholders who have concerns or questions. You and your staff should maintain ongoing connections with key stakeholders and opinion leaders, or delegate this work to someone who can manage these responsibilities.

Regular communication needs to happen at many levels: with participants, sponsors, the protocol team, site teams, community advisory boards (CABs), the Ministry of Health (MOH), the general public, regulatory bodies, selected news media, and others.

Approaches may include:

- Responding promptly and respectfully to e-mailed inquiries
- Accepting invitations to give overview and update presentations on your study at local and national meetings and consultations
- Proactively arranging meetings with community leaders, parliamentarians, or news media to explain or discuss scientific concepts relevant to your trial
- Developing explanatory fact sheets and other documents targeted to different audiences

Over time, the research team’s willingness to engage in dialogue—and the respect shown in such communications—builds trust that will help you manage controversies that may emerge.
As a rule, it is better for a research team to focus on the low-key education of stakeholders than to engage in highly visible publicity.

**Internal communications**

It is essential to establish systems to maintain good internal communications throughout the course of a trial. Try to include individuals and organizations that are involved in the study, such as the trial’s staff, participants, the host organization, and funders or sponsors. Each member of the internal team has a role to play. When all members are informed and able to contribute to a feedback loop, the team works more efficiently and can respond to unexpected events that may arise.

**Keeping staff informed.** Staff can be ambassadors for your trial and should be appropriately informed during every stage of the trial. Team members should be provided appropriate levels of detail, depending on their roles in the organization.

To keep your staff informed, you should hold regular meetings with senior staff members and other relevant, key staff members. Some sites meet every week to exchange information, including any concerns or misconceptions that were raised by participants.

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**Box 4.3. Implementing our plan: ongoing communication at multiple levels is key**

*By Quarraisha Abdool Karim, PhD, Regional Director, Center for the AIDS Programme of Research in South Africa (CAPRISA), Durban, South Africa*

When we started to prepare for the CAPRISA 004 tenofovir gel trial, we first had to assess the community and the preparedness of potential participants to be in trials. Would microbicides be acceptable to women and their partners in the communities? Would it be acceptable for community members to participate in a microbicide trial? Would potential participants be able to understand their rights and the basic principles of informed consent? We had to figure out how to establish structures for dialogue between the community and the researchers, and to set up cohorts and see if there were sufficient incident rates of HIV to allow the trial to be completed. That went on for about two years before we enrolled the first participant. All of these steps involved communication, which was important for both information-gathering and building trust. We used many fora to share what the trial was about and the rationale and justification for doing this work.

I've never taken an approach of “flying below the radar screen,” but I instead aim for openness and transparency. In the almost 25 years of doing AIDS research, I've learned that the public interest in HIV/AIDS research is very different than it is in other types of research. You need to share information as much as possible, with all of the stakeholders. This includes participants, the sponsors of the trial, the site teams and protocol teams, and community advisory boards or research support groups. Other groups we talk to include the Department of Health, regulatory bodies, and our ethics committee. It is important to keep of all these players in the loop, up to date, and engaged in the process early on. This means providing regular updates, as opposed to waiting for when you have a study milestone. Ongoing communication at multiple levels is key.
Ensuring an ongoing dialogue with trial stakeholders

- Use your staff as communicators, and ask them to contribute when developing messages about the trial.
- Keep all stakeholders informed and engaged from the beginning of the research process—don’t wait for a milestone in the study.
- Show concern for all members of the community; be careful not to show preference for one group or political party over another.
- Be considerate of various learning styles, and use a range of techniques to ensure communication on multiple levels.
- Keep your materials updated, especially as new information or concerns emerge.
- Use available opportunities, venues, and mechanisms to ensure consistent communications with stakeholders.
- Initiate meetings with trial stakeholders when necessary. Be flexible about the meeting’s location: Some meetings are more appropriate at the trial site, whereas others may be more appropriate in a church, a government building, or another public place.

Staff meetings may include:

- Status reports from the past week: You can discuss new staff hires, participation in meetings or conferences, site events, operational updates, information, misinformation or rumors heard from study participants and others, and so on.
- Media and communications update: Discuss media inquiries about the study, interviews that were conducted, and the status of any materials that are being developed or used by the study.
- An update from each site (for multisite studies): This will allow sites to learn about emerging challenges from each other.
- Scientific updates for the team: Provide news about technical publications and news reports (and their implications for your trial). Also, discuss information about related trials or even political concerns that may affect the trial.
- Community meetings: If an important community issue arises, the community liaison (who should attend community meetings) can quickly arrange a meeting with traditional and local government leaders.

As your study proceeds, use opportunities during all-staff meetings (such as annual investigator meetings) to provide refresher training in communications, including media training for any
trial spokespersons. For any meetings you hold, be sure to take meeting minutes and to save them in an archive for future reference.

Communications log. You may want to keep a communications log. Multisite trials may want several—one per site plus one central log. Staff members can fill out simple paper templates or forms to record events that happen throughout the week. For example, the site may have a visitor or may be receiving inquiries on a certain topic. These events could be recorded in the log for later analysis.

The principal investigator (PI) can review the log regularly and can contact the relevant team member if something needs to be addressed. Logs can be reviewed and referenced during weekly, monthly, and joint site meetings, as well as meetings with other groups within your institution or externally.

Communications logs can be important for catching potential communications issues early on. Some events may not be a concern at the time, but a trend may become apparent later. These logs provide a record of progress, challenges, and collaboration. They may also provide information that can help you document your impact and report back to the sponsor (see Box 4.4 and Appendix 4.1).

Box 4.4. Internal communications within the Male Circumcision Consortium: monthly updates

By Silas Achar, Communications Officer, Family Health International, Kisumu, Kenya

For the Male Circumcision Consortium in Kenya—a research and capacity-building project that works with the Kenyan Ministry of Health and other partners—we have a monthly update system that helps facilitate internal communications among our team.

We use a communications log in the form of a simple grid (see Appendix 4.1) that each project partner fills out and brings to the monthly meeting. Each partner notes which communications activities have been implemented and which are planned, whether misinformation or rumors are emerging, among whom, and whether any materials have been planned or completed. These updates are discussed during monthly meetings, allowing partners to plan ahead and collaborate in a coordinated fashion to develop key messages, responses to misinformation, or other issues.

As the project’s communications coordinator, I then take the filled-out forms and use some of the most salient items to compile a project e-newsletter that gives prominent credit to the individuals and organizations it mentions. The newsletter also provides a venue to share links to new publications on male circumcision for HIV prevention and local news articles on the procedure.

These updates help us track our progress over time and help ensure collaboration and communication between all partners. We also share these updates with our sponsor and use them during the reporting process.
Communications that require ethics committee review. Research regulations and norms primarily address communications related to recruitment, enrollment, and keeping participants informed about any issues that may affect a volunteer’s decision to participate in a trial. Site teams should refer to the specific protocol and site-specific SOPs on communications with participants; these communications would also be referenced in trainings on Good Clinical Practices (GCP) for the site staff members.

In the Carraguard trial, the ethics committee asked to see the slides that would be used when briefing government entities on the release of the results. This is something we didn’t expect.

—Melissa May, Former Director of Public Information, Population Council

Institutional review boards (IRBs) generally want to review and approve any communications product that reaches potential and enrolled participants during the period of active recruitment or study implementation. Ethics committees have considerable latitude in setting their own standards about the materials they want to review and approve, and policies can vary across sites. Some—but not all—IRBs prefer to review all materials developed for potential participants, including flyers, advertisements, posters, and brochures specifically designed for recruitment, as well as educational materials (such as PowerPoint presentations) for community meetings where potential trial participants may be present. Generally, any written material that includes contact information is considered a potential recruitment tool, and therefore must be reviewed and approved by the IRB that oversees the trial.

Consult your research ethics committee at the beginning of the study about its expectations for the review of materials for participants.

Social scientists often have critical insights that can help craft messages and have useful skills for helping to field test communication materials. Consider making them a part of your communications team. Pictured here are Dr. Ariane van der Straten, Director of the Women’s Global Health Imperative, RTI International (left) and Dr. Cynthia Woodsong, Director of Social and Behavioral Science at IPM in South Africa, discussing a microbicide protocol.
Box 4.5. Lessons learned regarding ethical clearance for communications efforts

By Mitzy Gafos, Co-investigator of the MDP 301 study at the Africa Centre site, South Africa

Research Ethics Committees (RECs—as IRBs are called in South Africa) are required to review study-related information sheets. The REC for the Africa Centre reviewed all participant information relating to the MDP 301 study, a multicentre trial that investigated the safety and effectiveness of the candidate microbicide PRO 2000. However, our REC wanted to review all information that the study team disseminated in the community even if it was not directly related to the study—for example, talks about World AIDS Day or the No Violence Against Women campaign. The Africa Centre had to get REC approval for all forms of media; this included study updates in community magazines and drafts of talks for radio shows, even a draft Q&A sheet that would be used during radio phone-in shows.

The turnaround times for the review and approval of the materials proved to be a real challenge. For example, when the cellulose sulfate (CS) microbicide trial closed unexpectedly, the Africa Centre MDP team immediately produced a leaflet explaining why the CS study had closed, reinforcing that the products being tested in the two trials were different and that the MDP study testing PRO2000 would continue. We submitted the CS information sheet to the REC in early February 2007 but only received approval, with no recommended changes, three months later despite regular requests for approval. By then, our research team had already verbally informed all of the participants about the closure of the CS trial and its implications for the MDP 301 study.

Following the CS closure, we adopted various strategies at the Africa Centre to reduce the time between review and approval of communications resources, including:

Flagging urgent communications needs. When the 2% PRO 2000 gel arm of the MDP 301 study was unexpectedly discontinued, we built on the lessons from the CS closure and were better prepared in terms of managing the turnaround time of communications. As soon as we were informed of the Data and Safety Monitoring Board (DSMB) recommendation, I contacted the chair of the ethics committee and informed him that we would be submitting an information sheet about the discontinuation within 24 hours. I stressed the urgency of being able to inform the community and requested an urgent approval by the chair to use the materials, pending a full review by the committee. This time the materials were turned around within seven days, and we were able to support verbal explanations about the protocol change with written materials, which helped participants further explain the discontinuation to partners and family members.

Getting materials pre-approved. We put together a series of documents with standard messages about the study, which we submitted for pre-approval by the ethics committee. These materials were not used regularly but could be utilized immediately if needed.

Scenario planning for upcoming results. Two months before the investigators were aware of the MDP 301 trial results, we submitted three separate information sheets to the ethics committee for review: all with a standard background section, then three different scripts based on the possible outcomes of the trial—not effective, marginally effective, and effective—and the related implications of each scenario. All of the information sheets were pre-approved by the ethics committee, so the minor changes that were required once the results were known could be addressed within 24 hours by e-mail. This enabled the site to disseminate the information sheet on the day of public release.

Get it in writing. Different ethics committees and chairs interpret international and national regulations differently. We learned that asking the committee to put in writing what they expected of the study, and proactively asking for updates if committee members changed, helped enormously in streamlining the ethics review and approval process.
Keeping participants informed. Since communication with participants is regulated by the study protocol, it is not covered in detail in this handbook. However, research literacy should be emphasized throughout the course of your trial. Trial staff should be well equipped to explain to participants (and their partners, when relevant) why and how research is done in simple, easily understood terms (in all official languages used at the trial site).

Depending on emerging events, you may need to share information with participants about the trial you are conducting and about other trials. What goes on in related trials is often conveyed through local media or word of mouth to community members, so such news may have an impact on your trial. Keep your participants informed, and listen to and respond to their questions. This will ensure that your participants understand their roles and their contributions throughout the course of the trial.

Keeping funders and sponsors informed. Communicate with your sponsor regularly by sharing status reports. This can be done by e-mail. It will probably be beneficial to also conduct conference calls on a monthly basis. If your study has a newsletter, ensure that it is sent to the sponsor. If you are organizing an event at your site, send the invitation to your sponsor regardless of where they are based—even if only as a courtesy. Other reporting requirements will depend on the sponsor. If your study is part of a network, these communications may be streamlined through a coordinated effort.

Keeping CAB members informed. You should have regular meetings with your CAB, or local research support groups, following any sponsor- or protocol-mandated requirements related to trial communications. The individuals on these committees can then provide regular feedback to you about the study and community perceptions or concerns. Regular meetings provide the opportunity for the study’s staff and CAB members to collaboratively address emerging issues. You should also ensure that newsletters are sent to members of the CAB or other research support groups.

External communications

Communicating with external stakeholders—including the trial community, advocates, the media, the wider scientific community, other researchers, and national policymakers—is essential from the time you launch your trial to the time you complete your trial and release your trial results.
Based on the strategic communications plan you developed before your trial began (see Chapter 3), you can develop systems and use routine methods to ensure regular communication with external stakeholders.

To reach multiple external groups, you might:

- Send out an e-newsletter or e-mail updates about your trial, including milestones, events held, and links to news coverage or informational resources. Always include some description of the trial’s specific public health purpose, as e-mails and e-newsletters are often forwarded by recipients to others less familiar with your trial.
Depending on staff capacity, you might aim for monthly or quarterly distribution of such updates. Frequency is important to keep the lines of communication open and to convey that you care that stakeholders stay well informed.

Make your newsletter as visual as possible, including photographs and other graphic elements. For example, if your site has produced new low-literacy graphics to help participants adhere to the product, consider using them to highlight an article.

Invite small groups of stakeholders—including study sponsors, policymakers, journalists, or community members—on tours of your study site.

A tour could include a visit to the clinical exam facilities, the document storage room, and the laboratory. Such visits can be very instructive to individuals unfamiliar with research implementation. Visitors can be walked through a mock counseling session for participant screening, shown how blood is drawn, or meet with nursing staff to ask questions about participant care and referral systems.

Consider taking photographs of the visit. If you receive permission from those on the tour, use a photograph in your next newsletter with a caption explaining which groups or policymakers were involved.

Community media, including radio, can be an effective way to communicate with a wide range of stakeholders during a trial. Some trials have trained producers and announcers on various topics. These individuals host community radio programs where issues are raised and information about the trial is communicated directly to the listeners.

Photographs at trial sites. Photographs can be a very effective way to show community members, sponsors, and other stakeholders what research looks like, where it takes place, and why it is important. Photographing a study tour is a great way to document a visit and put a human face on your trial.

Nevertheless, be aware that it is unethical to show trial participants in photographs without their explicit permission. In fact, many ethics committees do not allow current participants to be photographed during a trial, even if a participant gives his or her permission. It could be unintentionally stigmatizing to the participant, causing social harm. For example, community members might assume incorrectly that the participant in the photo is HIV positive, or a husband might become angry that his wife has joined a study without his knowledge. For the trial participants who eagerly want the opportunity to be photographed and to tell their stories, it is advisable to wait until they have completed their study visits and are no longer officially enrolled in the study.
Keeping the trial community informed. Just as it is important to hold regular internal meetings, it is also essential to engage community members through regular meetings. A wide range of trial staff members (not just the PI) should be visible to the community on a regular basis at community meetings and events. Community engagement demonstrates to community members that you care not only about your trial but also about their general health and welfare.

Building trust is an ongoing process—one that should begin before the trial even starts (see Chapter 2) and should continue throughout the trial. Community staff members, especially when equipped with the proper information, can facilitate lasting relationships between the community and the trial.

### Keeping the community informed

#### Provide regular community education.

- **To provide ongoing education to the community about research and the research process, a community education plan should be developed and facilitated by the research team, including the community educator at each site. This will also establish and maintain open pathways of communication from community members to the research team.**

- **In addition to your area of research, you can identify other health areas that the community wants to know about and provide education in these areas as well (family planning, HIV/AIDS, nutrition, infant health, etc.). Such activities help develop trust between the study site and the community, and the meetings also help reinforce or create a sense of community.**

- **Regular education sessions will allow you to monitor emerging concerns, build relationships of trust with key community members, and identify opportunities to pass messages about the trial to local community members and opinion leaders. Depending on the context, you may need to start with traditional leaders, and then go from there (this will be determined by the information gathered in your environmental scan—see Chapter 2).**

#### Be visible in the community.

- **Throughout the clinical trial, the trial team should maintain relationships with civil society groups during and after the site preparedness phase.**

- **Community education forums and community meetings can be initiated by your study and held either at the study site or at a well-known community site (such as a school or place of worship).**

- **You should consider participating in established local events, celebrations, and community health forums. Each community event could be an opportunity for you to communicate with the local public, not only about your trial, but about health issues more generally.**

#### Include civil society groups.

- **While you conduct general community outreach, you should also target specific civil society groups.**

- **You may want to invite individuals to your meetings, or arrange one-on-one meetings with well-known community members, faith-based leaders, advocates, heads of other nongovernmental organizations (NGOs) or research organizations, and others.**
When working with the community, be creative and take advantage of opportunities that may arise. You may even want to combine some form of entertainment with your educational techniques. The following are some creative ideas that different research sites have used to keep communities informed:

- Appear on community radio shows that provide scientific messages to the community and offer them the opportunity to ask questions of researchers.
- Perform songs or plays at community events to share messages about the study with the community.
- Organize a theater group with people from the community.
- Organize contests that motivate community members to be an active part of the process.
- Publish a quarterly column in a local newspaper, explaining the trial’s progress.
- Arrange information booths at local health forums or other community events.
- Share photos of trial-related events to promote your trial’s visibility.

**Keeping the larger scientific community informed.** A wide range of individuals and groups within the larger scientific community should be regularly informed about the progress of your trial. These include:

- Other researchers and public health professionals
- Researchers working on related studies in your institution, town, province, or country
- Government or health authorities, regulatory authorities, and IRBs or ethics committees who reviewed and approved the study protocol
- Professional associations that focus on your research topic

To communicate with these groups, you might:

- Develop a trial newsletter to communicate to other scientists in the field and other interested parties (see Appendix 3.4).
- Update your mailing lists continuously to include new scientific colleagues, individuals you meet at relevant conferences, or opinion leaders whom you want to keep informed.
- Participate in working groups that hold regular meetings with scientists from other pivotal trials to share information on emerging methodological or scientific issues, trial updates, and communications needs.
- Contribute written updates to electronic venues (such as list servers) that promote dialogue among communities of practice for the disease or health area in which you work.
- Present updates on your work at scientific meetings whenever possible.

**Keeping the government, MOH, and other officials informed.** You may want to organize regular briefing sessions, perhaps quarterly, for MOH officials to keep them up to date with the study and any emerging scientific issues related to the topic. One study in South Africa, for example, has a quarterly meeting with provincial-level officials in the Department of Health, giving updates and reports on the trial. Alternatively, you may want to schedule individual
face-to-face meetings with key government officials. You may also want to provide written information on a regular basis.

**Keeping media contacts informed.** As you develop your strategic communications plan (see Chapter 3), you should identify a small group of journalists with whom you will share information about the trial. These journalists should be selected based on previous balanced and accurate health coverage that they have written, knowledge of the issues in your field (such as HIV/AIDS), and the relative importance of their media outlet.

When your study begins, consider contacting a few of these journalists to explain the study goals and the basics of clinical trials. A low-key introduction to study goals and methods may help preempt future misunderstandings. From that point forward, exactly when you contact the media will depend on the needs of your study. Just as with other trial stakeholders, it is important to maintain regular contact with selected journalists throughout your trial. This fosters relationships based on trust and aims to ensure that they (and the audiences they serve) are adequately informed.

You can also consider using national holidays, anniversaries, or other events to engage with journalists. In Peru, for example, one research team organized a luncheon event on their national “Day of the Journalist,” with the goal of keeping local journalists aware of the type of health information that research staff can provide. At the luncheon, the team acknowledged the work of journalists and highlighted their contribution in keeping the population informed. The trial staff also awarded a prize to the journalist who had published the largest number of articles on HIV/AIDS in the preceding year, and took the opportunity to brief luncheon attendees on the status of the HIV/AIDS epidemic and the efforts to combat it, including the HIV/AIDS research being implemented by the team.

For more on building relationships with media during your trial, see Chapter 9.
Communications etiquette

The manner in which you communicate with participants, staff, partners, and external stakeholders will have an important impact on how information about your trial is perceived and understood. Notably, the emotional tone of your communications matters, particularly in contexts where any research may be considered potentially exploitative of vulnerable populations. Of course, the style or approach you may use to communicate with various groups will differ, depending on the group. But if proper communications etiquette—respectful communication—is practiced by all staff members from the beginning, it will benefit the trial as a whole.

Why is etiquette important? Because it opens the way for candid dialogue. For example, when the university provost who serves as one of the authorized spokespersons for your trial treats a local advocate dismissively, it might be more difficult to count on the advocate’s support later on. On the other hand, when a principal investigator takes the time to sit, unhurried, with community opinion leaders and answer all questions that are posed, this helps ensure that local community members will understand the trial. The relationships one builds through respectful communications can help stakeholders feel comfortable going directly to the principal investigator—for example, should they have a concern during the course of the trial—instead of taking their complaint to the media. Manners and basic civility matter. Respectful communication and a willingness to listen are paramount.

III Tracking and responding to emerging issues

Monitoring media, community voices, and stakeholder views throughout your study will help you stay abreast of any situations or issues that need to be addressed. In order to prevent misinformation and to ensure that your trial runs smoothly, address any problems as quickly as possible. Be sure to use proper communications etiquette as you handle these situations. For information and tools for handling crisis situations (for example, unexpected trial closures, or negative or sensational media coverage of your trial), see Chapter 5.

Monitoring media

At least one staff member at your site should pay close attention to media coverage as a formal part of his or her job duties. However, all staff members who consume news can be asked to alert the site’s point person responsible for media monitoring whenever they hear a local-language broadcast or come across news coverage in local papers about the trial or that might affect the trial.
The staff member assigned to monitor the media should pay attention to negative tones conveyed in local media reports on clinical trials or other opposition to some aspect of the research. Track local and national media (print and broadcast), and whenever possible, monitor media in local languages as well. It is also important to look at international media sources, which give your trial staff some context; your review of the media should include larger dialogues and international trends.

See Chapter 9 for more on how to monitor and respond to media when necessary.

**Monitoring and responding to community voices and stakeholder views**

*Check with community outreach workers regularly to see what questions community members are asking and what concerns are being voiced.*

- Develop expectations and methods for community outreach workers to report arising issues immediately to the PI or the community liaison officer.
- Any findings should be documented to track actions and resolutions and to inform future trials.
- Regular staff meetings will allow you time to keep abreast of any community issues that arise.

**Monitor community rumors.**

- Regular community meetings may provide an opportunity for you to hear any misinformation or rumors circulating in the community.
- In addition, participants often reveal concerns during their clinic visits that may reflect larger community concerns.
- It is important for the study’s staff members to notify the PI of any “social harms” reported by participants, so issues can be tracked and problems averted.
- Another good strategy is to have a staff member (sometimes an outreach worker or peer educator) in the study waiting room. Not only can he or she address unhappiness that participants may express about the trial (such as long wait times), but the staff member can attend to budding rumors and misconceptions that participants discuss. (See Box 4.7.)
- You can also place a suggestion or feedback box in the waiting room.
- When you attend local and site meetings, listen for hallway chatter that may reveal concerns or issues with the trial (internally or externally).

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**Responding to community concerns is not always a question of finding a better message or adapting your communications strategy. Sometimes, it requires addressing the cause of the concern. Stakeholder objections sometimes identify real problems with how a trial is being implemented. In such instances, correcting the problem is a more effective strategy than trying to “manage” it away.**

—Lori Heise, Former Director, Global Campaign for Microbicides
Pay attention to signs of disquiet among stakeholders.

- Watch for expressions of concern by government officials that support for the trial could cause them political embarrassment or signs that a stakeholder is using criticism of the trial as an opportunity to push his or her own agenda.

Monitoring and communicating about other trials

All stakeholders should receive the information they need about any related studies that may affect your study in a timely way. For example, senior management should notify stakeholders about the future release of results from related trials. When the results are made public, staff members should be briefed on what to say to participants and community members who ask about the related trial, since participants often hear about other trials through the media. To ensure that the site’s staff are providing consistent and accurate information on the related trial, it is a good idea to write down and share the key points you want to convey.

For some external stakeholders, such as government officials or local NGOs, it may be adequate to simply forward an e-mailed copy of a well-written article that provides some background on the related trial. A personal note from you explaining how you interpret the news can help provide some context for the recipients. Alternatively, you could provide links to news summaries of the related trial in your next e-newsletter.
News from other trials may also present an opportunity for you to provide a refresher on research literacy to interested parties.

**IV Preparing for interim analyses**

Most large-scale studies undergo interim data and safety monitoring reviews to assess the product’s efficacy and to uncover potential concerns with the safety of the participants. These are significant events because a study could be modified or halted in the wake of an interim review. Plan ahead for the communications activities that you will need to implement for these reviews. In most instances, the initial review of a trial does not have enough data to justify the modification of a trial, but early closures can happen. Trials are usually well under way before a review board has enough data to identify an efficacy or safety issue that could affect the study.

Once the first Data Safety and Monitoring Board (DSMB), sometimes referred to as a data monitoring committee (DMC), meeting has been scheduled, you should:

- Contact appropriate regulatory bodies, your IRB, trial sponsors, and other investigators doing similar trials to inform them of the upcoming, planned review. Let them know that you will inform them of the DSMB findings and recommendations and that you will be available to answer any questions. A short note, as shown in Box 4.8, should suffice. Briefly outline possible outcomes for your stakeholders, so they can be alert to possible ramifications of the DSMB recommendations.

- Prepare materials (such as Q&As or backgrounders) that outline questions that might be asked following an interim review. Some of these materials may have already been written (see Chapter 3). Get help from site staff and individuals such as CAB members who understand the local languages and can help you pre-test messages or materials to ensure that they are clear and understandable.

- Prepare messages for all possible scenarios related to the DSMB review.

- Develop a tentative plan for how you would share unexpected information with key trial stakeholders, according to each of the scenarios you have identified (see Chapter 6 for more on scenario planning).

If the DSMB recommends a halt to the study, you will need to follow procedures related to unexpected closures (see Chapter 5).
Dear Colleagues,

The independent Data and Safety Monitoring Board (DSMB) for the Bangkok Tenofovir Study will meet October 26 and 27 in Atlanta, GA, for its planned interim review of trial data. This clinical trial is a joint collaboration of the U.S. Centers for Disease Control and Prevention, the Bangkok Metropolitan Administration, and the Thailand Ministry of Public Health, and is examining the safety and efficacy of once-daily tenofovir as pre-exposure prophylaxis (PrEP) for HIV prevention among injection drug users in Thailand.

At the upcoming meeting, the DSMB will conduct a regular review of the safety data and will review the HIV infection rate in both arms of the trial for the first time to determine if there is enough evidence to determine efficacy at this point. While the most likely outcome of the meeting is that the DSMB will recommend the trial continue to its planned completion, it is possible that the panel could recommend that the trial be stopped. CDC and our Thai colleagues are therefore preparing for all possible outcomes.

The DSMB could make four possible recommendations:

1) That the study continue as planned.

2) That the study be stopped early because data show strong evidence that once-daily use of tenofovir significantly reduces the risk of HIV infection among injection drug users.

3) That the study be stopped because the data suggest that once-daily tenofovir will not prove effective in reducing the risk of HIV infection among injection drug users and continued study is not warranted.

4) That the study be stopped due to concerns about participant safety.

We hope this information is helpful to you in your own planning and will continue to keep you abreast of developments in this trial, including the outcome of the DSMB meeting.

Sincerely,

Disseminating results

Once your trial closes, you should disseminate the results to all of the stakeholders you identified in your strategic communications plan. Since planning for the dissemination of results is a lengthy process, you should begin to develop your plan while the trial is still in progress. Your dissemination plan will include specific objectives, identify audiences interested in the results, and outline a feasible strategy for releasing information to both internal and external parties. For more on results dissemination, including a timeline on the steps involved, see Chapter 6.

Key points to remember

- Consider your goals, budget, setting, timing, global and local context, and the benefits and risks of attracting public and media attention when deciding which type of launch is right for your study.

- Maintaining ongoing communication with interested parties throughout your study is essential to building trust.

- Good communication starts at home—with strong internal communication. Internal stakeholders are important ambassadors for your trial and should be appropriately informed during every stage of the trial.

- Monitoring news media, community voices, and the views of opinion leaders throughout your study will help you stay aware of emerging issues that need to be addressed. In order to prevent misinformation and to ensure that your trial runs smoothly, address any problems as quickly as possible.

- Never underestimate the power of emotional tone in communications. Respectful, transparent, and courteous communications are paramount, particularly in contexts where any research may be viewed as exploiting vulnerable groups.