

## Lesson 10 Work Assignment

*Remember to save a personal copy of this completed work assignment for future reference.*

### Purpose

Now that you have identified and analyzed your stakeholders and selected specific engagement objectives to achieve for each stage of the research process, it's time to complete your stakeholder engagement work plan.

We have learned that there is no 'one size fits all' model for stakeholder engagement. Stakeholders need to be engaged in different ways, depending on the trial site's goals, barriers, opportunities, resources available and stakeholders' own preferences and interests. We have also learned that engagement is ongoing, and stakeholder needs can change over time.

In selecting the methods of engagement, you also need to ensure that the activities you are selecting fit with your research timelines, are adequately resourced, and that responsibility for the engagement activity is clearly identified.

### Step 1: Completing Your Stakeholder Engagement Plan

- Begin by briefly reviewing your responses from previous work assignments, and reflect again on what you are seeking as a result of the engagement process.
- Pay special consideration to any barriers and opportunities you identified in the work assignments for Modules 2, 3, and 6.
- Follow the instructions in the table below and complete the stakeholder engagement work plan template.

**Provide the requested information in the template provided on the next page, or you can create your own.**

1) Beginning with your objectives for **trial planning** (stage 1), fill in the template below, based on the following definitions:

- » **Goal:** a broad statement (or statements) that describes the overall purpose of your stakeholder engagement efforts. List the goals you drafted in Section 2.1 at the top of the template.
- » **Objective:** the specific results that will help you achieve your goals within a designated time frame using available resources. Begin by listing your highest-priority objectives for the stage you're addressing, and work your way through to those you've determined are less essential.
- » **Activity:** specific actions taken to meet the objective, such as convening forums, conducting focus groups, facilitating workshops, and distributing newsletters. Under each objective, list the activities required to carry it out.

For each activity, list the following:

- **Stakeholder:** the group or individual/s you are seeking to engage
- **Timeline:** time frame for carrying out the activity
- **Deliverable:** the report or other tangible that will be delivered upon completion of the activity
- **Related GPP topic area/s:** the GPP topic area/s on which you are seeking stakeholder input and expertise
- **Indicator of success:** an agreed upon measure of the activity's impact
- **Estimated budget:** financial resources required for the activity

2) Using a separate sheet for each trial stage, fill out a template for **trial conduct** (stage 2) and then **post-trial activity** (stage 3). (You may also want to designate a sheet for activities that span more than one trial stage or will extend beyond the post-trial period.)

Stakeholder Engagement Goals						
<ul style="list-style-type: none"> <li>» <b>Trial Planning:</b></li> <li>» <b>Increase awareness, knowledge and support for the use of PrEP in Black MSM communities where the study is being conducted.</b></li> </ul>						
Activity	Stakeholder	Timeline	Deliverable	Related GPP topic areas	Indicator of success	Estimated budget
<b>Objective 1: Strengthen input from Black MSM community leaders and former participants to improve future trial design</b>						
Identify leaders and key organizations in the Black MSM communities where the study is being conducted	Advocacy group and local CABs	Prior to trial initiation	Mapping of Black MSM leaders and key organizations	Formative Research activities	Black MSM leaders and key organizations identified	
Convene briefing with key Black MSM community leaders – local and national	Local Black MSM community organizations – three or more local CBOs	Prior to and early on in trial development and ongoing	Briefing held	Formative research activities Stakeholder engagement plan Stakeholder education plan Issues Management Plan	Increased awareness of and support for planned study Identification of key concerns/ issues/question/ barriers to	

				Protocol development	participation/trial acceptance	
<b>Objective 2: Obtain input from Black MSM community and former trial participants to identify and make plans to address potential social harms</b>						
Interview or convene focus groups with former trials participants	Former participants	Prior to and early on in trial development and ongoing	Selected Interviews and/or focus group	Formative research activities Stakeholder engagement plan Issues Management Plan Protocol development	Identification of key issues faced by participants identification of best approaches for addressing participant needs/concerns/questions	
Meet with advocacy organizations and local provider/service organizations to develop referrals for psychosocial, counselling, peer support and other support services	Advocates , regulators, providers and health officials, including three local CBOs, local CAB, the appropriate office in the department of public health, and two major public health providers of services for	Prior to and early on in trial development	Meetings held	Issues Management Plan	Referrals identified	

	substance abuse disorder, other providers with resources for housing, employment, etc.					
Work with CAB, former trial participants and other stakeholders to identify and strategize about how to encourage participants to report and seek help to address social harms	CABs, former trial participants, local advocacy organizations	Prior to and early on in trial development	Meetings held	Issues management plan	Specific strategies identified	
<b>Objective 3: Ensure involvement of relevant stakeholder throughout all stages of research process</b>						
Include CAB members on protocol team; meet with local CABs and Black advocacy group	Network CAB reps and Local site CABs, key Black advocacy group	Prior to and early on in trial development and ongoing	Regular meetings with CAB held, meetings with key Black advocacy group	Stakeholder engagement plan	Community input solicited on trial design, informed consent, messaging, issues management	

to obtain input on trial design						
Convene a consultation with to discuss proposed research	Advocates , regulators, providers and health officials, including CBO reps	Prior to and early on in trial development and ongoing	Meeting help	Stakeholder engagement plan	Input solicited on trial design, informed consent, messaging, issues management	
Discuss trial plans with relevant community groups within the network, research enterprise e.g.	Global CAB, Community Partners, Legacy Project as appropriate	Prior to and early on in trial development and ongoing	Meetings held	Stakeholder engagement plan		
<b>Objective 4: Increase stakeholder awareness/knowledge of clinical research process and PrEP in particular</b>						
Convene stakeholder forums/briefings	Outreach through CBO partners, local and national advocacy group, local CABs, and other stakeholders	Prior to and throughout trial development and conduct	Forums, consultations held	Stakeholder education plan Stakeholder engagement plan	Increased knowledge of clinical trials research and PrEP	
Utilize other tools to increase awareness/ understanding of PrEP – written	Media Community stakeholders (use of	Throughout trial conduct	Materials developed Messages disseminated using multiple approaches	Stakeholder education plan	Increased awareness/ understanding/knowledge of PrEP	

materials, social and other media	websites/blogs/news letters etc.)					
<b>Trial Conduct: Maintain stakeholder engagement throughout trial implementation and conduct</b>						
<b>Objective 1: Ensure community stakeholder input throughout trial conduct</b>						
Hold regular meetings with local CABs	Community stakeholders	From implementation through trial conduct	Meetings held, study progress discussed, specific topics addressed (e.g, barriers to participation, social harms etc.) Trainings held as appropriate on communications, clinical trials research, PrEP etc.	Stakeholder engagement plan Stakeholder education plan		
Hold regular meetings with Black Caucus	Black MSM leaders	From implementation through trial conduct	Meetings held, study progress discussed, specific topics addressed (e.g, barriers to participation, social harms etc.)	Stakeholder engagement plan	Dialog related to study progress, input	
Convene forums on PrEP with local advocacy	Local Black MSM community stakeholders	From implementation	Meetings held, study progress discussed, specific	Stakeholder engagement plan	Increased awareness of trial, increased	

and provider organizations	(CBOs, advocacy groups, CABS.)	through trial conduct	topics addressed (e.g, benefits of PrEP, benefits of trial participation, barriers to participation)	Stakeholder education plan	support for trial participation	
<b>Trial Closure: Strengthen community input on message development and dissemination</b>						
<b>Objective 3: Obtain input from local advocates, service providers, leaders and CAB to ensure effective channels of communication</b>						
Convene meeting with local and national leaders and advocates in Black MSM community, local and network CABS	Local CABS, CBOs, and other advocacy organizations	During trial and in particular in preparation for study closure and at time of study closure	Meetings held focusing on trial closure, results, message development, channels of communication	Communications plan	Clear messages developed Effective channels of communication identified Information broadly disseminated in a timely manner	



## Step 2: Wrapping Up and Way Forward

- Congratulations! You have completed your stakeholder engagement work plan and GPP Blueprint!
- Remember to revisit the GPP Blueprint again for future trials, and use it as a discussion guide with your research team to inform and improve GPP planning and implementation.
- Your work plan can also be used as a progress report for your specific engagement objectives. Analyze your successes and unmet objectives, and weave this information into your future engagement plans to improve the overall process.
- Even after you have finished a set of engagement activities, you should continue your engagement with your stakeholders as part of your long-term strategy.
- Now be prepared to discuss your stakeholder engagement work plan and the following question during the final discussion forum:
  - What strategies will you employ to sustain engagement with stakeholders after trial closure and results dissemination?
  - Which stakeholders are most influential in terms of post-trial access issues? Do other stakeholders need to be engaged? Explain.