Describe Key Features of the Research Context
Introduction

In Step Three, you established a framework for monitoring and evaluating your stakeholder engagement efforts. In Step Four, you will identify key features of the context — local, national, regional and international — in which your trial will take place.

International HIV prevention trials are often conducted by researchers and research organizations that are outside the country where the research occurs. As a result, researchers may have a limited understanding of the various factors that might have a profound effect on the trial. An understanding of these factors will help researchers to:

- Become familiar with critical, nonlocal features that can have a bearing on how the research is conceptualized, planned, conducted, and disseminated.
- Efficiently overcome barriers — and build on enabling factors — that are specific to a context, such as a history with previous trials, access to research outcomes, and any issues related to the political, cultural and economic climate.
- Engage the stakeholders as partners in the research endeavor.

The challenge to be addressed by this chapter is multifaceted: to identify, describe and constructively address the multiple factors — at various levels — that may affect your trial.
Goals of Step Four

- Partner with stakeholders to create a multilayered description of the local, regional, national and international contexts for the trial.
- Identify questions, current issues and historical precedents that may affect how your trial is perceived at the local level — as well as strategies for how to address them.
- Incorporate national, regional and international issues into plans for the trial’s conduct.
- Develop an appreciation for the complexity of the research process and the importance of relationships — between people, between competing priorities and among social groups, organizations and institutions.

Why you need to describe key features of the research context

A systematic approach in Step Four will lead to the following benefits and outcomes:

- You will be able to more readily identify local, national, regional and international stakeholders whose views and engagement — whether supportive, critical or both — will affect your trial.
- You will better understand the relationships and networks that link stakeholders — from the local to the international — and help to build such relationships where they are lacking.
- The research concept — its relevance and potential acceptability — will be more easily communicated and explored with national, regional and international stakeholders.
- You will learn how the project’s local context relates to the national and regional context; this knowledge can guide and support the conduct of formative research, the identification of potential research sites and the identification of staffing needs.
- You will be able to develop a research project that is well adapted to the broad context.
1. **Describe the local context for the trial**

**Action:** Develop a multilayered description of the boundaries — social, political, economic, transportation, religious and others — in the community where you will be conducting the trial.

**Result:** Your research project will be better understood and accepted because it was developed with an understanding of the local context.

**Explanation:** Research happens in the context of many factors that can profoundly influence the outcome of a trial — and those factors may not always be apparent to a trial team. Many trials have used community-based mapping to develop a literal and figurative map for the trial’s location. This process can be done in collaboration with community members, and the process itself may build trust and facilitate relationships. The maps can be used to select research sites, identify priorities for formative research and guide other decisions during the trial.

Be sure to ask these basic questions of your key informants: What do you consider to be the boundaries of this community in geographical, social and cultural terms? Where does the community start and end? Who are the “insiders,” and who are the “outsiders”? Also investigate the social and cultural history of the location. How are the people in this community perceived by people in other parts of the country? How do they perceive themselves? How and where is power consolidated within the community? Who are the recognized leaders? Who makes decisions in less formally recognized ways? How is the community tied to the country as a whole in terms of its relationship to political power? Is it a region affiliated with the ruling party or with the opposition? Is it perceived to be the beneficiary of many public health services, or is it neglected?

Table 4.1 summarizes some of the important characteristics to consider when describing stakeholder communities. It also offers examples of how these characteristics vary relative to some different types of communities that researchers often work with.
Examples are aboriginal, Kahnawake; geographic/political, Jackson, MI, and Iceland; religious, Amish; disease, HIV; ethnic/racial, Ashkenazim; occupational, nurses; and virtual, email discussion group (adapted from Weijer C, Emanuel EJ. Protecting communities in biomedical research. Science 2000:289, 5482:1142-1144). Used by permission.

### Table 4.1: Characteristics of types of communities in biomedical research.

<table>
<thead>
<tr>
<th>Community characteristic</th>
<th>Aboriginal</th>
<th>Geographical/Political</th>
<th>Religious</th>
<th>Disease</th>
<th>Ethnic/Racial</th>
<th>Occupational</th>
<th>Virtual</th>
</tr>
</thead>
<tbody>
<tr>
<td>Common culture and traditions, cannon of knowledge, and shared history</td>
<td>++</td>
<td>+</td>
<td>++</td>
<td>+/-</td>
<td>+</td>
<td>++</td>
<td>+</td>
</tr>
<tr>
<td>Comprehensiveness of culture</td>
<td>++</td>
<td>+/-</td>
<td>++</td>
<td>-</td>
<td>+</td>
<td>+/-</td>
<td>-</td>
</tr>
<tr>
<td>Health-related common culture</td>
<td>++</td>
<td>+</td>
<td>++</td>
<td>++</td>
<td>+</td>
<td>+/-</td>
<td>-</td>
</tr>
<tr>
<td>Legitimate political authority</td>
<td>++</td>
<td>++</td>
<td>+/-</td>
<td>_</td>
<td>_</td>
<td>+/-</td>
<td>-</td>
</tr>
<tr>
<td>Representative group/individuals</td>
<td>++</td>
<td>++</td>
<td>++</td>
<td>+</td>
<td>+</td>
<td>+/-</td>
<td>+/-</td>
</tr>
<tr>
<td>Mechanism for priority setting in health care</td>
<td>+</td>
<td>+</td>
<td>+/-</td>
<td>+</td>
<td>+/-</td>
<td>+/-</td>
<td>-</td>
</tr>
<tr>
<td>Geographic localization</td>
<td>+</td>
<td>++</td>
<td>+/-</td>
<td>+/-</td>
<td>+/-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Common economy/shared resources</td>
<td>++</td>
<td>++</td>
<td>+/-</td>
<td>+/-</td>
<td>+/-</td>
<td>-</td>
<td>-</td>
</tr>
<tr>
<td>Communication network</td>
<td>++</td>
<td>+</td>
<td>+</td>
<td>+/-</td>
<td>+/-</td>
<td>+</td>
<td>++</td>
</tr>
<tr>
<td>Self-identification as community</td>
<td>++</td>
<td>++</td>
<td>++</td>
<td>+/-</td>
<td>+</td>
<td>+/-</td>
<td>+</td>
</tr>
</tbody>
</table>

++ The community nearly always or always possesses the characteristic. + The community often possesses the characteristic. +/- The community occasionally or rarely possesses the characteristic. – The community rarely or never possesses the characteristic.
2 Describe the broad context in which the trial will take place.

**Action:** Survey and analyze the social, political and historical factors that are relevant to your trial at the local, national, regional and international levels.

**Result:** You will have compiled information that can help you identify and anticipate challenges, and guide messaging, stakeholder outreach and other critical decisions.

**Explanation:** Clinical trials do not take place in isolation. A trial’s success can be altered by any number of factors, including a region’s history, economy, politics, culture and its approach to providing services in the communities where you will be working. International perceptions of the trial from groups outside of the country or region can also have a profound effect on the trial’s outcome.

For example, early trials of PrEP for HIV prevention came under intense international scrutiny in 2004. Concerns from local groups were amplified by critiques from international groups, and these actions eventually halted PrEP trials in Cambodia and Cameroon. Subsequently, in the Pre-exposure Prophylaxis Initiative (iPrEx) trial of men who have sex with men and transgender women, the trial team worked with local advocates from the gay community to understand their needs, which included safe, respectful counseling and health services, the availability of condoms and lubricants, and spaces for community gathering. The result was an approach that implemented the trial in partnership with local nongovernmental organizations (NGOs). The research team also sought the support of global advocacy groups. In Thailand, stakeholders who were engaged in discussions about the proposed RV144 AIDS vaccine trial voiced their frustrations with prior internationally sponsored research that had not resulted in benefits.

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**Tips**

Identify a civil society partner who is interested in convening stakeholder dialogues about the broad context. Offer to present and participate, but support the civil society group in taking the lead in convening, identifying participants and following up. This ensures that your research project is situated in the broad context of relevance to some of your key allies. It provides an opportunity for you to listen and engage without placing your trial at the center of the discussion. These meetings often work as a series of updates, not one-off conversations.
to the participating community. Understanding past sources of disappointment and distrust guided the trial team’s decisions about the roles of the various international and national partners. In South Africa, the Centre for the AIDS Programme of Research in South Africa (CAPRISA) tenofovir gel trial (CAPRISA 004) took place in a rural community where the research team had been previously approached by the local chief to help him find solutions to a high prevalence of HIV among his people.

Different questions should be posed to different stakeholder groups. For example, some groups — district or provincial health authorities and political, religious and civil society leaders — can help you identify the existing services and the services you may need locally. Have other research projects taken place in a similar context? Policymakers at national and regional levels can share their views on how your research relates to their current challenges and priorities. What are their concerns or questions about the proposed project? Are they interested in — or are they wary of — the implementation of an effective intervention? Members of civil society groups can be queried about what did or did not work when the research team tried to engage the local stakeholders. Were the stakeholder engagement strategies, such as the dissemination of results, effective? What strengths and weaknesses do these informants identify in health services at the national and local level? How do they think the research will fit (or not fit) into the bigger picture?

Other questions to consider include these:

- Historically, are any related trials viewed as successful (or problematic) with respect to their conduct, the dissemination of results and eventual access to the intervention?
- What are the strengths and weaknesses of existing prevention or treatment services that are related to the intervention you will be evaluating?
- Are there national, regional or international mobilization efforts that are relevant to your research? For example, are there campaigns about funding, access or implementation of proven strategies?
- What is the human rights landscape (including legislation criminalizing HIV transmission, sex work and homosexuality) in the country and the region?
- Have international groups raised issues about similar studies? Are there local groups that have strong ties to international groups with specific views or agendas?
- Have the results of a similar trial triggered actions in a different country? Were those situations successfully resolved? If so, by whom?
National stakeholder engagement on PrEP research in Uganda

Patrick Ndase, Microbicides Trial Network (MTN) and Partners in Prevention trial, Kampala, Uganda

In Uganda, national stakeholder engagement of PrEP research has been a key activity. In 2009, the Partners in Prevention trial participated in a capacity-building session for civil society and a meeting for a broad group of stakeholders that was initiated by AVAC and other in-country partners. Those meetings have been followed by smaller briefings with Uganda’s Ministry of Health AIDS Control Program, the National Drug Authority and other stakeholders not directly involved in the trial but crucial to the broader context. A meeting for high-level stakeholders occurred in 2010, and now we are planning a briefing to help put recent research results in context. At each of these meetings, we presented information and learned about questions from implementers. We also took note of specific action items such as follow-up briefings or provision of additional materials that we could accomplish immediately.

In the context of a clinical trial that is being conducted for the benefit of public health, we do not want to get into a situation where trial stakeholders begin to discuss the intervention only after the result was released. The goal of our broad engagement strategy is promoting a wider acceptance of, first, the intervention and then the science of the intervention. We want to help would-be implementers think through some of the operational challenges that may come with the intervention should it be proven to work. One goal is to hasten the implementation process. The recent experience with [long delays in the implementation of] male circumcision for HIV prevention in Uganda highlights why broad engagement is crucial far in advance of a clinical trial finding.

Patrick Ndase is the Africa regional physician for MTN and Partners in Prevention.
3 Get to know the national and regional stakeholders.

**Action:** Initiate and develop relationships with stakeholders at national, regional and international levels.

**Result:** You will cultivate a group of allies at various levels who understand the goals of your research and can help guide decision-making and strategy.

**Explanation:** Step 5 and Step 6 focus on identifying and engaging with stakeholders who are directly involved in the trial's conduct. It is also critical to engage with stakeholders who are part of the broad context — including international, regional and local activists and advocates; program implementers and policymakers; and representatives of normative agencies such as WHO and UNAIDS. A perception among any of these individuals that they were not informed or engaged with the research process early on may result in conflicts once the trial is underway or after the results are disseminated. By the same token, these stakeholders can serve as allies, information sources and champions, providing insights on how to explain your project to different audiences. In this step, consider allies who are already working on related issues and who might be interested in attending discussion forums about your research project. Consider having an outside partner from civil society and nonresearch institutions not only attend but convene the conversations — with the representatives of the trial team attending as one of many participants. Wherever possible, be part of the conversation rather than the subject of discussion.

4 Identify global issues and engage international audiences and allies.

**Action:** Gather information about the global context from international conferences, email forums, trials-network meetings and from knowledgeable individuals.

**Result:** You will acquire an understanding of the issues, the individuals and the organizations at an international level that can facilitate routine communications. This will help you to develop appropriate messages for unexpected issues.

**Tips**

Use international conferences as an opportunity to engage with stakeholders working at international, national and regional levels. Consider joint sponsorship — with other research partners and other stakeholder partners — of roundtable discussions or satellite events to facilitate updates and discussions of news and challenges.
Broad stakeholder engagement as a part of the planning for trial success

Manju Chatani, AVAC, New York City

In January 2011, AVAC partnered with the Microbicide Trials Network (MTN), Southern African AIDS Trust and the Treatment Action Campaign in Johannesburg, South Africa, to organize a consultation with civil society. The “Next Steps for ARV-based Prevention” consultation focused on follow-up research that might take place after the VOICE trial (Vaginal and Oral Interventions to Control the Epidemic). VOICE is evaluating different ARV regimens for HIV prevention: daily oral tenofovir (TDF), daily TDF and emtricitabine (FTC), and daily 1 percent tenofovir gel. Such preparations were important in light of the rapidly emerging results from various HIV prevention trials with ARVs, including the CAPRISA 004 microbicide trial, the iPrEx trial, the Partners PrEP trial, the TDF2 trial and the FEM-PREP trial.

Part of the civil society consultation was allocated to discussions of MTN 018, or CHOICE, a planned follow-on trial that would be initiated if one or more of the strategies being evaluated in the VOICE trial were found to be safe and effective. The 40 advocates from eastern and southern Africa discussed the proposed design of the MTN 018 trial as well as the regulatory process for approving the gel should it show effectiveness in VOICE. Following this community consultation, the MTN 018 protocol development team met and incorporated feedback from the consultation into its deliberations. Engaging civil society while the trial protocol is in development is an example of good participatory practice guidelines in action.

VOICE used the same gel candidate (1 percent tenofovir) as the CAPRISA 004 trial, but with a different dosing strategy. The 1 percent tenofovir gel arm of the VOICE trial was stopped in 2011 due to futility, but other trials continue to evaluate 1 percent tenofovir gel.

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associated with trial closure, data and safety monitoring board (DSMB) recommendations and other events.

**Explanation:** In the past few years, trials have flourished or faltered on the basis of feedback from individuals and organizations that were well outside the community or country where the trial occurred. Rapid global communication means that no trial takes place in a vacuum. International discussions on trial-related ethics, evolving standards of care and prevention, funding and research priorities can have a direct bearing on the outcome of your trial.

Here are some strategies for engaging with knowledgeable individuals and learning about the international context:

- Provide staff time and resources for structured engagement with open-forum email lists and information sources on relevant topics. For example, one might consider the African Microbicide Advocacy Group, the International Rectal Microbicides Alliance and webinars hosted by the AVAC Advocates’ Network and by others.
- Provide staff time for participation in multistakeholder communications — such as the Microbicides Media and Communications Initiative (MMCI) and the PrEP Communications Working Group — and other initiatives where information can be shared at a global level.
- Invite members of civil society and other stakeholders to open sessions of your trial’s team meetings; encourage them to present information and engage in discussions and to report back to constituencies afterwards.
- Have quarterly or twice-yearly meetings where the stakeholder engagement team and the science leadership share information on meetings, conferences and workshops at the national, regional and global levels of stakeholder engagement.

5. **Review the implications of your information-gathering and relationship-building activities.**

**Action:** Conduct a formal discussion of your broad contextual analysis and community mapping with the trial team to ensure that members of the trial team are aware of the findings, and that your plans are modified accordingly.

**Result:** The design and conduct of your research project will be relevant and acceptable to stakeholders at national, regional and international levels.
**Explanation:** It may seem obvious that information gleaned from the engagement of stakeholders should be used to adjust the proposed research project, but this does not always take place. This can cause difficulties if stakeholders are asked to provide advice or opinions and then do not perceive that their thoughts have been considered. Hold one or more meetings to discuss and document the stakeholders’ ideas, your proposed responses and potential alterations to your trial. Always follow up with stakeholders. Thank them for their input, tell them how you are acting on their advice, and offer to keep them informed.

**6 Develop a system for ongoing engagement with national and international stakeholders.**

**Action:** Create two-way channels of communication with stakeholders at national, regional and international levels.

**Result:** You will create an up-to-date contextual analysis of factors affecting your trial and a basis for building trust and solving problems with stakeholders who are not directly engaged in the trial or its advisory system (see Step Six: Engage Stakeholders and Sustain Relationships).

**Explanation:** One of the best strategies for ensuring that your trial team is aligned with and cognizant of the broad context is to have a system for sharing and receiving regular updates. A formal strategy, such as a newsletter or portion of the trial website oriented to international audiences, can help. Just as important are individual relationships between site staff members (who are designated to communicate about the trial) and key stakeholders in the international arena. Establish trust by sharing concerns, questions and information about the trial as well as explaining how concerns will be acted upon. There is no single approach to establishing these relationships — the keys are mutual respect and a willingness to listen to and work with partners who have expertise outside of the research arena.
**Checklist: Step Four**

Use this checklist to make sure that you accomplished all the tasks required in Step Four.

- Develop and initiate processes for describing local, national, regional and international contexts.

- Identify key partners who will help you convene discussions on topics relevant to the broader context of your project.

- Identify some of the key national issues or processes that may have an impact on your research — for example, related technologies (female condoms, ARV therapy and postexposure prophylaxis), financing issues (President’s Emergency Plan for AIDS Relief, Global Fund to Fight AIDS, Tuberculosis and Malaria [GFATM]), and other research projects.

- Develop a series of stakeholder forums, small meetings or one-on-one interviews to gather information on these issues, upcoming developments or changes that might take place over the project’s life span.

- Discuss the findings from your analysis of the broad context, develop plans for responding to concerns and ensure that all of your stakeholders understand the actions that have (or have not) been taken to address their concerns.

- Use international forums, the open-forum email lists, or the networks (or groups) you are working with to identify key questions, priorities, precedents or relevant topics on an international scale. Consider different ways to generate feedback on the proposed research — a global teleconference call, a forum at an international meeting or a fact sheet for an international audience.

- Develop key messages, contingency plans and communications strategies to address international issues.

- Revisit your “maps” of the local, national and international issues over the course of the trial. The maps are fluid and may change with time. Be alert to changing priorities, questions and potentially controversial issues that may arise. Update your strategies accordingly.