

# 1. The importance of good participatory practice

## 1.1 Who are stakeholders?

The starting point of good participatory practice is the identification of key stakeholders in the conduct of a biomedical HIV prevention trial. **Stakeholders** are individuals, groups, organisations, government bodies, or any other individuals or collections of individuals who can influence or are affected by the conduct or outcome of a biomedical HIV prevention trial. In this guidance document, the term “stakeholders” is all-encompassing. It describes any individual or collection of individuals who have a stake in a biomedical HIV prevention trial.

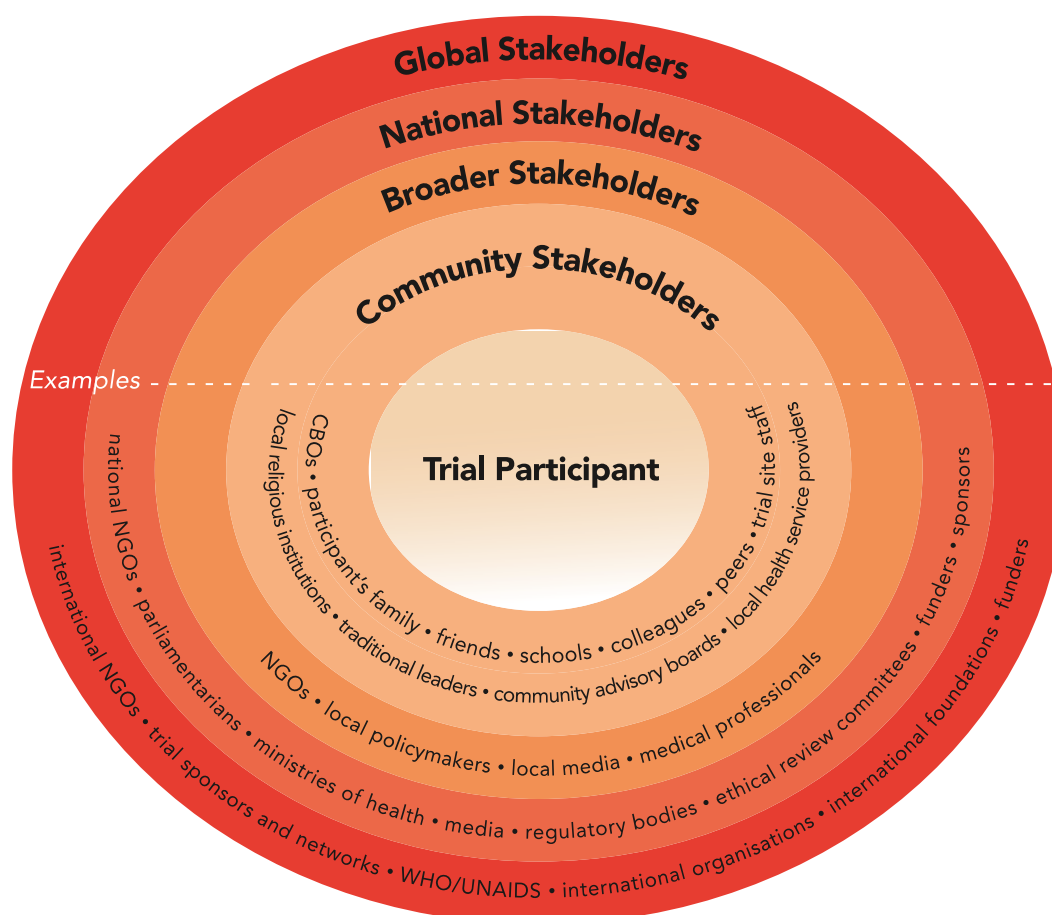
Examples of stakeholders are illustrated in Figure 2 and can include trial participants, families of trial participants, prospective trial participants, individuals resident within, or surrounding, the area where research is conducted, people living with HIV or affected by HIV, prevention and treatment advocates and activists, non-governmental organisations (NGOs), community-based organisations (CBOs), community groups, religious leaders, opinion leaders, media, government bodies, national and local health-care authorities, service providers, trial funders, trial sponsors, and trial implementers.

The definition of “community” is more complicated, as it is a dynamic term that has different meanings to different people.<sup>19</sup> This term is often used to refer to a group of people who have a common set of interests, share a common set of characteristics, or live in a common area. Individuals can be a part of multiple “communities” at the same time. The term “community” is also used to refer to the public at large or to a physical location.

In the GPP guidelines, the preferred term is “**community stakeholders**”, rather than “community”, and refers to both individuals and groups that are ultimately representing the interests of people who would be recruited to or participate in a trial, and others locally


affected by a trial. Examples of “community stakeholders” are the population to be recruited, trial participants, people living in the area where the research is conducted, people living with HIV in the area, local HIV-positive groups or networks, people in the area who are affected by the HIV epidemic, local non-governmental organisations, community groups, and community-based organisations. Trial funders, sponsors, and implementers, as well as government bodies or representatives of high-level authority structures, are explicitly excluded from the term “community stakeholders” but are clearly considered trial stakeholders.

Figure 2. Layers of Biomedical HIV Prevention Trial Stakeholders



Various stakeholders may influence or be affected by a biomedical HIV prevention trial. Stakeholders include trial participants and other community stakeholders as well as a broader range of national and international stakeholders.

## 1.2 What is stakeholder engagement?



Of key importance in good participatory practice is sustained, collaborative partnering with stakeholders. In the GPP guidelines, the term “stakeholder engagement” refers to processes through which trial funders, sponsors, and implementers build transparent, meaningful, collaborative, and mutually beneficial relationships with interested or affected individuals, groups of individuals, or organisations, with the ultimate goal of shaping research collectively.

Successful stakeholder engagement requires a broad, inclusive, and multifaceted understanding of the context in which a biomedical HIV prevention trial is conducted. It begins with an inclusive perspective for identification of potential stakeholders. Stakeholder identification is a dynamic process, as stakeholders, interests, priorities, perspectives, and aspects of culture may change over time. Research teams are responsible for identifying stakeholders, a process which begins by determining the trial population to be recruited, considering those who are affected by the trial in the local area, consulting with already known stakeholders, and building on that expertise to develop a richer understanding of potential and known stakeholders.

Different stakeholders will have different perspectives. Some stakeholders will have competing interests or power imbalances within groups, as well as differences in social organisation, hierarchies, gender issues, and relative social and economic status that may then create division and disagreement during the course of a trial. If there is opposition or disagreement among stakeholders, then those issues must be addressed in a way that is honest, transparent, and respectful to all parties.

Stakeholders in biomedical HIV prevention research can learn from other fields that have successfully adopted participatory research approaches, which seek to engage community stakeholders as equal members who share control over all aspects of the research process.<sup>20,</sup>

<sup>21, 22, 23, 24</sup>


## 1.3 The wider context of HIV

There is an urgent need to develop additional strategies to address the HIV pandemic. Along with necessary behavioural and structural changes, a broad range of biomedical HIV prevention and treatment options is required to meet the diverse needs of individuals and populations. There are many inherent complexities in conducting biomedical HIV prevention trials. By acknowledging and understanding these challenges and complexities, trial funders, sponsors, and implementers can more appropriately and effectively facilitate a mutually beneficial participatory approach to conducting biomedical HIV prevention trials.



Biomedical HIV prevention research cannot succeed without meaningful stakeholder engagement, particularly given the need to involve large numbers of healthy, HIV-negative volunteers as trial participants. It is optimal that experimental HIV prevention options are tested for safety and effectiveness in populations who need these interventions the most and are likely to use them should they prove effective. However, the very factors that increase HIV risk in such populations may contribute to increased vulnerability to exploitation. This underscores the importance of meaningful partnerships with community stakeholders.

A wide range of factors creates, enhances, and perpetuates the risk of HIV infection. Structural determinants can increase vulnerability to HIV at an individual or population level by undermining ability to avoid HIV exposure. Underlying determinants of the HIV epidemic can be entrenched in the social, cultural, legal, institutional, or economic fabric of society. Examples of these determinants include gender and other power inequalities, gender-based violence, economic instability including poverty, migration, human rights violations, homophobia, discriminatory practices, HIV-related stigma, social marginalisation, and criminalisation of HIV transmission. Recognition of these factors is the first step in developing practices



that avoid inadvertently replicating or reinforcing them in the design and conduct of biomedical HIV prevention trials. While stakeholder engagement helps empower and equip community stakeholders to engage in the research process in a meaningful fashion, it also harnesses the expertise that community stakeholders can contribute to the design and conduct of research.

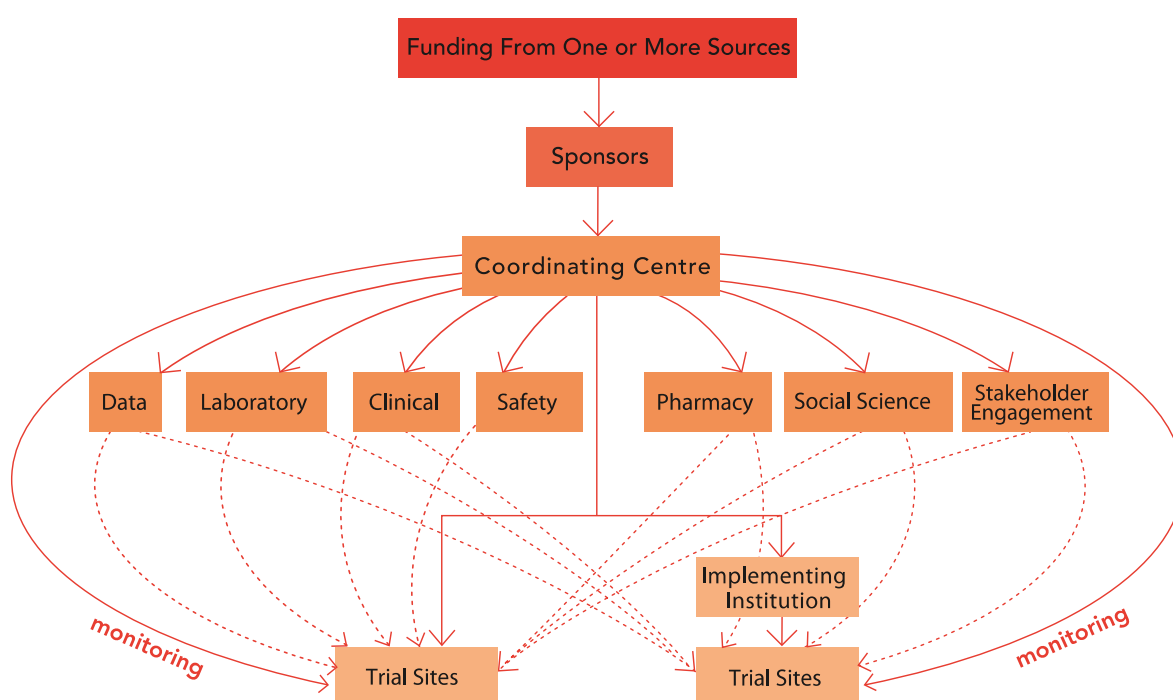
## 1.4 The dynamics of biomedical HIV prevention trials

Power inequalities always exist between funders and funding recipients with respect to a range of issues, such as decision-making processes, priority setting, control of resources, and equitable recognition of input. Biomedical HIV prevention trials are often funded by institutions in developed countries and conducted with multiple partner institutions worldwide, including those in developing countries. Disparities among these institutions and partners can introduce or reinforce power inequalities between and among trial implementers and the funders or sponsors of trials. This can then translate into inequalities between trial implementers and other stakeholders.

The fact that many biomedical HIV prevention trials are conducted in multiple settings and countries introduces another level of complexity. Variation in cultures, physical environments, infrastructure, research experience, health policies, and national laws can introduce inequalities among research teams and between research teams and site-level community stakeholders. Power inequalities between research teams and community stakeholders can include imbalances in literacy, education, and economic resources, as well as those inherent in patient-provider relationships. National, racial, ethnic, and linguistic differences between members of research teams and community stakeholders can also exacerbate inequalities.

In order to achieve meaningful community stakeholder participation and partnership, it is essential to recognise these various power inequalities and address them.


Figure 3. Example of a Trial Network



Basic structure of a typical biomedical HIV prevention trial network. Funding from one or more sources is distributed through a network coordinating centre directly to trial sites or to implementing institutions such as universities that then send funds to trial sites. Trial networks may have several centres responsible for different aspects of trial conduct: data management, laboratory, pharmacy, clinical, safety, social science, and stakeholder engagement. Monitoring of trial conduct may be executed through the coordinating centre or outsourced to an independent monitoring organisation.

## 1.5 Rationale for GPP guidelines

Constructive long-term stakeholder engagement helps ensure the ethical and scientific quality of research as well as its relevance to community stakeholders.<sup>1,25</sup> Stakeholders, in particular community stakeholders, have unique expertise to contribute to the research process. They possess critical knowledge and understandings of local cultures and perspectives, languages, dynamics of the local HIV epidemic, concerns of vulnerable or marginalised populations, and local priorities that trial funders, sponsors, and implementers may lack.



Stakeholder collaboration can help ensure that research questions and procedures are culturally sensitive and appropriate, thus improving recruitment, retention, adherence, and other trial outcomes. It can help avoid reinforcing existing inequalities and increase sensitivity to the needs of vulnerable populations. An essential component of stakeholder engagement is improving stakeholder knowledge and understanding of the research process, building research literacy and competencies. This, in turn, enables stakeholders to contribute more effectively to the process of guiding research and helps to address the power imbalance between research teams and community stakeholders.

Strengthening meaningful collaboration among stakeholders fosters greater trust and respect between trial funders, sponsors, and implementers, and other stakeholders. Stakeholder engagement that is transparent and mutually respectful can minimise misunderstandings and reduce the chances of unnecessary conflict or controversy. Following good participatory practices through the entire research life-cycle helps facilitate local ownership of research, enables more equitable relationships, and increases the likelihood of successful research conduct, trial completion, and application of research results.

## 1.6 Applying GPP

The GPP guidelines broadly describe systematic ways to establish and maintain effective stakeholder engagement that can be applied in diverse locations globally. The specificity of the content of the GPP guidelines enables monitoring of stakeholder engagement activities.

The most effective way for the GPP guidelines to be implemented is for trial sponsors to adopt them as a requirement in trial conduct and to monitor their implementation and evaluate their effectiveness. As an essential element of successful trial implementation, effective



stakeholder engagement requires that trial sponsors provide ample time allocation, adequate human resources, and sufficient funds in site budgets for implementation of Section 3 of the GPP guidelines.

Other stakeholders, such as national authorities, institutions, ethics committees, institutional review boards, and community stakeholders can also require that the GPP guidelines be followed when research is conducted in their country, institution, or area.

Monitoring stakeholder engagement is a complex process. To measure whether the GPP guidelines are being followed, stakeholders can first consult the list of optimal practices in each topic area of Section 3 and determine if the various activities have been executed. Because stakeholder engagement is based on relationships, it may be perceived differently by different stakeholders and may be difficult to measure. Comprehensive monitoring of GPP compliance includes documenting and analysing how well practices have been followed as well as to what extent stakeholders feel the practices have been followed. Comprehensive evaluation of stakeholder engagement requires determining how stakeholders feel regarding the impact of those participatory practices on research and stakeholder relationships. This information can be gained through site records, meeting minutes, monitoring report forms, surveys, interviews, focus group discussions, and other methods.

A variety of other resources and tools may help stakeholders understand, implement, and monitor GPP. Users can refer to AVAC's website for new or revised materials. UNAIDS and AVAC welcome requests for additional tools as well as submissions of materials that are already in use.

