

ENGAGEMENT & FOR IMPACT



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The Tools

- This document presents the tools that are currently uploaded onto the server.
- This document serves as a hard copy of the tools in printable format.
- The tools are divided into 4 sets – A, B, C, D. The tools are used at different intervals, the specifics of which would be determined by each individual CSE’s M&E Program.
- The tools are presented in this document – however their format is slightly different on the database where questions are presented 2-3 per page. In addition the post coded options are presented in a more user friendly manner on the database. This pack however, can be useful if you need to reproduce paper copies of the tools.

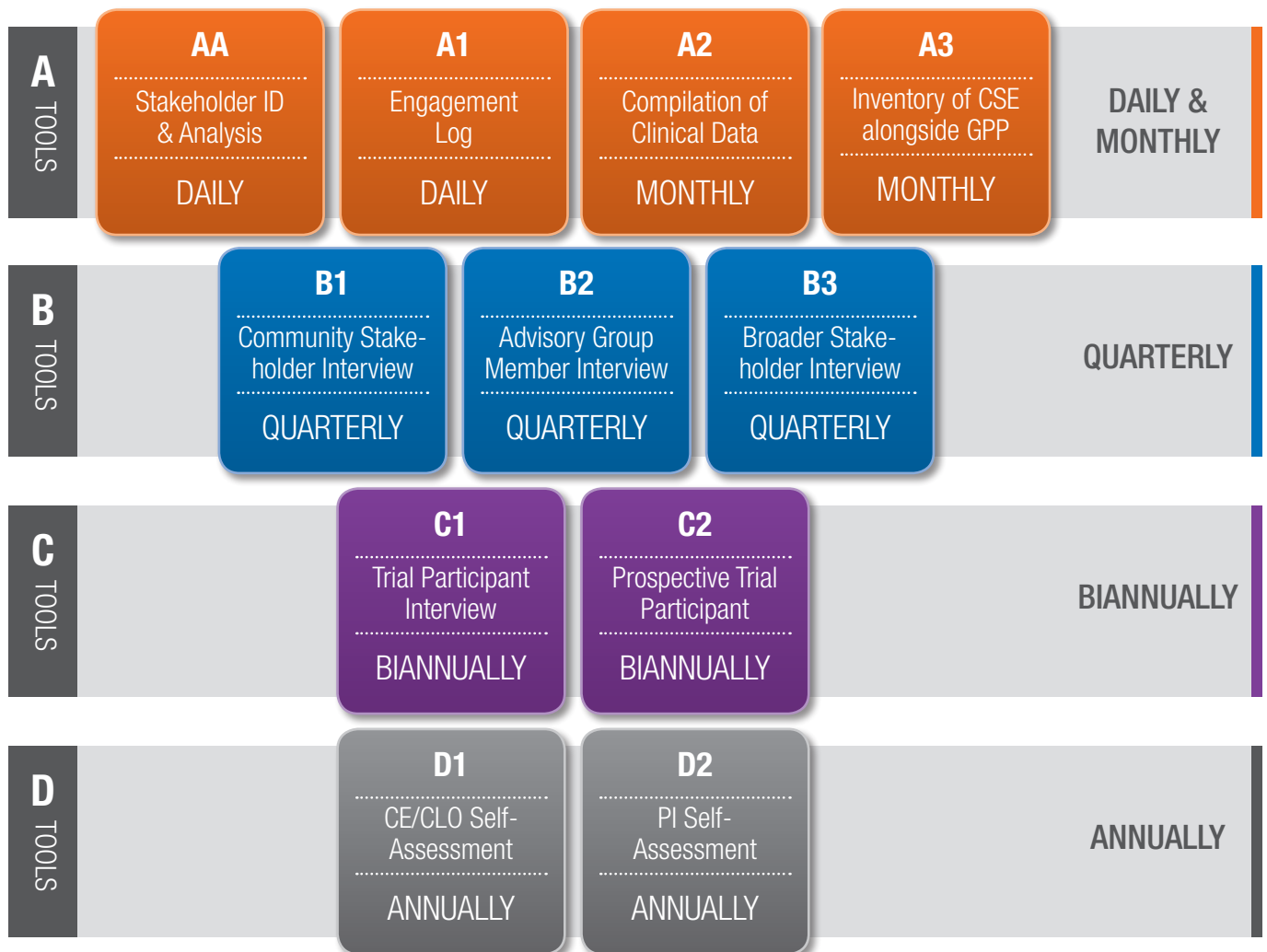


Figure 1: Tool Matrix

Tools – SET AA

Stakeholder ID and Analysis

When to complete

- Daily or equivalent.
- To be completed whenever a new stakeholder is engaged.
- Updated automatically via A1.
- Revisited to rate power and engagement intermittently.

Number to complete

- There is no defined sample size.
- The more stakeholders you consult with the more information you will have in your database to use for effective planning or M&E.

Estimated Time

- 15 minutes the database.

TOOL AA – Stakeholder ID and Analysis

AA-1.1 STUDY SITE					
AA-1.2 REFERENCE (always used for this SH)					
AA-1.3 STAKEHOLDER NAME					
AA-1.4 STAKEHOLDER TYPE		<input type="checkbox"/> Community SH <input type="checkbox"/> Broader SH <input type="checkbox"/> National SH <input type="checkbox"/> International SH			
AA 1.5 TYPE OF STAKEHOLDER <i>Select one only</i>		<input type="checkbox"/> INDIVIDUAL RESIDENT <input type="checkbox"/> ADVOCATE or ACTIVIST <input type="checkbox"/> CBO STAFF <input type="checkbox"/> SCHOOL TEACHER <input type="checkbox"/> YOUTH WORKER <input type="checkbox"/> HEALTH FACILITY STAFF <input type="checkbox"/> TRADITIONAL HEALER <input type="checkbox"/> LOCAL FAITH BASED LEADER <input type="checkbox"/> LOCAL LEADERSHIP - GOVT OR ELECTED <input type="checkbox"/> LOCAL LEADERSHIP - TRADITIONAL <input type="checkbox"/> COMMUNITY HEALTH WORKER <input type="checkbox"/> LOCAL BUSINESS OWNERS <input type="checkbox"/> LEGAL EXPERT <input type="checkbox"/> MEDIA /JOURNALISTS <input type="checkbox"/> LOCAL POLICY MAKERS <input type="checkbox"/> LOCAL BUSINESS <input type="checkbox"/> NGO STAFF <input type="checkbox"/> INTERNATIONAL ADVISORY BOARD <input type="checkbox"/> SPONSOR/COORDINATOR <input type="checkbox"/> DONOR <input type="checkbox"/> OTHER <i>Specify in detail:</i>			
AA-1.6.1 - AA-1.6.4 Dates of Engagement <i>List all dates when this stakeholder was engaged in some way</i> <i>Automatic update from A1</i>		Date	Link to Engagement Log - date	Link to a key informant interview	
		dd/mm/yyyy			
		dd/mm/yyyy			
		dd/mm/yyyy			
AA-1.7 WHY ARE YOU ENGAGING WITH THIS STAKEHOLDER <i>Narrate in detail why you are engaging with this stakeholder –i) why are you engaging this person/group i) what can the stakeholder/group benefit from engagement and how can the trial benefit from his or her engagement.</i>			Narrative		
AA-1.8 <i>Is this stakeholder supportive or resistant to engagement? Only choose one.</i>			RESISTANT/CONFLICT <input type="checkbox"/>		
			COLLABORATIVE/SUPPORTIVE <input type="checkbox"/>		
AA - 1.9 <i>Personally rate the power this stakeholder or stakeholders holds in the area where he or she has a sphere of influence.</i>			High	Med	Low/None
KNOWLEDGE & SKILLS – <i>does this stakeholder have knowledge or skills relating to the disease or its management or to community dynamics, education, etc. of relevance to the trial locally or more broadly?</i>			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
COMMUNICATION CONTROL WITH PARTICULAR GROUPS – <i>does this stakeholder have access to important groups who should be reached to open lines of communication from and to the trial?</i>			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
AUTHORITY – REGULATORY – <i>does this stakeholder hold influence or power over authorization or regulations in the community or more broadly?</i>			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
PRESTIGE/STATUS – <i>does this stakeholder hold a status in his sphere or in his community or in the broader arena which enables him or her to open lines of communication from and to the trial?</i>			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
SOCIAL TIES/CONNECTIONS – <i>does this stakeholder hold social ties or connections in the community or in the broader arena which enables him or her to open lines of communication from and to the trial?</i>			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
ECONOMIC – FINANCIAL – <i>does this stakeholder have economic or financial influence locally or more broadly?</i>			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
In your opinion does this stakeholder have a PERCEIVED RIGHT to be involved in the trial or components of the trial?			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
In your opinion does this stakeholder have a PERCEIVED RESPONSIBILITY to be involved in the trial or components of the trial.			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
In your opinion does this stakeholder have a PERCEIVED RESOLVE or DETERMINATION to be involved in the trial or components of the trial.			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
AA-1.10 <i>Select the extent of the stakeholders' relationship with the trial at this point in time.</i>					
INFORMED – stakeholder has been provided with information.			<input type="checkbox"/>		
CONSULTED – stakeholder is regularly approached for feedback on certain key issues as they arise.			<input type="checkbox"/>		
INVOLVED – stakeholder is working directly and actively with the trial or representatives to ensure that public concerns and aspirations are consistently understood and considered.			<input type="checkbox"/>		
COLLABORATING – stakeholder is in regular partnership at some level, wherever relevant overlaps exist between their work and the trial interests.			<input type="checkbox"/>		
EMPOWERED – the stakeholder has been engaged regularly over time and is able to independently inform and engage with relevant parties in relation to the trial and or the stakeholder engagement process.			<input type="checkbox"/>		

AA - 1.11 <i>Select the nature of this stakeholders' participation.</i>	UNCONCERNED/PASSIVE	<input type="checkbox"/>
	CONCERNED/NOT ACTIVE	<input type="checkbox"/>
	INFLUENTIAL/NOT ACTIVE	<input type="checkbox"/>
	ACTIVE/NOT INFLUENTIAL	<input type="checkbox"/>
	INFLUENTIAL/ACTIVE	<input type="checkbox"/>

Tools – SET A1

Engagement Log

When to complete

- Daily or the equivalent.
- To be completed as soon after any of the following:
 - CSE Consultation in person-email or on the phone.
 - CAB/Advisory Mechanism planning or implementation (meeting or event).
 - Media consultation – planning or implementation or exchange in person or in writing.
 - Outreach – planning or implementation.

Number to complete

- There is no defined sample size.
- As many entries as needed each day – this data is entered directly into the database.
- The log is intended to capture all your CSE activities in brief – from planning through to implementation.
- The more committed you are to logging your CSE activities, the richer your M&E Data will be and the greater the justification for your work and its potential impact on trial outcomes.

Estimated Time

- 5 minutes per log.

TOOL A1 – COMMUNITY ENGAGEMENT LOG

Instructions: This form is to be completed as soon as CSE takes place – relating to consultations, CAB/CAG/CR; outreach and media.

KINDS OF COMMUNITY ENGAGEMENT – RECORDED IN TOOL A1	
CONSULTATION – with individuals and small groups	<p>These are conversations and meetings and check ins you may carry out with specific stakeholders to address a wide variety of issues.</p> <p>Consultation may include any:</p> <ul style="list-style-type: none"> • Meetings with community stakeholders . • Discussions around community entry, mobilization and education, participant recruitment in relation to community engagement, updates and feedback during and after the trial. • May also include phone calls with stakeholders or a visit to the clinic to 'pop in' to touch base or update – consultations can be scheduled or unscheduled with any of the relevant community stakeholders. • Written communication if introductory or of significance in the form of 'consultation' can also be included.
COMMUNITY ADVISORY GROUP/BOARD/FORUM	<p>These include any / all activities related to the CAB. For example, meetings to plan a CAB meeting, recruiting members, training of members and any CAB initiated outreach activities.</p>
OUTREACH – to large groups	<p>These include outreach related to any health calendar events, screening days, community meetings, dialogues, barazas, theatre or music events, education sessions in institutions (schools, clinics, and universities), training of peer educators. Outreach must involve activities that directly or indirectly relate to the trial and its relevance to the community where you are doing the outreach. This may also include results dissemination.</p>
MEDIA	<p>These include radio, flyers, posters, newsprint, television, press releases and social media of any kind.</p>

# A1	A1.1 NAME OF PERSON WHO DID THE ENGAGEMENT:	TITLE/POSITION OF PERSON WHO DID THE ENGAGEMENT:	
1. DAY/MONTH AND YEAR _____/_____/_____	6. FORM OF ENGAGEMENT CONSULTATION <input type="checkbox"/> EMAIL <input type="checkbox"/> ONE TO ONE MEETING (NOT CAB) <input type="checkbox"/> ROUTINE/ SCHEDULED MEETING (NOT CAB) <input type="checkbox"/> UNSCHEDULED OR EMERGENCY GROUP MEETING (NOT CAB) <input type="checkbox"/> SMALL SUBCOMMITTEE MEETING (NOT CAB) <input type="checkbox"/> OTHER _____SPECIFY _____ CAB <input type="checkbox"/> ROUTINE/ SCHEDULED CAB MEETING <input type="checkbox"/> UNSCHEDULED OR EMERGENCY CAB MEETING <input type="checkbox"/> EXECUTIVE COMMITTEE CAB MEETING <input type="checkbox"/> OTHER _____SPECIFY _____ OUTREACH <input type="checkbox"/> GLOBAL HEALTH EVENT <input type="checkbox"/> HEALTH or RESEARCH EDUCATION <input type="checkbox"/> HEALTH SCREENING <input type="checkbox"/> GENERAL COMMUNITY MEETING <input type="checkbox"/> PEER EDUCATION <input type="checkbox"/> HEALTH WORKER TRAINING <input type="checkbox"/> THEATRE/MUSIC EVENT <input type="checkbox"/> SPORT EVENT <input type="checkbox"/> OTHER _____SPECIFY _____ MEDIA <i>choose those relating to this engagement log</i> <input type="checkbox"/> LOCAL RADIO ADVERTISEMENT <input type="checkbox"/> LOCAL RADIO INTERVIEW <input type="checkbox"/> REGIONAL/NATIONAL RADIO ADVERTISEMENT <input type="checkbox"/> REGIONAL/NATIONAL <input type="checkbox"/> RADIO INTERVIEW <input type="checkbox"/> TELEVISION ADVERT <input type="checkbox"/> TELEVISION INTERVIEW <input type="checkbox"/> LOCAL NEWS/PRINT ARTICLE <input type="checkbox"/> LOCAL PRESS RELEASE <input type="checkbox"/> NATIONAL NEWS/PRINT <input type="checkbox"/> NATIONAL PRESS RELEASE <input type="checkbox"/> SOCIAL MEDIA UPDATE <input type="checkbox"/> INTERNET PLATFORM <input type="checkbox"/> POSTERS <input type="checkbox"/> FLYERS <input type="checkbox"/> BILLBOARDS <input type="checkbox"/> OTHER _____SPECIFY _____	7. ATTENDANCE OR REACH <i>NOTE: Enter the exact number of people in attendance or reached through consultation or outreach. If this is not possible, then enter the approximate number in attendance at the event. In the case of media, you can indicate the number you expect will be reached through your media avenues.</i> EXACT - ENTER NUMBER OF PEOPLE IN ATTENDANCE AT MEETING OR OUTREACH _____ OR APPROXIMATE - IF EXACT NUMBER NOT KNOWN- APPROXIMATE NUMBER OF PEOPLE ATTENDING OR BEING REACHED _____ OR EXPECTED - IF NUMBER NOT APPROXIMATED- ENTER NUMBER OF PEOPLE EXPECTED TO BE REACHED BY THE ENGAGEMENT _____	9. PLACE – LOCATION /GPS COORDINATES <input type="checkbox"/> MY OFFICE <input type="checkbox"/> PHONE CALL <input type="checkbox"/> RESEARCH CLINIC <input type="checkbox"/> DOH/MOH <input type="checkbox"/> HEALTH FACILITY <input type="checkbox"/> HOME VISIT <input type="checkbox"/> IN COMMUNITY <input type="checkbox"/> CONFERENCE <input type="checkbox"/> WORKSHOP <input type="checkbox"/> SHOPPING AREA <input type="checkbox"/> SOCIAL CLUBS <input type="checkbox"/> LEARNING INSTITUTION <input type="checkbox"/> OTHER
2. TYPE OF COMMUNITY ENGAGEMENT Read definitions and choose ONE <input type="checkbox"/> CONSULTATION <input type="checkbox"/> COMMUNITY ADVISORY GROUP/BOARD/FORUM Name of CAB: _____ <input type="checkbox"/> OUTREACH <input type="checkbox"/> MEDIA	3. TRACKING NUMBER A unique consecutive number (generated by software).	8. TRAINING DID ANY TRAINING TAKES PLACE AT MEETING: <input type="checkbox"/> YES <input type="checkbox"/> NO Specify kind <input type="checkbox"/> RESEARCH LITERACY <input type="checkbox"/> GPP <input type="checkbox"/> GCP <input type="checkbox"/> TB PREVENTION AND TREATMENT <input type="checkbox"/> HIV PREVENTION AND TREATMENT <input type="checkbox"/> OTHER _____SPECIFY _____	
4. FOCUS OF ENGAGEMENT <i>(can choose many)</i> <input type="checkbox"/> Planning <input type="checkbox"/> Training <input type="checkbox"/> Implementation <input type="checkbox"/> Communication <input type="checkbox"/> Follow up			
5. TIME SPENT ON THIS SPECIFIC ENGAGEMENT ACTIVITY BEING LOGGED Start: _____ Finish: _____ Total: _____			

10. SPECIFICS OF MEDIA ENGAGEMENT

Can only be answered if "MEDIA" was selected for NUMBER 2

NAME OF RADIO STATIONS USED FOR MEDIA CAMPAIGN OR RELEASE
(attach sound clip if possible or text)

NAME OF TV STATION FOR MEDIA CAMPAIGN OR RELEASE
(attach clip if possible or text)

NAME OF NEWSPAPER FOR MEDIA CAMPAIGN OR RELEASE
(make sure to attach newspaper article)

NAME OF SOCIAL MEDIA FOR MEDIA CAMPAIGN OR RELEASE
OR POSTINGS
(make sure to attach screen shots of any comments or communication)

NAME OF POSTER
(make sure to attach copy)

NAME OF FLYER
(make sure to attach copy)

OTHER _____ (specify and attach)

11. PURPOSE OF COMMUNITY ENGAGEMENT/ISSUES ADDRESSED

Choose multiple

- ADHERENCE ISSUES
- CAB MANAGEMENT
- COMMUNICATION PLAN
- COMMUNITY ENTRY/INTRO
- DOCUMENTATION OF PRACTICES & LESSONS LEARNED
- POST TRIAL ACCESS TO CARE
- FOLLOW UP ISSUES
- FORMATIVE WORK
- INFORMED CONSENT REVIEW/DISCUSSION/TRAINING
- ISSUES MANAGEMENT PLAN
- MOBILIZATION/SENSITIZATION/EDUCATION AT DIFFERENT SITES
- PLANNING FOR EVENTS
- POST TRIAL ACCESS TO CARE
- PROTOCOL DEVELOPMENT
- PROTOCOL REVIEW
- POST TRIAL ACCESS TO CARE
- RECRUITMENT CA
- RECRUITMENT RESEARCH PARTICIPANTS
- RECRUITMENT CAB
- RESOURCE IDENTIFICATION
- RESULTS DISSEMINATION
- RETENTION ISSUES
- ROLE CLARIFICATION
- SITE SELECTION
- STAKEHOLDER ADVISORY PLAN
- STAKEHOLDER EDUCATION PLAN
- STUDY BRIEFING/TRAINING
- STUDY INFO UPDATES
- TRAINING IN COMMUNITIES
- TRAINING OF CAB
- UPDATES/FEEDBACK RELATED TO EVENTS (NOT STUDY UPDATES)
- OTHER _____ (specify)

12. COMMUNITY STAKEHOLDERS INVOLVED/REACHED/TARGETED

Choose multiple

- ADVOCATES & ACTIVISTS
- BUSINESS SECTOR
- COMMUNITY BASED/CIVIL SOCIETY ORG
- COMMUNITY OUTREACH HEALTHCARE WORKERS
- DEPARTMENT OF HEALTH LOCAL/ZONAL
- DEPARTMENT OF HEALTH NATIONAL
- DEPARTMENT OF HEALTH REGIONAL
- DISABLED PEOPLE
- KEY (MARGINALIZED - AT RISK) POPULATIONS
- GLOBAL CAB MEMBERS
- GENERAL PUBLIC
- If you can specify -
 - GENERAL PUBLIC - CHILDBEARING AGE – FEMALE
 - GENERAL PUBLIC - CHILDBEARING AGE – MALE
 - GENERAL PUBLIC - PREGNANT WOMEN
 - GENERAL PUBLIC - ELDERLY – FEMALE
 - GENERAL PUBLIC - ELDERLY – MALE
 - GENERAL PUBLIC - OUTSIDE CATCHMENT AREA
 - GENERAL PUBLIC - YOUTH/YOUNG ADULTS - FEMALE - IN EDUCATION
 - GENERAL PUBLIC - YOUTH/YOUNG ADULTS - MALE - IN EDUCATION
 - GENERAL PUBLIC - YOUTH/YOUNG ADULTS - FEMALE - OUT OF EDUCATION
 - GENERAL PUBLIC - YOUTH/YOUNG ADULTS - MALE - OUT OF EDUCATION
 - FAITH BASED LEADERS
 - FAMILY MEMBERS, FRIENDS & CAREGIVERS OF TRIAL PARTICIPANTS
 - FRONTLINE HEALTH FACILITY STAFF
 - HOME BASED CARERS
 - LOCAL GOVERNMENT LEADERSHIP
 - LOCAL TRADITIONAL LEADERSHIP
 - NON GOVERNMENT/COMMUNITY BASED/CIVIL SOCIETY BASED
 - ORGANISATIONS
 - POLICY/LAW SECTOR
 - PROSPECTIVE PARTICIPANTS
 - REGION/NATIONAL POLITICAL LEADERS
 - REGION/NATIONAL TRADITIONAL LEADERS
 - RESIDENTS (unspecified) IN THE CATCHMENT AREA
 - SCIENTIFIC COMMITTEE MEMBERS
 - SPONSOR/DONOR
 - TEACHERS/LECTURERS/PROFESSORS
 - TRADITIONAL HEALERS
 - TRIAL PARTICIPANTS
- OTHER _____ (specify)

13. OUTCOME NARRATIVE

PLEASE DESCRIBE IF THIS COMMUNITY ENGAGEMENT EVENT WAS USEFUL OR NOT USEFUL AND WHY. DID IT ACHIEVE WHAT WAS EXPECTED? DO YOU KNOW IF IT ACHIEVED ANYTHING? ANY FOLLOW UP?

15. NEXT STEPS:

- 1) _____
- 2) _____
- 3) _____
- 4) _____

14. OUTCOME SUMMARY

THIS COMMUNITY ENGAGEMENT EVENT WAS: *Choose one from each category*

- USEFUL
- NOT USEFUL
- EFFECTIVE
- NOT EFFECTIVE
- TIME CONSUMING
- NOT TIME CONSUMING
- SUSTAINABLE
- NOT SUSTAINABLE

16. FURTHER COMMENTS

Tools – SET A2

Compilation of Clinical Trial Data

When to complete

- Monthly.
- This form is to be compiled monthly - at the end of each month and the information should be extracted from clinical trial recruitment and retention data.

Number to complete

- There is no defined sample size.
- The more committed you are to extracting the clinical data and developing your own system to ensure it is done efficiently, means that you will have a complete data set which will have more value in the long term.
- The richer your M&E Data will be and the greater the justification for your work and its potential impact on trial outcomes.

Estimated Time

- 15 minutes to 30 minutes – including planning access to data with your data management team.

TOOL A2 – Clinical Trial Data Extraction Form

Instructions: This form is to be compiled monthly - at the end of each month and the information should be extracted from clinical trial recruitment and retention data.

SECTION 1: GENERAL INFORMATION		
A2 - 1.0	NAME OF TRIAL	
A2 - 1.1	NAME OF SITE – STUDY LOCATION	
A2 - 1.2	PROTOCOL/SUB-STUDY NUMBER	
A2 - 1.3	MONTH BEING COMPILED <i>(all data will be collected about this month)</i> Choose one:	<input type="checkbox"/> JANUARY <input type="checkbox"/> FEBRUARY <input type="checkbox"/> MARCH <input type="checkbox"/> APRIL <input type="checkbox"/> MAY <input type="checkbox"/> JUNE <input type="checkbox"/> JULY <input type="checkbox"/> AUGUST <input type="checkbox"/> SEPTEMBER <input type="checkbox"/> OCTOBER <input type="checkbox"/> NOVEMBER <input type="checkbox"/> DECEMBER
A2 - 1.4	YEAR	20__ __
A2 - 1.5	YEAR OF TRIAL <i>Choose one</i>	<input type="checkbox"/> YEAR ONE OF TRIAL <input type="checkbox"/> YEAR TWO OF TRIAL <input type="checkbox"/> YEAR THREE OF TRIAL <input type="checkbox"/> YEAR FOUR OF TRIAL
A2 - 1.6	NAME OF PERSON COMPILING	

SECTION 2: CLINICAL TRIAL STAGES FOR THE MONTH

Check each stage that has occurred during the month. You may choose multiple. Some of these stages may take place abroad and you may or may not have been involved. However, if you know that these stages took place during the MONTH that you are compiling, and then focus on that stage.

Section 3 applies only to **REC** – For recruiting, **RET-ADH** – Retention and Adherence and **PFU** – Participant follow up

<input type="checkbox"/> F – Formative work	<input type="checkbox"/> RET-ADH – Retention and Adherence
<input type="checkbox"/> PD – Protocol review/development	<input type="checkbox"/> PFU – Participant follow up
<input type="checkbox"/> PR – Protocol review	<input type="checkbox"/> END REC – End of recruitment
<input type="checkbox"/> TS – Training staff in protocol use	<input type="checkbox"/> END DU – End of study drug use
<input type="checkbox"/> SS – Site selection	<input type="checkbox"/> END TR – End of Trial
<input type="checkbox"/> CE – Community Entry	<input type="checkbox"/> DA – Data Analysis
<input type="checkbox"/> SA – Site Activation	<input type="checkbox"/> CT – POST TRIAL ACCESS TO CARE/ Compassionate Treatment
<input type="checkbox"/> REC – For recruiting	<input type="checkbox"/> DIS PRELIM – dissemination of preliminary results
	<input type="checkbox"/> DIS FINAL – dissemination of final results

SECTION 3: CLINICAL TRIAL RECORDS		
A2 - 1.6	Number of participants you are expected to enrol this month (this is the monthly target).	<input type="text"/> <input type="text"/> <input type="text"/>
A2 - 1.7	Number of potential participants screened this month.	<input type="text"/> <input type="text"/> <input type="text"/>
A2 - 1.8	Number of participants actually enrolled into the trial this month (this is not cumulative).	<input type="text"/> <input type="text"/> <input type="text"/>
A2 - 1.8 a	Zone/Region/ _____ Number of potential participants screened this month from this zone/region/ward (ADD up to 12).	<input type="text"/> <input type="text"/> <input type="text"/>
A2 - 1.8 b	Recruiting Facility _____ Number of potential participants screened this month for the trial at this facility (ADD up to 12 recruiting facilities).	<input type="text"/> <input type="text"/> <input type="text"/>
A2 - 1.9	Success of enrolment for this month - % of expected participants actually enrolled (an indication of how well targets are being met).	<input type="text"/> <input type="text"/> <input type="text"/>
A2 - 1.9 a	Outcome of screening - % of cumulative Number of potential participants screened by the trial this month divided by the Number of participants actually enrolled on the trial this month.	<input type="text"/> <input type="text"/> <input type="text"/>
A2 - 1.10	Cumulative Number of expected enrolment on the trial up to and including this month.	<input type="text"/> <input type="text"/> <input type="text"/>
A2 - 1.11	Cumulative Number of potential participants screened by the trial up to and including this month.	<input type="text"/> <input type="text"/> <input type="text"/>
A2 - 1.12	Cumulative Number of participants actually enrolled on the trial up to and including this month.	<input type="text"/> <input type="text"/> <input type="text"/>
A2 - 1.13	Cumulative Number of participants retained on the trial up to and including this month.	<input type="text"/> <input type="text"/> <input type="text"/>
A2 - 1.14	Success of enrolment for the trial - % of expected enrolment on the trial up to and including this month divided by Cumulative Number of participants actually enrolled on the trial up to and including this month.	<input type="text"/> <input type="text"/> <input type="text"/>
A2 - 1.15	Outcome of screening - % of cumulative Number of potential participants screened by the trial up to and including this month divided by Cumulative Number of participants actually enrolled on the trial up to and including this month.	<input type="text"/> <input type="text"/> <input type="text"/>
A2 - 1.16	Number of participants who kept appointments this month Inside Window Outside Window	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/>
A2 - 1.17	Number of participants who missed appointments this month	<input type="text"/> <input type="text"/> <input type="text"/>
A2 - 1.18	Cumulative Number of defaulters or lost to follow up on the trial up until and including this month	<input type="text"/> <input type="text"/> <input type="text"/>
A2 - 1.19	Comments:	

Tools – SET A3

Inventory of CSE alongside GPP Guidelines

When to complete

- Monthly.
- This form is to be compiled monthly - at the end of each month and the information should be extracted from your notes and minutes.

Number to complete

- One form per month addressing all GPP alignment and linkages.

Estimated Time

- 10 minutes.

TOOL A3 – Compilation of Clinical Trial Data

Instructions: This form is to be compiled monthly - at the end of each month and the information should be extracted from clinical trial recruitment and retention data.

SECTION 1: GENERAL INFORMATION		
A3 - 1.0	NAME OF TRIAL	
A3 - 1.1	PROTOCOL/SUB-STUDY NUMBER	
A3 - 1.2	STUDY SITE	
A3 - 1.3	MONTH BEING COMPILED <i>(all data will be collected about this month)</i> Choose one:	<input type="checkbox"/> JANUARY <input type="checkbox"/> FEBRUARY <input type="checkbox"/> MARCH <input type="checkbox"/> APRIL <input type="checkbox"/> MAY <input type="checkbox"/> JUNE <input type="checkbox"/> JULY <input type="checkbox"/> AUGUST <input type="checkbox"/> SEPTEMBER <input type="checkbox"/> OCTOBER <input type="checkbox"/> NOVEMBER <input type="checkbox"/> DECEMBER
A3 - 1.4	YEAR	20__ __
A3 - 1.5	YEAR OF TRIAL <i>Choose one</i>	<input type="checkbox"/> YEAR ONE OF TRIAL <input type="checkbox"/> YEAR TWO OF TRIAL <input type="checkbox"/> YEAR THREE OF TRIAL <input type="checkbox"/> YEAR FOUR OF TRIAL
A3 - 1.6	PERSON COMPILING	

SECTION 2: INVENTORY of COMMUNITY ENGAGEMENT – Based on GPP Guidelines

Note - CSH – community stakeholders BSH – broader stakeholders

A3 - 1.6		SUGGESTIONS RECEIVED FROM CSE REGARDING FORMATIVE RESEARCH PROCESS			
A3 - 1.6-1	During the month was there CSH or BSH engagement of any kind in FORMATIVE RESEARCH PROCESS? <input type="checkbox"/> CSH <input type="checkbox"/> BSH <input type="checkbox"/> None				
A3 - 1.6-2	If yes, please enter how many engagements?	CSH <input type="text"/> <input type="text"/> BSH <input type="text"/> <input type="text"/> N/A – none (skip to A3 1.5-5)			
A3 - 1.6-3	If yes, were the engagements above managed internationally, regionally, nationally or locally? <i>(enter frequency for the month for each)</i>		CSH	BSH	
		Internationally	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>	
		Nationally	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>	
		Regionally	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>	
		Locally	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>	
A3 - 1.6-4	If yes, through which different mechanisms? (e.g. community scientific subcommittee, concept presentation to CAB, etc). <i>(enter frequency for the month for each)</i>		Frequency of Different Mechanisms		
		Community Scientific Subcommittee	<input type="text"/> <input type="text"/>		
		Other Community Structures	<input type="text"/> <input type="text"/>		
		CAB/CAG/CR	<input type="text"/> <input type="text"/>		
		Other _____	<input type="text"/> <input type="text"/>		
A3 - 1.6-5	Describe any suggestion made DURING THE MONTH specifically by the CSH and BSH regarding the FORMATIVE RESEARCH PROCESS. And indicate with a Y if it was acted upon.		Acted Upon (Y)		Acted Upon (Y)
		1)		6)	
		2)		7)	
		3)		8)	
		4)		9)	
		5)		10)	
A3 - 1.7		SUGGESTIONS RECEIVED FROM CSE REGARDING TRIAL PROTOCOL DEVELOPMENT			
A3 - 1.7-1	During the month was there CSH or BSH engagement of any kind in FORMATIVE RESEARCH PROCESS? <input type="checkbox"/> CSH <input type="checkbox"/> BSH <input type="checkbox"/> None				
A3 - 1.7-2	If yes, please enter how many engagements?	CSH <input type="text"/> <input type="text"/> BSH <input type="text"/> <input type="text"/> N/A – none (skip to A3 1.5-5)			
A3 - 1.7-3	If yes, were the engagements above managed internationally, regionally, nationally or locally? <i>(enter frequency for the month for each)</i>		CSH	BSH	
		Internationally	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>	
		Nationally	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>	
		Regionally	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>	
		Locally	<input type="text"/> <input type="text"/>	<input type="text"/> <input type="text"/>	
A3 - 1.7-4	If yes, through which different mechanisms? (e.g. community scientific subcommittee, concept presentation to CAB, etc). <i>(enter frequency for the month for each)</i>		Frequency of Different Mechanisms		
		Community Scientific Subcommittee	<input type="text"/> <input type="text"/>		
		Other Community Structures	<input type="text"/> <input type="text"/>		
		CAB/CAG/CR	<input type="text"/> <input type="text"/>		
		Other _____	<input type="text"/> <input type="text"/>		
A3 - 1.7-5	Describe any suggestion made DURING THE MONTH specifically by the CSH and BSH regarding the TRIAL PROTOCOL DEVELOPMENT? And indicate with a Y if it was acted upon.		Acted Upon (Y)		Acted Upon (Y)
		1)		6)	
		2)		7)	
		3)		8)	
		4)		9)	
		5)		10)	

A3 - 1.8		SUGGESTIONS RECEIVED FROM CSE REGARDING INFORMED CONSENT FORMS AND PROCESSES					
A3 - 1.8-1	During the month was there CSH or BSH engagement of any kind in INFORMED CONSENT FORMS AND PROCESSES ? <input type="checkbox"/> CSH <input type="checkbox"/> BSH <input type="checkbox"/> None						
A3 - 1.8-2	If yes, please enter how many engagements?	CSH <input type="checkbox"/> <input type="checkbox"/> BSH <input type="checkbox"/> <input type="checkbox"/> N/A – none (skip to A3 1.7-5)					
A3 - 1.8-3	If yes, were the engagements above managed internationally, regionally, nationally or locally? <i>(enter frequency for the month for each)</i>		CSH		BSH		
		Internationally	<input type="checkbox"/> <input type="checkbox"/>		<input type="checkbox"/> <input type="checkbox"/>		
		Nationally	<input type="checkbox"/> <input type="checkbox"/>		<input type="checkbox"/> <input type="checkbox"/>		
		Regionally	<input type="checkbox"/> <input type="checkbox"/>		<input type="checkbox"/> <input type="checkbox"/>		
		Locally	<input type="checkbox"/> <input type="checkbox"/>		<input type="checkbox"/> <input type="checkbox"/>		
A3 - 1.8-4	If yes, through which different mechanisms? (e.g. community scientific subcommittee, concept presentation to CAB, etc). <i>(enter frequency for the month for each)</i>	Frequency of Different Mechanisms					
		Community Scientific Subcommittee	<input type="checkbox"/> <input type="checkbox"/>				
		Other Community Structures	<input type="checkbox"/> <input type="checkbox"/>				
		CAB/CAG/CR	<input type="checkbox"/> <input type="checkbox"/>				
		Other _____	<input type="checkbox"/> <input type="checkbox"/>				
A3 - 1.8-5	Describe any suggestion made DURING THE MONTH specifically by the CSH and BSH regarding the INFORMED CONSENT FORMS AND PROCESSES . And indicate with a Y if it was acted upon.		Acted Upon (Y)			Acted Upon (Y)	
		1)		6)			
		2)		7)			
		3)		8)			
		4)		9)			
		5)		10)			
A3 - 1.9		SUGGESTIONS RECEIVED FROM CSE REGARDING COMMUNICATIONS PLAN					
A3 - 1.9-1	During the month was there CSH or BSH engagement of any kind about COMMUNICATIONS PLAN ? <input type="checkbox"/> CSH <input type="checkbox"/> BSH <input type="checkbox"/> None						
A3 - 1.9-2	If yes, please enter how many engagements?	CSH <input type="checkbox"/> <input type="checkbox"/> BSH <input type="checkbox"/> <input type="checkbox"/> N/A – none (skip to A3 1.8-5)					
A3 - 1.9-3	If yes, were the engagements above managed internationally, regionally, nationally or locally? <i>(enter frequency for the month for each)</i>		CSH		BSH		
		Internationally	<input type="checkbox"/> <input type="checkbox"/>		<input type="checkbox"/> <input type="checkbox"/>		
		Nationally	<input type="checkbox"/> <input type="checkbox"/>		<input type="checkbox"/> <input type="checkbox"/>		
		Regionally	<input type="checkbox"/> <input type="checkbox"/>		<input type="checkbox"/> <input type="checkbox"/>		
		Locally	<input type="checkbox"/> <input type="checkbox"/>		<input type="checkbox"/> <input type="checkbox"/>		
A3 - 1.9-4	If yes, through which different mechanisms? (e.g. community scientific subcommittee, concept presentation to CAB, etc). <i>(enter frequency for the month for each)</i>	Frequency of Different Mechanisms					
		Community Scientific Subcommittee	<input type="checkbox"/> <input type="checkbox"/>				
		Other Community Structures	<input type="checkbox"/> <input type="checkbox"/>				
		CAB/CAG/CR	<input type="checkbox"/> <input type="checkbox"/>				
		Other _____	<input type="checkbox"/> <input type="checkbox"/>				
A3 - 1.9-5	Describe any suggestion made DURING THE MONTH specifically by the CSH and BSH regarding the COMMUNICATIONS PLAN ? And indicate with a Y if it was acted upon.		Acted Upon (Y)			Acted Upon (Y)	
		1)		6)			
		2)		7)			
		3)		8)			
		4)		9)			
		5)		10)			

A3 - 1.10		SUGGESTIONS RECEIVED FROM CSE REGARDING TRIAL RESULTS DISSEMINATION			
A3 - 1.10-1	During the month was there CSH or BSH engagement of any kind in TRIAL RESULTS DISSEMINATION ? <input type="checkbox"/> CSH <input type="checkbox"/> BSH <input type="checkbox"/> None				
A3 - 1.10-2	If yes, please enter how many engagements?	CSH <input type="checkbox"/> <input type="checkbox"/> BSH <input type="checkbox"/> <input type="checkbox"/> N/A – none (skip to A3 1.9-5)			
A3 - 1.10-3	If yes, were the engagements above managed internationally, regionally, nationally or locally? <i>(enter frequency for the month for each)</i>		CSH		BSH
		Internationally	<input type="checkbox"/> <input type="checkbox"/>		<input type="checkbox"/> <input type="checkbox"/>
		Nationally	<input type="checkbox"/> <input type="checkbox"/>		<input type="checkbox"/> <input type="checkbox"/>
		Regionally	<input type="checkbox"/> <input type="checkbox"/>		<input type="checkbox"/> <input type="checkbox"/>
A3 - 1.10-4	If yes, through which different mechanisms? (e.g. community scientific subcommittee, concept presentation to CAB, etc). <i>(enter frequency for the month for each)</i>		Frequency of Different Mechanisms		
		Community Scientific Subcommittee	<input type="checkbox"/> <input type="checkbox"/>		
		Other Community Structures	<input type="checkbox"/> <input type="checkbox"/>		
		CAB/CAG/CR	<input type="checkbox"/> <input type="checkbox"/>		
A3 - 1.10-5	Describe any suggestion made DURING THE MONTH specifically by the CSH and BSH regarding the TRIAL RESULTS DISSEMINATION . And indicate with a Y if it was acted upon.		Acted Upon (Y)		Acted Upon (Y)
		1)			6)
		2)			7)
		3)			8)
		4)			9)
		5)			10)
A3 - 1.11		SUGGESTIONS RECEIVED FROM CSE REGARDING DEVELOPMENT OF ISSUES PLAN			
A3 - 1.11-1	During the month was there CSH or BSH engagement of any kind about DEVELOPMENT OF ISSUES PLAN ? <input type="checkbox"/> CSH <input type="checkbox"/> BSH <input type="checkbox"/> None				
A3 - 1.11-2	If yes, please enter how many engagements?	CSH <input type="checkbox"/> <input type="checkbox"/> BSH <input type="checkbox"/> <input type="checkbox"/> N/A – none (skip to A3 1.10-5)			
A3 - 1.11-3	If yes, were the engagements above managed internationally, regionally, nationally or locally? <i>(enter frequency for the month for each)</i>		CSH		BSH
		Internationally	<input type="checkbox"/> <input type="checkbox"/>		<input type="checkbox"/> <input type="checkbox"/>
		Nationally	<input type="checkbox"/> <input type="checkbox"/>		<input type="checkbox"/> <input type="checkbox"/>
		Regionally	<input type="checkbox"/> <input type="checkbox"/>		<input type="checkbox"/> <input type="checkbox"/>
A3 - 1.11-4	If yes, through which different mechanisms? (e.g. community scientific subcommittee, concept presentation to CAB, etc). <i>(enter frequency for the month for each)</i>		Frequency of Different Mechanisms		
		Community Scientific Subcommittee	<input type="checkbox"/> <input type="checkbox"/>		
		Other Community Structures	<input type="checkbox"/> <input type="checkbox"/>		
		CAB/CAG/CR	<input type="checkbox"/> <input type="checkbox"/>		
A3 - 1.11-5	Describe any suggestion made DURING THE MONTH specifically by the CSH and BSH regarding the DEVELOPMENT OF ISSUES PLAN ? And indicate with a Y if it was acted upon.		Acted Upon (Y)		Acted Upon (Y)
		1)			6)
		2)			7)
		3)			8)
		4)			9)
		5)			10)

A3 - 1.12		SUGGESTIONS RECEIVED FROM CSE REGARDING PROCEDURES FOR PARTICIPANT EXIT FROM TRIAL			
A3 - 1.12-1	During the month was there CSH or BSH engagement of any kind in <u>PROCEDURES FOR PARTICIPANT EXIT FROM TRIAL</u> ? <input type="checkbox"/> CSH <input type="checkbox"/> BSH <input type="checkbox"/> None				
A3 - 1.12-2	If yes, please enter how many engagements?	CSH <input type="checkbox"/> <input type="checkbox"/> BSH <input type="checkbox"/> <input type="checkbox"/> N/A – none (skip to A3 1.11-5)			
A3 - 1.12-3	If yes, were the engagements above managed internationally, regionally, nationally or locally? <i>(enter frequency for the month for each)</i>		CSH	BSH	
		Internationally	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>	
		Nationally	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>	
		Regionally	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>	
A3 - 1.12-4	If yes, through which different mechanisms? (e.g. community scientific subcommittee, concept presentation to CAB, etc). <i>(enter frequency for the month for each)</i>		Frequency of Different Mechanisms		
		Community Scientific Subcommittee	<input type="checkbox"/> <input type="checkbox"/>		
		Other Community Structures	<input type="checkbox"/> <input type="checkbox"/>		
		CAB/CAG/CR	<input type="checkbox"/> <input type="checkbox"/>		
A3 - 1.12-5	Describe any suggestion made DURING THE MONTH specifically by the CSH and BSH regarding the <u>PARTICIPANT EXIT FROM TRIAL</u> . And indicate with a Y if it was acted upon.		Acted Upon (Y)		Acted Upon (Y)
		1)		6)	
		2)		7)	
		3)		8)	
		4)		9)	
		5)		10)	
A3 - 1.13		SUGGESTIONS RECEIVED FROM CSE REGARDING INTERVENTION AND TRIAL PRODUCT IMPLEMENTATION			
A3 - 1.13-1	During the month was there CSH or BSH engagement of any kind about <u>INTERVENTION AND TRIAL PRODUCT IMPLEMENTATION</u> ? <input type="checkbox"/> CSH <input type="checkbox"/> BSH <input type="checkbox"/> None				
A3 - 1.13-2	If yes, please enter how many engagements?	CSH <input type="checkbox"/> <input type="checkbox"/> BSH <input type="checkbox"/> <input type="checkbox"/> N/A – none (skip to A3 1.12-5)			
A3 - 1.13-3	If yes, were the engagements above managed internationally, regionally, nationally or locally? <i>(enter frequency for the month for each)</i>		CSH	BSH	
		Internationally	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>	
		Nationally	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>	
		Regionally	<input type="checkbox"/> <input type="checkbox"/>	<input type="checkbox"/> <input type="checkbox"/>	
A3 - 1.13-4	If yes, through which different mechanisms? (e.g. community scientific subcommittee, concept presentation to CAB, etc). <i>(enter frequency for the month for each)</i>		Frequency of Different Mechanisms		
		Community Scientific Subcommittee	<input type="checkbox"/> <input type="checkbox"/>		
		Other Community Structures	<input type="checkbox"/> <input type="checkbox"/>		
		CAB/CAG/CR	<input type="checkbox"/> <input type="checkbox"/>		
A3 - 1.13-5	Describe any suggestion made DURING THE MONTH specifically by the CSH and BSH regarding the <u>INTERVENTION AND TRIAL PRODUCT IMPLEMENTATION</u> ? And indicate with a Y if it was acted upon.		Acted Upon (Y)		Acted Upon (Y)
		1)		6)	
		2)		7)	
		3)		8)	
		4)		9)	
		5)		10)	

Linkages

For each type of linkage, choose YES (Y) or No (N) if linkage has been made during the MONTH. If yes, indicate how many of each nature.

Q# A3- 1.14	QUESTION Kind of linkages with CSH & BSH based structures		Nature of Linkages				
			Very strong	Strong	Average	Weak	Very Weak
A3- 1.14-1	NEW Linkages with Community Based Organisations.	Y N	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
A3- 1.14-2	NEW Linkages with Civil Society Organizations.	Y N	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
A3- 1.14-3	NEW Linkages with Professional Associations.	Y N	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
A3- 1.14-4	NEW Linkages with Tertiary Institutions/ Vocational.	Y N	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
A3- 1.14-5	NEW Linkages with Secondary Schools.	Y N	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
A3- 1.14-6	NEW Linkages with Primary Schools.	Y N	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
A3- 1.14-7	NEW Linkages with Industries /Shops/ Markets.	Y N	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
A3- 1.14-8	NEW Linkages with Faith Based Organizations – churches/mosques/ temples etc.	Y N	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
A3- 1.14-9	NEW Linkages with clinics and hospitals.	Y N	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
A3- 1.14-10	Other NEW Linkages.	Y N	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

INFORMATION GIVING - List the number and types of information giving conducted during the month

A3- 1.15	QUESTION Kind of Trainings Conducted		
	TYPE OF TRAINING this month	NUMBER OF TRAININGS this month	DETAILS OF TRAINING this month
A3- 1.15-1		<input type="checkbox"/> <input type="checkbox"/>	
A3- 1.15-2		<input type="checkbox"/> <input type="checkbox"/>	
A3- 1.15-3		<input type="checkbox"/> <input type="checkbox"/>	
A3- 1.15-4		<input type="checkbox"/> <input type="checkbox"/>	
A3- 1.15-5		<input type="checkbox"/> <input type="checkbox"/>	
A3- 1.15-6		<input type="checkbox"/> <input type="checkbox"/>	
A3- 1.15-7		<input type="checkbox"/> <input type="checkbox"/>	
A3- 1.15-8		<input type="checkbox"/> <input type="checkbox"/>	
A3- 1.15-9		<input type="checkbox"/> <input type="checkbox"/>	

Tools – SET B1

Community Stakeholder Interview

When to complete

- Monthly - Quarterly.

Target

- Community based organisations (CBOs), the families and friends of trial participants, schools, trial site staff, local religious institutions, traditional leaders, local health service providers, home care workers from each relevant location or region represented in your trials' catchment area – or as seen appropriate by your team.
- Be reminded that this interview is not targeting broader stakeholders (form B3) – which would include non-governmental organisations (NGOs), local health department directors, managers or policy makers, politicians, local media and medical professionals.

Number to complete

- There is no defined sample size – however we suggest that you conduct a minimum of 2 per month.
- This will spur you on to actively reach out to new stakeholders every month.
- The more committed you are to scheduling key informant interviews with a wide array of community stakeholders and enquiring about their experience or lack of experience with your unit or trial, means that over time you will have a rich data set which will have more value in the long term.
- The richer your M&E Data will be and the greater the justification for your work and its potential impact on trial outcomes.

Key terms for this tool

- Post Code: Coding is an analytical process in which both quantitative (such as questionnaires) and qualitative (such as narratives) data are categorised to facilitate analysis. In the case of these questionnaires, you are required to record the narrative of the respondent, word for word and then post code or select the applicable code that corresponds with the response.

Estimated Time

- ½ hour.

TOOL B1 – COMMUNITY STAKEHOLDER INTERVIEW

SECTION 1: GENERAL INFORMATION		
B1 - 1.0	INTERVIEW NUMBER	
B1 - 1.1	NAME OF RESEARCH TRIAL PROTOCOL or SUB-STUDY NUMBER	
B1 - 1.2	STUDY SITE	
B1 - 1.3	DATE OF INTERVIEW	<input type="text"/> <input type="text"/> DAY <input type="text"/> <input type="text"/> MONTH <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> YEAR
B1 - 1.4	NAME OF INTERVIEWER	
B1 - 1.5	TIME INTERVIEW STARTED	<input type="text"/> <input type="text"/> HOUR <input type="text"/> <input type="text"/> MINUTE

Preamble: **Note to interviewer: Depending on your institutions rules, you may need to develop a consent form. Note – that this is a monitoring and evaluation tool and not a research tool.**

Hello – I am the community liaison officer/manager for this research unit. To be sure that we are communicating and engaging with the different stakeholders properly around our studies, we would like to speak to you to find out more about how you have been reached by this study. I have a few questions to ask you and request that you be completely honest in your reply. We need to hear what you know about these studies and how you were reached. This will help to make us better at effectively engaging with various stakeholders around the clinical research trials we are conducting. Thank you for your time.

SECTION 2: INTERVIEW			
B1 - 1.6	Mark the sex of the interviewee	Male	<input type="checkbox"/>
		Female	<input type="checkbox"/>
B1 - 1.7	What is the highest level of schooling you have completed?	I never attended school	<input type="checkbox"/>
		I did part of Primary – incomplete	<input type="checkbox"/>
		I completed Primary	<input type="checkbox"/>
		I did part of Secondary - incomplete	<input type="checkbox"/>
		I completed Secondary	<input type="checkbox"/>
		I attended College	<input type="checkbox"/>
		I attended University - Tertiary	<input type="checkbox"/>

B1 - 1.8	<p>Mark the kind of community or broader stakeholder this interviewee represents.</p> <p>You may not need to ask this question if you can establish the answer on your own.</p>	<p><i>Type your response and then match your response to a category below – if there is no match to your response, choose other.</i></p>	
		<p><i>NOTE – Do not use this questionnaire if the interviewee is a TRIAL PARTICIPANT (use C1), or a PROSPECTIVE TRIAL PARTICIPANT (use C2) or a CAB REPRESENTATIVE (use C1) OR BROADER STAKEHOLDER (use B3)</i></p>	
		INDIVIDUAL RESIDENT IN THE TARGET AREA	<input type="checkbox"/>
		COMMUNITY BASED ORGANISATION STAFF	<input type="checkbox"/>
		SCHOOL TEACHER	<input type="checkbox"/>
		YOUTH WORKER	<input type="checkbox"/>
		LOCAL HEALTH FACILITY STAFF	<input type="checkbox"/>
		TRADITIONAL HEALER	<input type="checkbox"/>
		LOCAL FAITH BASED LEADER	<input type="checkbox"/>
		LOCAL LEADERSHIP - TRADITIONAL	<input type="checkbox"/>
		COMMUNITY HEALTH WORKER	<input type="checkbox"/>
		Other (specify)	<input type="checkbox"/>
B1 - 1.9	<p>Do you know of or have you heard of the research unit I represent as a community liaison officer/manager?</p>	Yes	<input type="checkbox"/>
		No (SKIP TO)	<input type="checkbox"/>
B1 - 1.10 QUAL	<p>If you know - please share with me, what this organization/institute does in your community?</p>	<p><i>Type your response and then match your response to a category below – if there is no match to your response, choose other.</i></p>	
		<p>POSTCODE –select best option from below</p>	
		I don't know what your organisation/group/Institute does (NO to question above)	<input type="checkbox"/>
		Your organisation treats adults/or children who are sick	<input type="checkbox"/>
		Your organisation teaches/trains about health related issues	<input type="checkbox"/>
		Your organisation conducts health related (TB/HIV) prevention/treatment research	<input type="checkbox"/>
Other (specify)	<input type="checkbox"/>		
<p>If this person does not know what the research organisation does – please provide a thorough briefing at this point.</p>			
B1 - 1.11	<p>This organization works through clinics/health facilities to reach people - do you know where any of the research clinics are located?</p>	Yes	<input type="checkbox"/>
		No (SKIP TO B1 – 1.13)	<input type="checkbox"/>

B1 - 1.12	If yes, to the question above, where do you live relative to one of the research clinics?	I don't know the clinic is/I don't know about the research	<input type="checkbox"/>			
		5 – 15 minutes on foot	<input type="checkbox"/>			
		16 – 30 minutes by foot	<input type="checkbox"/>			
		>30 minutes by foot	<input type="checkbox"/>			
		5 – 15 minutes in a bus/taxi/daladala/matatu	<input type="checkbox"/>			
		16 – 30 minutes in a bus/taxi/daladala/matatu	<input type="checkbox"/>			
		>30 minutes in a bus/taxi/daladala/matatu	<input type="checkbox"/>			
		Note: if the respondent does not know about the research sites or does not know where the research sites are located – you may need to elaborate so the respondent can tell you where she or he lives in relation to one of the research sites.				
B1 - 1.13	How well known is the organization that is conducting the study in the community that you currently represent?	Very well known throughout my community	<input type="checkbox"/>			
		Well known in trial sites or around research clinics only	<input type="checkbox"/>			
		Only known by small groups of people	<input type="checkbox"/>			
		In general not known by people I mingle with	<input type="checkbox"/>			
		I can't answer – as I don't know about the work that this organization is doing/have never heard about this organisation	<input type="checkbox"/>			
		List of studies – indicated in Setup	S1	S2	S3	S4
B1 - 1.14	How well known do you think these studies are in the communities where you live? Note: list all the studies underway that you are responsible for as CLO	I don't know how well known this specific study is	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		The specific study is very well known throughout the target communities	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		The specific study is only known by small groups of people	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		In general the specific study is not known by anyone apart from trial participants	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		The specific study is only known by health staff who have been oriented to the study	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		The specific study is only known by health staff who have been oriented to the study AND trial participants	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		I can't answer – as I don't know about this specific study	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
B1 - 1.15 QUAL	This organisation carries out clinical research to improve the health of populations. Can you share anything you know about the research that this organisation conducts?	Type the response here.				
		I have never heard about the organisation or this specific research	<input type="checkbox"/>			
		List of studies – indicated in Setup	S1	S2	S2	S4
B1 - 1.16	How well do you think you understand the purpose of these research studies?	I know nothing about this research	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		I understand this trial very well – I have no questions	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		I understand their trial but I still have a few questions	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		I do not understand this trial – I have many questions	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

		List of studies – indicated in Setup	S1	S2	S3	S4
B1 - 1.17	How involved/engaged/occupied are you with the work /research – how often do you do something to do with this study?	Never	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		Every day	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		Every week at least once	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		Every month at least once	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		Every 3 months at least once	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		At least twice a year	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		Other (specify)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		List of studies – indicated in Setup	S1	S2	S3	S4
B1 - 1.18	Would you like to be more or less involved in these clinical trials?	MORE INVOLVED	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		THE SAME INVOLVEMENT	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		LESS INVOLVED	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		INDIFFERENT/DON'T CARE/DON'T KNOW ABOUT IT	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
B1 - 1.19 QUAL	Can you explain why you feel this way (referring to response above) and how you imagine, in your position you could support or be more involved with this research work?	Type the response here.				
B1 - 1.20	Are you very satisfied, satisfied, unsatisfied, very satisfied or indifferent about the way the research team on this trial consults with you as a community stakeholder?	No one consults with me/I have never heard about this research	<input type="checkbox"/>			
		Indifferent/Don't care	<input type="checkbox"/>			
		Unsatisfied	<input type="checkbox"/>			
		Satisfied	<input type="checkbox"/>			
		Very Satisfied	<input type="checkbox"/>			
B1 - 1.21 QUAL	Please tell me why you feel this way (as described in the above question)?	Type the response here.				
B1 - 1.22	Have you ever made suggestions to the researchers/research staff of this study about things they can do or change?	YES	<input type="checkbox"/>			
		NO (SKIP B1 - 1.24)	<input type="checkbox"/>			
		Not applicable as have never heard of this study before (SKIP B1 - 1.24)	<input type="checkbox"/>			
B1 - 1.23 QUAL	Please share any suggestions on how things could be changed to improve the way the trials are run in order to improve the relationship with the stakeholders, including health personnel or policy makers?	Type the response here.				
B1 - 1.24	Have you been aware of any negative messages about this study circulating in this or the surrounding community?	YES	<input type="checkbox"/>			
		NO (SKIP B1 - 1.26)	<input type="checkbox"/>			
		Not applicable as have never heard of this study before today (SKIP B1 - 1.25)	<input type="checkbox"/>			
B1 - 1.25 QUAL	Can you share any of the negative messages/rumours you may have heard about this study?	Type the response here.				

B1 - 1.26	Have you been aware of any positive messages about this study circulating in your community?	YES	<input type="checkbox"/>			
		NO	<input type="checkbox"/>			
		Not applicable as have never heard of this study before	<input type="checkbox"/>			
B1 - 1.27 QUAL	Can you share any of the positive messages you may have heard about this study?	Type the response here.				
B1 - 1.28	Over the past 6 months, how would you rate the strength of the community's relationship/ engagement with these various research projects?	Very Strong The community is involved in all (90 - 100%) aspects of the research, from planning through dissemination of the research.	<input type="checkbox"/>			
		Strong The community is involved in most (70 to 89%) aspects of the research but no necessarily all development and planning.	<input type="checkbox"/>			
		Medium The community is involved in about 60 to 70% of the research process.	<input type="checkbox"/>			
		Weak The community is involved in very few aspects (40 -60%) of the research activities.	<input type="checkbox"/>			
		Very Weak The community is involved in less than 40% of the research activities.	<input type="checkbox"/>			
		I don't know – Not in a position to judge	<input type="checkbox"/>			
		List of studies – indicated in Setup	S1	S2	S3	S4
B1 - 1.29	How did you first hear about this/these research studies?	I have never heard about any of these research studies	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		I heard about this research through a colleague	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		I heard about this research through a committee meeting	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		I heard about this research through the health department	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		I heard about this research through the radio/TV/ newspaper/posters/flyers	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		I heard about this research while at a health event	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		I heard about this research while at a health training	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		I was visited by the study reps at my place of work	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		I was informed by our coordinator/supervisor at work	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		I was informed when someone from the research unit visited my organisation/company/resource	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		I was informed through a conference/briefing workshop	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		Other (specify)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		List of studies – indicated in Setup	S1	S2	S3	S4
		B1 - 1.30	How often do you receive an update about this research?	I never receive updates	<input type="checkbox"/>	<input type="checkbox"/>
I receive updates – irregularly/from time to time	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I receive updates every day	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I receive updates every week	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I receive updates every two weeks	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I receive updates every month	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I receive updates every two months	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I receive updates every 3 months	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I receive updates every 4 – 6 months	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I receive updates once a year	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
I receive updates every few years	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
Other (specify)	<input type="checkbox"/>			<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

B1 - 1.31 QUAL	Which groups of people with whom you work do you think should know about this research?	<i>Type your response and then match your response to a category below – if there is no match to your response, choose other.</i>	
		POSTCODE –select best option from below –choose multiple	
		INDIVIDUAL RESIDENTS IN THE TARGET AREA	<input type="checkbox"/>
		PEOPLE AFFECTED BY THE DISEASE BEING STUDIED	<input type="checkbox"/>
		PEOPLE WHO WILL BENEFIT FROM THE INTERVENTION BEING STUDIED	<input type="checkbox"/>
		PEOPLE WHO MAY BE ELIGIBLE TO PARTICIPATE IN THE STUDY	<input type="checkbox"/>
		HEALTH ADVOCATE or ACTIVIST	<input type="checkbox"/>
		COMMUNITY BASED ORGANISATION STAFF	<input type="checkbox"/>
		NON GOVERNMENTAL ORGANISATION STAFF	<input type="checkbox"/>
		SCHOOL TEACHERS	<input type="checkbox"/>
		STUDENTS/CHILDREN	<input type="checkbox"/>
		LOCAL HEALTH FACILITY STAFF/HEALTH WORKERS /COMMUNITY HEALTH WORKERS	<input type="checkbox"/>
		LOCAL FAITH BASED LEADERS	<input type="checkbox"/>
		LOCAL LEADERSHIP – GOVERNMENT OR ELECTED	<input type="checkbox"/>
		LOCAL LEADERSHIP – TRADITIONAL	<input type="checkbox"/>
LOCAL – DEPARTMENT OF HEALTH STAFF/MANAGERS	<input type="checkbox"/>		
MEDIA PERSONNEL/JOURNALISTS	<input type="checkbox"/>		
LOCAL BUSINESS OWNERS/BUSINESSES	<input type="checkbox"/>		
LEGAL SPECIALISTS	<input type="checkbox"/>		
LOCAL POLICY MAKERS	<input type="checkbox"/>		
Other (specify)	<input type="checkbox"/>		
B1 - 1.32	Do you know a specific person or persons on the research team or at the research centre whom you could speak to about this study?	YES	<input type="checkbox"/>
		NO	<input type="checkbox"/>
B1 - 1.33	Do you know about the CAB – Community Advisory Board/Community Advisory Group/CR – community representatives (please use a term appropriate to your study or insert new term)?	YES	<input type="checkbox"/>
		NO (SKIP B1 - 1.35)	<input type="checkbox"/>
B1 - 1.34 QUAL	If you know about the CAG/CAB/CR please describe what you think its purpose is?	<i>Type the response here</i>	
B1 - 1.35	Time Interview Ended	<input type="checkbox"/> <input type="checkbox"/> HOUR <input type="checkbox"/> <input type="checkbox"/> MINUTE	
B1 - 1.36 QUAL	Observations – Comments Note down any further comments or impressions and any lessons learned that require further follow up or sharing		
	Observation 1	Any Follow up required	
	Observation 2	Any Follow up required	
	Observation 3	Any Follow up required	
	Observation 4	Any Follow up required	

Tools – SET B2

Community Advisory Group Member or Community Representative Interview

When to complete

- Monthly and Quarterly.

Target

- CAB Members or Community Representatives on a the advisory forum or the equivalent.

Number to complete

- There is no defined sample size – however we suggest that you conduct a minimum of 2 per month.
- This will spur you on to actively reach out to new stakeholders every month.
- The more committed you are to scheduling key informant interviews with a wide array of community stakeholders and enquiring about their experience or lack of experience with your unit or trial, means that over time you will have a rich data set which will have more value in the long term.
- The richer your M&E Data will be and the greater the justification for your work and its potential impact on trial outcomes.

Key terms for this tool

- Post Code: Coding is an analytical process in which both quantitative (such as questionnaires) and qualitative (such as narratives) data are categorised to facilitate analysis. In the case of these questionnaires, you are required to record the narrative of the respondent, word for word and then post code or select the applicable code that corresponds with the response.

Estimated Time

- ½ hour.

TOOL B2 – CAB - ADVISORY GROUP MEMBER OR COMMUNITY REPRESENTATIVE INTERVIEW

SECTION 1: GENERAL INFORMATION		
B2 - 1.0	INTERVIEW NUMBER	
B2 - 1.1	NAME OF RESEARCH TRIAL PROTOCOL/SUB-STUDY NUMBER	
B2 - 1.2	STUDY SITE	
B2 - 1.3	DATE OF INTERVIEW	<input type="text"/> <input type="text"/> DAY <input type="text"/> <input type="text"/> MONTH <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> YEAR
B2 - 1.4	NAME OF INTERVIEWER	
B2 - 1.5	TIME INTERVIEW STARTED	<input type="text"/> <input type="text"/> HOUR <input type="text"/> <input type="text"/> MINUTE

Preamble: **Note to interviewer: Depending on your institutions rules, you may need to develop a consent form. Note – that this is a monitoring and evaluation tool and not a research tool.**

Hello – I am the community liaison officer/manager for this research unit. To be sure that we are communicating and engaging with the different stakeholders properly around our studies, we would like to speak to you to find out more about how you have been reached by this study. I have a few questions to ask you and request that you be completely honest in your reply. We need to hear what you know about these studies and how you were reached. This will help to make us better at effectively engaging with various stakeholders around the clinical research trials we are conducting. Thank you for your time.

SECTION 2: INTERVIEW			
B2 - 1.6	Mark the sex of the interviewee	Male	<input type="checkbox"/>
		Female	<input type="checkbox"/>
B2 - 1.7	What year were you born in? (estimate adequate)		
B2 - 1.8	What is the highest level of schooling you have completed?	I never attended school	<input type="checkbox"/>
		I did part of Primary – incomplete	<input type="checkbox"/>
		I completed Primary	<input type="checkbox"/>
		I did part of Secondary - incomplete	<input type="checkbox"/>
		I completed Secondary	<input type="checkbox"/>
		I attended College	<input type="checkbox"/>
		I attended University - Tertiary	<input type="checkbox"/>

B2 - 1.9	Mark the kind of community or broader stakeholder this interviewee represents.	<i>Type your response and then match your response to a category below – if there is no match to your response, choose other.</i>						
		NOTE – Do not use this questionnaire if the interviewee is a TRIAL PARTICIPANT (use C1), or a PROSPECTIVE TRIAL PARTICIPANT (use C2) or a CHS (use B1) or BHS (use B3)						
		INDIVIDUAL RESIDENT IN THE TARGET AREA						<input type="checkbox"/>
		ADVOCATE or ACTIVIST						<input type="checkbox"/>
		COMMUNITY BASED ORGANISATION STAFF						<input type="checkbox"/>
		SCHOOL TEACHER						<input type="checkbox"/>
		YOUTH WORKER						<input type="checkbox"/>
		LOCAL HEALTH FACILITY STAFF						<input type="checkbox"/>
		TRADITIONAL HEALER						<input type="checkbox"/>
		LOCAL FAITH BASED LEADER						<input type="checkbox"/>
		LOCAL LEADERSHIP – GOVERNMENT OR ELECTED						<input type="checkbox"/>
		LOCAL LEADERSHIP - TRADITIONAL						<input type="checkbox"/>
		COMMUNITY HEALTH WORKER						<input type="checkbox"/>
		LOCAL BUSINESS OWNERS						<input type="checkbox"/>
		LEGAL EXPERT						<input type="checkbox"/>
		MEDIA PERSONNEL/JOURNALISTS						<input type="checkbox"/>
		LOCAL POLICY MAKERS						<input type="checkbox"/>
LOCAL BUSINESS						<input type="checkbox"/>		
NON GOVERNMENTAL ORGANISATION STAFF						<input type="checkbox"/>		
Other (specify)						<input type="checkbox"/>		
B2 - 1.10	How many months or years have you participated on this study's advisory group - CAB?	0-3 months	4-6 months	7-12 months	13-24 months	2-3 years	>3 years	
		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
B2 - 1.11	What is your role as a CAB member?	<i>Type your response and then match your response to a category below – if there is no match to your response, choose other.</i>						
		POSTCODE – Choose all that apply.						
		TO PROVIDE INPUT ON CLINICAL TRIAL PLANS AND PROTOCOL						<input type="checkbox"/>
		TO CONSULT WITH THE RESEARCH TEAM – to gather opinions/ideas/suggestions from outside research circles						<input type="checkbox"/>
		TO OFFER OUR SUPPORT – to facilitate the research						<input type="checkbox"/>
		TO CREATE AWARENESS IN OUR SECTORS & KEEP OUR SECTORS INFORMED – to prevent rumours and resistance in the community						<input type="checkbox"/>
		TO BE AN EDUCATED RESOURCE ON THE RESEARCH						<input type="checkbox"/>
		TO HAVE THE RESEARCH TEAM LISTEN TO US & GATHER OUR FEEDBACK on how the study is being received in our communities						<input type="checkbox"/>
		Other (specify)						
		Other (specify)						

B2 - 1.12	How often does research team consult with you as a CAB?	Every month	<input type="checkbox"/>			
		Every two months	<input type="checkbox"/>			
		4 times a year	<input type="checkbox"/>			
		2- 3 times a year	<input type="checkbox"/>			
		Never	<input type="checkbox"/>			
B2 - 1.13	Where do you live relative to one of the research clinics? <i>Note: if the respondent does not know about the research sites or does not know where the research sites are located – you may need to elaborate.</i>	5 – 15 minutes on foot	<input type="checkbox"/>			
		16 – 30 minutes by foot	<input type="checkbox"/>			
		>30 minutes by foot	<input type="checkbox"/>			
		5 – 15 minutes in a bus/taxi/daladala/matatu	<input type="checkbox"/>			
		16 – 30 minutes in a bus/taxi/daladala/matatu	<input type="checkbox"/>			
		>30 minutes in a bus/taxi/daladala/matatu	<input type="checkbox"/>			
B2 - 1.14	How well known is the organization that is conducting the study in the community that you represent?	Very well known throughout my community	<input type="checkbox"/>			
		Well known in trial sites or around research clinics only	<input type="checkbox"/>			
		Only known by small groups of people	<input type="checkbox"/>			
		In general not known by people I mingle with	<input type="checkbox"/>			
		I can't answer – as I don't know about the work that this organization is doing/have never heard about this organisation	<input type="checkbox"/>			
		List of studies – indicated in Setup	S1	S2	S3	S4
B2- 1.15	How well known do you think these studies are in the communities or groups that you represent on the CAB? <i>Note to interviewer: Make sure to query using the list all the studies underway that you are responsible for as CLO.</i>	I don't know how well known this specific study is	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		The specific study is very well known throughout the target communities	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		The specific study is only known by small groups of people	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		In general the specific study is not known by anyone apart from trial participants	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		The specific study is only known by health staff who have been oriented to the study	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		The specific study is only known by health staff who have been oriented to the study AND trial participants	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		I can't answer – as I don't know about this specific study	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
B2 - 1.16 QUAL	This organisation carries out clinical research to improve the health of populations. Can you share anything you know about the research that this organisation conducts?	<i>Type your response and then match your response to a category below – if there is no match to your response, choose other.</i>				
		I have never heard about the organisation or this specific research	<input type="checkbox"/>			
		List of studies – indicated in Setup	S1	S2	S2	S4
B2 - 1.17	How well do you think you understand the purpose of these research studies?	I know nothing about this research	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		I understand this trial very well – I have no questions	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		I understand their trial but I still have a few questions	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		I do not understand this trial – I have many questions	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		List of studies – indicated in Setup	S1	S2	S2	S4
B2 - 1.18	How involved/engaged/occupied are you with the work /research – how often do you do something to do with this study?	Never	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		Every day	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		Every week at least once	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		Every month at least once	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

		Every 3 months at least once	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		At least twice a year	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		Other (specify)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		List of studies – indicated in Setup	S1	S2	S3	S4
B2 - 1.19	Would you like to be more or less involved in these clinical trials?	MORE INVOLVED	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		THE SAME INVOLVEMENT	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		LESS INVOLVED	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		INDIFFERENT/DON'T CARE/DON'T KNOW ABOUT IT	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
B2 - 1.20 QUAL	Can you explain why you feel this way (referring to response above) and how you imagine, in your position you could support or be more involved with this research work?	<i>Type your response and then match your response to a category below – if there is no match to your response, choose other</i>				
B2 - 1.21	How satisfied are you with the way the research team on this trial consults with you through the CAB?	No one consults with me/I have never heard about this research	<input type="checkbox"/>			
		Indifferent/Don't care	<input type="checkbox"/>			
		Unsatisfied	<input type="checkbox"/>			
		Satisfied	<input type="checkbox"/>			
		Very Satisfied	<input type="checkbox"/>			
B2 - 1.22 QUAL	Please tell me why you feel this way – very satisfied, satisfied, unsatisfied, indifferent /don't care (as described in the above question)?	<i>Type your response and then match your response to a category below – if there is no match to your response, choose other.</i>				
B2 - 1.23	Overall, since you joined the CAG/ CAB, have you ever made suggestions to the researchers/research staff of this study about things they can do or change?	YES	<input type="checkbox"/>			
		NO	<input type="checkbox"/>			
		DON'T KNOW	<input type="checkbox"/>			
B2 - 1.24 QUAL	Please explain your answer further – whether the research team has listened to your suggestions/made changes based on your suggestions.	Type the response here.				
B2 - 1.25	Have you been aware of any negative messages about this study circulating in this or the surrounding community?	YES	<input type="checkbox"/>			
		NO (SKIP B2 - 1.27)	<input type="checkbox"/>			
		Not applicable as have never heard of this study before today (SKIP B2 - 1.27)	<input type="checkbox"/>			
B2 - 1.26 QUAL	Can you share any of the negative messages/rumours you may have heard about this study?	Type the response here.				
B2 - 1.27	Have you been aware of any positive messages about this study circulating in your community?	YES	<input type="checkbox"/>			
		NO	<input type="checkbox"/>			
		Not applicable as have never heard of this study before today	<input type="checkbox"/>			
B2 - 1.28 QUAL	Can you share any of the positive messages you may have heard about this study?	Type the response here.				

B2 - 1.29	Over the past 6 months, how would you rate the strength of the community's relationship/ engagement with the research team?	Very Strong The community is involved in all (90 - 100%) aspects of the research, from planning through dissemination of the research.	<input type="checkbox"/>
		Strong The community is involved in most (71 to 89%) aspects of the research but no necessarily all development and planning.	<input type="checkbox"/>
		Medium The community is involved in about 60 to 70% of the research process.	<input type="checkbox"/>
		Weak The community is involved in very few aspects (40 - 59%) of the research activities.	<input type="checkbox"/>
		Very Weak The community is involved in less than 40% of the research activities.	<input type="checkbox"/>
		I don't know – Not in a position to judge	<input type="checkbox"/>
B2 - 1.30	How were you selected to participate in the CAG/CAB/CR?	I was asked to join by the research team based on my position in the community	<input type="checkbox"/>
		I was nominated/put forward/voted by people in the community/my sector	<input type="checkbox"/>
		I heard about the study & volunteered independently	<input type="checkbox"/>
		I am a leader in the community and I always represent the community	<input type="checkbox"/>
		Other (specify)	<input type="checkbox"/>
B2 - 1.31	Do you think the way in which people are selected to participate in the CAB is fair and effective?	YES	<input type="checkbox"/>
		NO	<input type="checkbox"/>
		DON'T KNOW – NOT SURE – NOT AWARE	<input type="checkbox"/>
B2 - 1.32 QUAL	Please share how you feel about how people are selected to participate in the CAG/CAB/CR?	Type the response here.	
B2 - 1.33	Do you think the people currently on the CAB represent all the important portions of the community who may be affected or may have an impact in an important way beyond this research study?	YES	<input type="checkbox"/>
		NO	<input type="checkbox"/>
		Don't know – not sure	<input type="checkbox"/>
B2 - 1.34	How satisfied are you with the way the CAB/ has worked as a study advisory structure during the last 6 months?	Very satisfied	<input type="checkbox"/>
		Satisfied	<input type="checkbox"/>
		Disappointed – Low satisfaction	<input type="checkbox"/>
		Unsatisfied	<input type="checkbox"/>
		Don't Know	<input type="checkbox"/>
B2 - 1.35 QUAL	Please share the way you feel about the way the CAB/CAG/CR works as an advisory structure?	Type the response here.	
B2 - 1.36	As a CAB member, do you feel that you are part of the research team, or an independent "watchdog" over the research?	I feel part of the research team	<input type="checkbox"/>
		I feel like an independent watchdog over the research	<input type="checkbox"/>
		I don't feel like I am part of the research nor do I feel like I am an independent watchdog over the research	<input type="checkbox"/>

B2 - 1.37	How much have you valued your participation in the CAB?	I have valued it greatly	<input type="checkbox"/>
		I have valued it	<input type="checkbox"/>
		I have valued it very little	<input type="checkbox"/>
		I have not valued it	<input type="checkbox"/>
		I am indifferent –I don't care	<input type="checkbox"/>
B2 - 1.38 QUAL	Please describe the reasons why you have valued or not valued your participation in the CAB?	Type the response here.	
B2 - 1.39	At present, how interested are you personally in this research study?	Very interested	<input type="checkbox"/>
		Interested	<input type="checkbox"/>
		Not interested	<input type="checkbox"/>
		Indifferent	<input type="checkbox"/>
B2 - 1.40 QUAL	Can you share why you are interested or not interested in the study?	Type the response here.	
B2 - 1.41	In general how much do you think the research team has trusted and valued the contribution of the CAB advisory group?	The research team has trusted and valued us	<input type="checkbox"/>
		The research team has not trusted and valued us	<input type="checkbox"/>
		DON'T KNOW – difficult to assess	<input type="checkbox"/>
B2 - 1.42	In general, how much do you think the members CAB have trusted and valued the research team?	In general we do trust and value the research team	<input type="checkbox"/>
		In general we do not trust and value the research team	<input type="checkbox"/>
		DON'T KNOW	<input type="checkbox"/>
B2 - 1.43 QUAL	Please can you explain to me in your own words why you feel this way (I trust the research team, I don't trust the research team; I am not sure – my opinion changes)	Type the response here.	
B2 - 1.44	Apart from the CAB have you met to discuss this study in any way on other occasions during the last 6 months?	YES	<input type="checkbox"/>
		NO	<input type="checkbox"/>
B2 - 1.45	In the last 6 months have you discussed this study in your community when you are going about your other business?	YES	<input type="checkbox"/>
		NO	<input type="checkbox"/>
B2 - 1.46	Do you believe that this study has brought any benefits to your community?	YES	<input type="checkbox"/>
		NO (SKIP B2-1.48)	<input type="checkbox"/>
		NOT YET (SKIP B2-1.48)	<input type="checkbox"/>
		DON'T KNOW (SKIP B2-1.48)	<input type="checkbox"/>
B2 - 1.47 QUAL	Please describe the benefits you think the study has brought. Note: if no benefits seen in Question above – leave empty.	Type the response here.	
B2 - 1.48	Has the study brought any problems to the communities that you represent?	YES	<input type="checkbox"/>
		NO (SKIP B2-1.49)	<input type="checkbox"/>
		NOT YET (SKIP B2-1.50)	<input type="checkbox"/>
		DON'T KNOW (SKIP B2-1.50)	<input type="checkbox"/>

B2 - 1.49 QUAL	Please describe the problems you think the study has brought to this community.	Type the response here.	
B2 - 1.50	Has the study brought any problems to since the beginning of this study do you see changes being made to the way in which the study is conducted based on the feedback from the CAB given during advisory meetings?	YES	<input type="checkbox"/>
		NO (SKIP B2-1.51)	<input type="checkbox"/>
		DON'T KNOW	<input type="checkbox"/>
B2 - 1.51 QUAL	If yes - can you list 1 to 3 changes you have seen the research make – based on the feedback that you or someone else in the CAB/CAG have given.	1)	
		2)	
		3)	
B2 - 1.52	How difficult or easy is it to reach someone on the research team if you have questions/concerns/suggestions you wish to share about the research trial?	Very Easy	<input type="checkbox"/>
		Easy	<input type="checkbox"/>
		Difficult	<input type="checkbox"/>
		Very Difficult	<input type="checkbox"/>
		I don't know - never tried	<input type="checkbox"/>
B2 - 1.53	If you have suggestions or advice for the study how would you go about letting the research team know?	1) I would call /sms the liaison person or the research hotline – I have their phone number!	<input type="checkbox"/>
		2) I would visit the community liaisons or research representative– I know where to go!	<input type="checkbox"/>
		3) I would write a letter or email – I know where to send it!	<input type="checkbox"/>
		4) I would mention this at the next CAB/CAG meeting – the meeting is scheduled!	<input type="checkbox"/>
		5) I cannot – there is no way to reach them	<input type="checkbox"/>
		6) I don't know what I would do – I don't have a plan/have not thought about this.	<input type="checkbox"/>
		7) OTHER	<input type="checkbox"/>
B2 - 1.54 QUAL	Please share with me any activities that the CAB carries out independently in the communities to support the research process?	The CAB/CAG does not carry out activities in the community to support the research	<input type="checkbox"/>
		Type the response here.	
B2 - 1.55	Time Interview Ended	<input type="checkbox"/> <input type="checkbox"/> HOUR <input type="checkbox"/> <input type="checkbox"/> MINUTE	
B2 - 1.56 QUAL	Observations – Comments Note down any further comments or impressions and any lessons learned that require further follow up or sharing.		
	Observation 1	Any Follow up required	
	Observation 1	Any Follow up required	
	Observation 1	Any Follow up required	
	Observation 1	Any Follow up required	

Tools – SET B3

Broader Stakeholder Interview

When to complete

- Monthly and Quarterly.

Target

- Broader Stakeholders - these include non-governmental organisations (NGOs), local health department directors, managers or policy makers, politicians, local media and medical professionals. Be reminded that this interview is not targeting community stakeholders.

Number to complete

- There is no defined sample size – however we suggest that you conduct a minimum of 2 per month, considering all the relevant locations or zones represented in your trials' catchment area – or as seen appropriate by your team.
- This will spur you on to actively reach out to new stakeholders every month.
- The more committed you are to scheduling key informant interviews with a wide array of community stakeholders and enquiring about their experience or lack of experience with your unit or trial, means that over time you will have a rich data set which will have more value in the long term.
- The richer your M&E Data will be and the greater the justification for your work and its potential impact on trial outcomes.

Key terms for this tool

- Post Code: Coding is an analytical process in which both quantitative (such as questionnaires) and qualitative (such as narratives) data are categorised to facilitate analysis. In the case of these questionnaires, you are required to record the narrative of the respondent, word for word and then post code or select the applicable code that corresponds with the response.

Estimated Time

- ½ hour.

TOOL B3 - BROADER STAKEHOLDER INTERVIEW

SECTION 1: GENERAL INFORMATION		
B3 - 1.0	INTERVIEW NUMBER	
B3 - 1.1	NAME OF RESEARCH TRIAL PROTOCOL/SUB-STUDY NUMBER	
B3 - 1.2	NAME OF LOCATION OR RESEARCH SITE	
B3 - 1.3	DATE OF INTERVIEW	<input type="text"/> <input type="text"/> DAY <input type="text"/> <input type="text"/> MONTH <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> YEAR
B3 - 1.4	NAME OF INTERVIEWER	
B3 - 1.5	TIME INTERVIEW STARTED	<input type="text"/> <input type="text"/> HOUR <input type="text"/> <input type="text"/> MINUTE

Preamble: **Note to interviewer: Depending on your institutions rules, you may need to develop a consent form. Note – that this is a monitoring and evaluation tool and not a research tool.**

Hello – I am the community liaison officer/manager for this research unit. To be sure that we are communicating and engaging with the different stakeholders properly around our studies, we would like to speak to you to find out more about how you have been reached by this study. I have a few questions to ask you and request that you be completely honest in your reply. We need to hear what you know about these studies and how you were reached. This will help to make us better at effectively engaging with various stakeholders around the clinical research trials we are conducting. Thank you for your time.

SECTION 2: INTERVIEW			
B3 - 1.6	Mark the sex of the interviewee	Male	<input type="checkbox"/>
		Female	<input type="checkbox"/>
B3 - 1.7	What is the highest level of schooling you have completed?	I never attended school	<input type="checkbox"/>
		I did part of Primary – incomplete	<input type="checkbox"/>
		I completed Primary	<input type="checkbox"/>
		I did part of Secondary - incomplete	<input type="checkbox"/>
		I completed Secondary	<input type="checkbox"/>
		I attended College	<input type="checkbox"/>
		I attended University - Tertiary	<input type="checkbox"/>
B3 - 1.8	Mark the kind of broader stakeholder this interviewee represents. <i>Note: You may not need to ask this question if you can establish the answer on your own.</i>	<i>Write your response and then match your response to a category below – if there is no match to your response, choose other</i>	
		NOTE – Do not use this questionnaire if the interviewee is a TRIAL PARTICIPANT (use C1), or a PROSPECTIVE TRIAL PARTICIPANT (use C2) or a CAB MEMBER (use B2)	
		LOCAL POLICY MAKER	<input type="checkbox"/>
		LOCAL LEGAL EXPERT/LAWYER ETC.	<input type="checkbox"/>
		MEDIA PERSONNEL/JOURNALISTS	<input type="checkbox"/>
		NON GOVERNMENTAL ORGANISATION	<input type="checkbox"/>
		LOCAL HEALTH DEPARTMENT MANAGER OR DIRECTOR	<input type="checkbox"/>
		LOCAL BUSINESS	<input type="checkbox"/>
Other (<i>specify</i>)	<input type="checkbox"/>		

B3 - 1.9	Apart from the CAB have you met to Do you know of or have you heard of the research unit I represent as a community liaison officer/manager?	YES	<input type="checkbox"/>			
		NO	<input type="checkbox"/>			
B3 - 1.10 QUAL	If you know - please share with me, what you think this organization/ institute does in your community?	<i>Type your response and then match your response to a category below – if there is no match to your response, choose other.</i>				
		POSTCODE – Choose all that apply.				
		I don't know what your organisation/group/Institute does (NO to question above)	<input type="checkbox"/>			
		Your organisation treats adults/or children who are sick				
		Your organisation teaches/trains about health related issues	<input type="checkbox"/>			
		Your organisation conducts health related (TB/HIV) prevention/ treatment research	<input type="checkbox"/>			
Other (specify)						
If this person does not know what the research organisation does – please provide a thorough briefing at this point.						
B3 - 1.11	This organization works through clinics/health facilities to reach people - do you know where any of the research clinics are located?	YES	<input type="checkbox"/>			
		NO	<input type="checkbox"/>			
B3 - 1.12	If yes, which facilities do you know about?	<i>Note: if the respondent does not know about the research sites or does not know where the research sites are located – you may need to elaborate so the respondent can tell you where she or he lives in relation to one of the research sites</i>				
B3- 1.13	How well known is the organization that is conducting the study in the community that you represent?	Very well known throughout my community	<input type="checkbox"/>			
		Well known in trial sites or around research clinics only	<input type="checkbox"/>			
		Only known by small groups of people	<input type="checkbox"/>			
		In general not known by people I mingle with	<input type="checkbox"/>			
		I can't answer – as I don't know about the work that this organization is doing/have never heard about this organisation	<input type="checkbox"/>			
		List of studies – indicated in Setup	S1	S2	S3	S4
B3- 1.14	How well known do you think these studies are in the communities being targeted? <i>Note: list all the studies underway that you are responsible for as CLO</i>	I don't know how well known this specific study is	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		The specific study is very well known throughout the target communities	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		The specific study is only known by small groups of people	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		In general the specific study is not known by anyone apart from trial participants	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		The specific study is only known by health staff who have been oriented to the study	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		The specific study is only known by health staff who have been oriented to the study AND trial participants	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		I can't answer – as I don't know about this specific study	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
B3 - 1.15 QUAL	This organisation carries out clinical research to improve the health of populations. Can you share anything you know about the research that this organisation conducts?	Write the response here.				
		I have never heard about the organisation or this specific research (Skip to B3 – 2.28)	<input type="checkbox"/>			

		List of studies – indicated in Setup	S1	S2	S2	S4
B3 - 1.16	How well do you think you understand the purpose of these research studies?	I know nothing about this research	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		I understand this trial very well – I have no questions	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		I understand their trial but I still have a few questions	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		I do not understand this trial – I have many questions	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		List of studies – indicated in Setup	S1	S2	S2	S4
B3 - 1.17	How involved/engaged/occupied are you with the work /research – how often do you do something to do with this study?	Never	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		Every day	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		Every week at least once	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		Every month at least once	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		Every 3 months at least once	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		At least twice a year	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		Other (specify)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		List of studies – indicated in Setup	S1	S2	S3	S4
B3 - 1.18	Would you like to be more or less involved in these clinical trials?	MORE INVOLVED	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		THE SAME INVOLVEMENT	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		LESS INVOLVED	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		INDIFFERENT/DON'T CARE/DON'T KNOW ABOUT IT	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
B3 - 1.19 QUAL	Can you explain why you feel this way (referring to response above) and how you imagine, in your position you could support or be more involved with this research work?	Write the response here.				
B3 - 1.20	In general, are you very satisfied, satisfied, unsatisfied, very satisfied or indifferent about the way this research institutions consults with you as a community stakeholder?	I have never heard about this research		<input type="checkbox"/>		
		Indifferent/Don't care		<input type="checkbox"/>		
		Unsatisfied		<input type="checkbox"/>		
		Satisfied		<input type="checkbox"/>		
		Very Satisfied		<input type="checkbox"/>		
B3 - 1.21 QUAL	Please tell me why you feel this way (as described in the above question)?	Write the response here.				
B3 - 1.22	Have you ever made suggestions to the researchers/research staff about things they can do or change in relation to any of the trials underway?	YES		<input type="checkbox"/>		
		NO (Skip to B3 – 1.24)		<input type="checkbox"/>		
		NO because I have never heard of these trials (Skip to B3 – 1.24)		<input type="checkbox"/>		
B2 - 1.23 QUAL	Please share any suggestions on how things could be changed to improve the way the trials are run in order to improve the relationship with the stakeholders, including health personnel or policy makers?	Write the response here.				

B3 - 1.24	Are you aware of any negative messages about this study circulating 3?	YES	<input type="checkbox"/>			
		NO (SKIP B3 - 1.26)	<input type="checkbox"/>			
		Not applicable as have never heard of this study before today (SKIP B3 - 1.26)	<input type="checkbox"/>			
B3 - 1.25 QUAL	Can you share any of the negative messages/rumours you may have heard about this study?	Write the response here.				
B3 - 1.26	Have you been aware of any positive messages about this study circulating in your community?	YES	<input type="checkbox"/>			
		NO	<input type="checkbox"/>			
		Not applicable - as never heard of this study before today	<input type="checkbox"/>			
B3 - 1.27 QUAL	Can you share any of the positive messages you may have heard about this study?	Write the response here.				
B3 - 1.28	Over the past 6 months, how would you rate the strength of your or your departments' engagement with these various research projects?	Very Strong We are involved in all (90 - 100%) aspects of the research, from planning through dissemination of the research.	<input type="checkbox"/>			
		Strong We are involved in most (71 to 89%) aspects of the research but no necessarily all development and planning.	<input type="checkbox"/>			
		Medium We are involved in about 60 to 70% of the research process.	<input type="checkbox"/>			
		Weak We are involved in very few aspects (40 - 59%) of the research activities.	<input type="checkbox"/>			
		Very Weak We are involved in less than 40% of the research activities.	<input type="checkbox"/>			
		I don't know – Not in a position to judge	<input type="checkbox"/>			
		List of studies – indicated in Setup	S1	S2	S3	S4
B3 - 1.29	How did you first hear about this/these research studies?	I have never heard about any of these research studies	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		I heard about this research through a colleague	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		I heard about this research through a committee meeting	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		I heard about this research through the health department	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		I heard about this research through the radio/TV/ newspaper/posters/flyers	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		I heard about this research while at a health event	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		I heard about this research while at a health training	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		I was visited by the study reps at my place of work	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		I was informed by our coordinator/supervisor at work	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		I was informed when someone from the research unit visited my organisation/company/resource	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		I was informed through a conference/briefing workshop	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		Other (specify)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

		List of studies – indicated in Setup	S1	S2	S3	S4
B3 - 1.30	How often do you receive an update about this research?	I never receive updates	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		I receive updates – irregularly/from time to time	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		I receive updates every day	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		I receive updates every week	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		I receive updates every two weeks	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		I receive updates every month	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		I receive updates every two months	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		I receive updates every 3 months	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		I receive updates every 4 – 6 months	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		I receive updates once a year	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		I receive updates every few years	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		Other (specify)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

B3 - 1.31 QUAL	Which groups of people with whom you work do you think should know about this research?	<i>Type your response and then match your response to a category below – if there is no match to your response, choose other.</i>	
		POSTCODE –select best option from below	
		INDIVIDUAL RESIDENTS IN THE TARGET AREA	<input type="checkbox"/>
		PEOPLE AFFECTED BY THE DISEASE BEING STUDIED	<input type="checkbox"/>
		PEOPLE WHO WILL BENEFIT FROM THE INTERVENTION BEING STUDIED	<input type="checkbox"/>
		PEOPLE WHO MAY BE ELIGIBLE TO PARTICIPATE IN THE STUDY	<input type="checkbox"/>
		HEALTH ADVOCATE or ACTIVIST	<input type="checkbox"/>
		COMMUNITY BASED ORGANISATION STAFF	<input type="checkbox"/>
		NON GOVERNMENTAL ORGANISATION STAFF	<input type="checkbox"/>
		SCHOOL TEACHERS	<input type="checkbox"/>
		STUDENTS/CHILDREN	<input type="checkbox"/>
		LOCAL HEALTH FACILITY STAFF/HEALTH WORKERS /COMMUNITY HEALTH WORKERS	<input type="checkbox"/>
		LOCAL FAITH BASED LEADERS	<input type="checkbox"/>
		LOCAL LEADERSHIP – GOVERNMENT OR ELECTED	<input type="checkbox"/>
		LOCAL LEADERSHIP – TRADITIONAL	<input type="checkbox"/>
		LOCAL – DEPARTMENT OF HEALTH STAFF/MANAGERS	<input type="checkbox"/>
MEDIA PERSONNEL/JOURNALISTS	<input type="checkbox"/>		
LOCAL BUSINESS OWNERS/BUSINESSES	<input type="checkbox"/>		
LEGAL SPECIALISTS	<input type="checkbox"/>		
LOCAL POLICY MAKERS	<input type="checkbox"/>		
Other (specify)	<input type="checkbox"/>		
B3 - 1.32	Do you know a specific person or persons on the research team or at the research centre whom you could speak to about this study?	YES	<input type="checkbox"/>
		NO	<input type="checkbox"/>
B3 - 1.33	Do you know about the CAB – community advisory board/Community Advisory Group/CR – community representatives (please use a term appropriate to your study or insert new term)?	YES	<input type="checkbox"/>
		NO (SKIP B3 - 1.35)	<input type="checkbox"/>
B3 - 1.34 QUAL	If you know about the Community Advisory Board please describe what you think its purpose is?	Write the response here.	
B3 - 1.35	Time Interview Ended	<input type="checkbox"/> <input type="checkbox"/> HOUR <input type="checkbox"/> <input type="checkbox"/> MINUTE	
B3 - 1.36 QUAL	Observations – Comments – Issues for Follow up		
	Observation 1	Any Follow up required	
	Observation 2	Any Follow up required	
	Observation 3	Any Follow up required	
	Observation 4	Any Follow up required	

Tools – SET C1

Trial Participant Interview

When to complete

- Monthly and Quarterly.

Target

- Enrolled Trial Participants at any stage of the trial.

Number to complete

- There is no defined sample size – however we suggest that you conduct a minimum of 2 trial participant interviews per month, factoring all the relevant locations or zones represented in your trials' catchment area – or as seen appropriate by your team.
- This will spur you on to actively reach out to trial participants each month and gauge their levels of engagement.

Key terms for this tool

- Post Code: Coding is an analytical process in which both quantitative (such as questionnaires) and qualitative (such as narratives) data are categorised to facilitate analysis. In the case of these questionnaires, you are required to record the narrative of the respondent, word for word and then post code or select the applicable code that corresponds with the response.

Estimated Time

- ½ hour.

TOOL C1 - TRIAL PARTICIPANT INTERVIEW

SECTION 1: GENERAL INFORMATION		
C1 - 1.0	INTERVIEW NUMBER	
C1 - 1.1	NAME OF RESEARCH TRIAL	
C1 - 1.2	PROTOCOL/SUB-STUDY NUMBER	
C1 - 1.3	NAME OF LOCATION OR RESEARCH SITE	
C1 - 1.4	DATE OF INTERVIEW	<input type="text"/> <input type="text"/> DAY <input type="text"/> <input type="text"/> MONTH <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> YEAR
C1 - 1.5	NAME OF INTERVIEWER	
C1 - 1.6	TIME INTERVIEW STARTED	<input type="text"/> <input type="text"/> HOUR <input type="text"/> <input type="text"/> MINUTE

Preamble: **Note to interviewer: Depending on your institutions rules, you may need to develop a consent form. Note – that this is a monitoring and evaluation tool and not a research tool.**

Hello – I am the community liaison officer/manager for this research unit. To be sure that we are communicating and engaging with the different stakeholders properly around our studies, we would like to speak to you to find out more about how you have been reached by this study. I have a few questions to ask you and request that you be completely honest in your reply. We need to hear what you know about these studies and how you were reached. This will help to make us better at effectively engaging with various stakeholders around the clinical research trials we are conducting. Thank you for your time.

SECTION 2: INTERVIEW			
C1 - 1.7	Mark the sex of the interviewee	Male	<input type="checkbox"/>
		Female	<input type="checkbox"/>
C1 - 1.8	What is the highest level of schooling you have completed?	I never attended school	<input type="checkbox"/>
		I did part of Primary – incomplete	<input type="checkbox"/>
		I completed Primary	<input type="checkbox"/>
		I did part of Secondary - incomplete	<input type="checkbox"/>
		I completed Secondary	<input type="checkbox"/>
		I attended College	<input type="checkbox"/>
		I attended University - Tertiary	<input type="checkbox"/>
C1 - 1.9	What did you come to the clinic for today?	A scheduled interview	<input type="checkbox"/>
		Scheduled Study Visit	<input type="checkbox"/>
		Unscheduled Medical Visit (illness, concern)	<input type="checkbox"/>
		Other	<input type="checkbox"/>
C1 - 1.10	Did you get the services you came for today?	YES	<input type="checkbox"/>
		NO	<input type="checkbox"/>
		NOT YET/ I have not been seen yet	<input type="checkbox"/>

C1 - 1.11 QUAL	<p>How do you feel about the overall quality of the services you got today?</p> <p>Once you have written the response you will be asked to select the postcode options that best match the answer.</p>	<p><i>Write the response here.</i> <i>Once you have written the response you will be asked to select the postcode options that best match the answer</i></p>	
		POSTCODE	
		Very Good Services	<input type="checkbox"/>
		Good Services	<input type="checkbox"/>
		Poor Services	<input type="checkbox"/>
		Very Poor Services	<input type="checkbox"/>
		NO	<input type="checkbox"/>
C1 - 1.12	<p>Are you aware that you are enrolled in a research study/clinical trial?</p>	Yes	<input type="checkbox"/>
		No (INTERRUPT INTERVIEW)	<input type="checkbox"/>
C1 - 1.13 QUAL	<p>Please describe how you first heard about this study or how were you first contacted by the study?</p>	<p><i>Write the response here.</i> <i>Once you have written the response you will be asked to select the postcode options that best match the answer</i></p>	
		POSTCODE	
		During a home visit	<input type="checkbox"/>
		Through a friend	<input type="checkbox"/>
		Through leaders in my community	<input type="checkbox"/>
		At the hospital/health centre/dispensary and then they referred me for screening	<input type="checkbox"/>
		During a community meeting	<input type="checkbox"/>
		Through the radio/television	<input type="checkbox"/>
		Through a poster	<input type="checkbox"/>
Other (specify)	<input type="checkbox"/>		
C1 - 1.14	<p>At the moment, how well do you think you understand this research in which you are enrolled and do you have questions about the study?</p>	I understand this study very well – I have no questions	<input type="checkbox"/>
		I understand this study – I still have a few questions	<input type="checkbox"/>
		I do not understand this study – I have many questions	<input type="checkbox"/>
		I know nothing about this study	<input type="checkbox"/>
C1 - 1.15	<p>Where do you live relative to one of the research clinics?</p> <p><i>Note: if the respondent does not know about the research sites or does not know where the research sites are located – you may need to elaborate.</i></p>	5 – 15 minutes on foot	<input type="checkbox"/>
		16 – 30 minutes by foot	<input type="checkbox"/>
		>30 minutes by foot	<input type="checkbox"/>
		5 – 15 minutes in a bus/taxi/daladala/matatu	<input type="checkbox"/>
		16 – 30 minutes in a bus/taxi/daladala/matatu	<input type="checkbox"/>
		>30 minutes in a bus/taxi/daladala/matatu	<input type="checkbox"/>

C1 - 1.16	How well known is this study in the community where you live?	Very well known throughout my community	<input type="checkbox"/>
		Well known around the research clinics only	<input type="checkbox"/>
		Only known by small groups of people within my community	<input type="checkbox"/>
		Only known by patients enrolled in the research or screened patients	<input type="checkbox"/>
		Not known by people in my community	<input type="checkbox"/>
		Other _____	<input type="checkbox"/>
C1 - 1.17	Do you think it's important for the study to inform certain people in the community while it is conducting research in or near your community?	YES	<input type="checkbox"/>
		NO (SKIP)	<input type="checkbox"/>
		DON'T KNOW – NOT SURE	<input type="checkbox"/>
C1 - 1.18 QUAL	Please share with me whom you think should know more about this study in your community?	<i>Write the response here. Once you have written the response you will be asked to select the postcode options that best match the answer</i>	
		POSTCODE - CHOOSE MANY	
		INDIVIDUAL RESIDENT IN THE TARGET AREA	<input type="checkbox"/>
		MY FRIENDS AND FAMILY or FRIENDS AND FAMILIES OF PARTICIPANTS	<input type="checkbox"/>
		PEOPLE IN NEED OF THE TREATMENT/CARE/PREVENTION	<input type="checkbox"/>
		ADVOCATE or ACTIVIST	<input type="checkbox"/>
		COMMUNITY BASED ORGANISATION STAFF	<input type="checkbox"/>
		NON GOVERNMENTAL ORGANISATION STAFF	<input type="checkbox"/>
		SCHOOL TEACHER	<input type="checkbox"/>
		YOUTH WORKER	<input type="checkbox"/>
		STUDENTS IN SCHOOLS	<input type="checkbox"/>
		LOCAL HEALTH FACILITY STAFF	<input type="checkbox"/>
		TRADITIONAL HEALER	<input type="checkbox"/>
		LOCAL FAITH BASED LEADER	<input type="checkbox"/>
		LOCAL LEADERSHIP – GOVERNMENT OR ELECTED	<input type="checkbox"/>
		LOCAL LEADERSHIP - TRADITIONAL	<input type="checkbox"/>
		COMMUNITY HEALTH WORKER	<input type="checkbox"/>
		MEDIA PERSONNEL/JOURNALISTS	<input type="checkbox"/>
		LOCAL BUSINESS OWNERS	<input type="checkbox"/>
		LOCAL POLICY MAKERS	<input type="checkbox"/>
		LOCAL BUSINESS	<input type="checkbox"/>
		LEGAL EXPERT	<input type="checkbox"/>
Other (specify)	<input type="checkbox"/>		
C1 - 1.19 QUAL	Please share with me why you feel these people should be informed?	<i>Write the response here.</i>	
C1 - 1.20 QUAL	Please can you tell me about any positive messages you have heard in the community about this study?	<i>Write the response here.</i>	
		I have not heard any positive messages	<input type="checkbox"/>

C1 - 1.21 QUAL	Please can you tell me about any negative messages or rumours you may have heard in the community about this study?	Type the response here.	
		I have not heard any negative messages	<input type="checkbox"/>
C1 - 1.22	Is there anything that you do not like about this study or something that worries you about the research?	YES	<input type="checkbox"/>
		NO (SKIP C1 - 1)	<input type="checkbox"/>
C1 - 1.23 QUAL	What do you not like or what worries you about participation in this study?	Type the response here.	
C1 - 1.24	What were the 3 most important reasons that made you willing to participate in this study? (Probe anything else-tick as many as possible)	Previous experience or reputation of research unit	<input type="checkbox"/>
		Free medical assistance/treatment for participants	<input type="checkbox"/>
		Better treatment/quality health care services for participants	<input type="checkbox"/>
		Transport to and from the clinic	<input type="checkbox"/>
		The study was well explained with information that convinced me to participate	<input type="checkbox"/>
		The views/influences of key people in the community convinced me to participate	<input type="checkbox"/>
		The intervention/drug/vaccine is beneficial for my wellbeing/future	<input type="checkbox"/>
		I wanted to test/check the rumours	<input type="checkbox"/>
		Availability of food at the clinic	<input type="checkbox"/>
		This research will benefit other people	<input type="checkbox"/>
		Others (specify)	<input type="checkbox"/>
C1 - 1.25	How do you feel about the decision you made to be involved in this study?	Happy	<input type="checkbox"/>
		Not happy	<input type="checkbox"/>
		Indifferent/Don't Care	<input type="checkbox"/>
C1 - 1.26	How much do you trust this research study and the research team?	I trust the research team	<input type="checkbox"/>
		I don't trust the research team	<input type="checkbox"/>
		I am not sure how I feel	<input type="checkbox"/>
C1 - 1.27 QUAL	Please can you explain to me in your own words why you feel this way (I trust the research team, I don't trust the research team; I am not sure – my opinion changes)	Type the response here.	
C1 - 1.28	Since joining the study, have you experienced any differences in how people treat you/your child/family?	YES	<input type="checkbox"/>
		NO	<input type="checkbox"/>

C1 - 1.29	What differences have you experienced?	I have not experienced any differences (NO above)					<input type="checkbox"/>
		We/I am segregated or excluded from community activities					<input type="checkbox"/>
		Our/my family treats me differently					<input type="checkbox"/>
		Government health facility staff treat me/ us differently					<input type="checkbox"/>
		Those who are not participating are envious/jealous and relate to me/us differently					<input type="checkbox"/>
		Other					<input type="checkbox"/>
C1 - 1.30	Do you know about the CAB – Community Advisory Board?	YES					<input type="checkbox"/>
		NO (SKIP B1 - 1.29)					<input type="checkbox"/>
C1 - 1.31 QUAL	If you know about the CAG/CAB/CR please describe what you think its purpose is?	Type the response here.					
C1 - 1.32	Do you remember the informed consent process before you enrolled?	YES					<input type="checkbox"/>
		NO					<input type="checkbox"/>
C1 - 1.33 QUAL	Can you recall the process and describe the informed consent process to me as you remember it?	Type the response here.					
C1 - 1.34	If you have questions or concerns about something to do with your participation (or participation of your child) in this research trial – how would you inform the research team?	1) I would call /sms the contact person – I have their phone number!					<input type="checkbox"/>
		2) I would visit the contact person – I know where to go!					<input type="checkbox"/>
		3) I would go to the clinic early before my next scheduled visit.					<input type="checkbox"/>
		4) I would wait until the next scheduled clinic visit.					<input type="checkbox"/>
		5) I would talk to the Chief or Local Leader.					<input type="checkbox"/>
		6) I would go to my local health centre.					<input type="checkbox"/>
		7) I would talk to a friend or neighbour.					<input type="checkbox"/>
		8) I would call/contact/visit another research volunteer/ participant.					<input type="checkbox"/>
		9) I would keep it to myself.					<input type="checkbox"/>
		10) I don't know what I would do – I don't have a plan/have not thought about this.					<input type="checkbox"/>
C1 - 1.35	How many months have you been enrolled in this study?	0-3 months	4-6 months	7-12 months	13-24 months	2-3 years	>3 years
		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
C1 - 1.36	Time Interview Ended	<input type="text"/> <input type="text"/> HOUR <input type="text"/> <input type="text"/> MINUTE					
C1 - 1.37 QUAL	Observations <i>Note down any further comments or impressions shared by the interviewee – recording their answers word for word exactly as they state them</i>						

Tools – SET C2

Prospective Trial Participant Interview

When to complete

- Monthly and Quarterly.

Target

- Prospective Trial Participants who have been briefed on the trial and have been screened but have not yet qualified for enrolment.

Number to complete

- There is no defined sample size – however we suggest that you conduct a minimum of 2 per month, considering all the relevant locations or zones represented in your trials' catchment area – or as seen appropriate by your team.
- This will spur you on to actively reach out to new stakeholders every month.
- The more committed you are to scheduling key informant interviews with a wide array of community stakeholders and enquiring about their experience or lack of experience with your unit or trial, means that over time you will have a rich data set which will have more value in the long term.
- The richer your M&E Data will be and the greater the justification for your work and its potential impact on trial outcomes.

Key terms for this tool

- Post Code: Coding is an analytical process in which both quantitative (such as questionnaires) and qualitative (such as narratives) data are categorised to facilitate analysis. In the case of these questionnaires, you are required to record the narrative of the respondent, word for word and then post code or select the applicable code that corresponds with the response.

Estimated Time

- ½ hour.

TOOL C2 - PROSPECTIVE VOLUNTEER – POST SCREENING INTERVIEW

SECTION 1: GENERAL INFORMATION		
C2 - 1.0	INTERVIEW NUMBER	
C2 - 1.1	NAME OF RESEARCH TRIAL	
C2 - 1.2	PROTOCOL/SUB-STUDY NUMBER	
C2 - 1.3	NAME OF LOCATION OR RESEARCH SITE	
C2 - 1.4	DATE OF INTERVIEW	<input type="text"/> <input type="text"/> DAY <input type="text"/> <input type="text"/> MONTH <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> YEAR
C2 - 1.5	NAME OF INTERVIEWER	
C2 - 1.6	TIME INTERVIEW STARTED	<input type="text"/> <input type="text"/> HOUR <input type="text"/> <input type="text"/> MINUTE

Preamble: **Note to interviewer: Depending on your institutions rules, you may need to develop a consent form. Note – that this is a monitoring and evaluation tool and not a research tool.**

Hello – I am the community liaison officer/manager for this research unit. To be sure that we are communicating and engaging with the different stakeholders properly around our studies, we would like to speak to you to find out more about how you have been reached by this study. I have a few questions to ask you and request that you be completely honest in your reply. We need to hear what you know about these studies and how you were reached. This will help to make us better at effectively engaging with various stakeholders around the clinical research trials we are conducting. Thank you for your time.

SECTION 2: INTERVIEW			
C2 - 1.7	Mark the sex of the interviewee	Male	<input type="checkbox"/>
		Female	<input type="checkbox"/>
C2 - 1.8	What is the highest level of schooling you have completed?	I never attended school	<input type="checkbox"/>
		I did part of Primary – incomplete	<input type="checkbox"/>
		I completed Primary	<input type="checkbox"/>
		I did part of Secondary - incomplete	<input type="checkbox"/>
		I completed Secondary	<input type="checkbox"/>
		I attended College	<input type="checkbox"/>
		I attended University - Tertiary	<input type="checkbox"/>
C2 - 1.9	What did you come to the clinic for today?	Enquiry about enrolling in study	<input type="checkbox"/>
		Eligibility/Screening for this study	<input type="checkbox"/>
		Informed Consent – Pre –Enrolment	<input type="checkbox"/>
		A scheduled interview	<input type="checkbox"/>
		Scheduled Study Visit for enrolled volunteer (you should complete form C3)	<input type="checkbox"/>
		Medical Visit – illness, concern (if respondent not screened for study – end interview now)	<input type="checkbox"/>
		Other (<i>specify</i>)	<input type="checkbox"/>

C2 - 1.10	Did you get the services you came for today?	YES	<input type="checkbox"/>
		NO	<input type="checkbox"/>
C2 - 1.11	How do you feel about the overall quality of the services you got today?	<i>Type the response here. Once you have written the response you will be asked to select the post options that best match the answer.</i>	
		POSTCODE	
		Very Good Services	<input type="checkbox"/>
		Good Services	<input type="checkbox"/>
		Poor Services	<input type="checkbox"/>
C2 - 1.12	Have you heard about this research study on _____ conducted by _____?	YES	<input type="checkbox"/>
		NO	<input type="checkbox"/>
C2 - 1.13	How did you first hear about this study or how were you first contacted by the study?	I don't know about any study	<input type="checkbox"/>
		During a home visit	<input type="checkbox"/>
		Through a friend	<input type="checkbox"/>
		Through leaders in my community	<input type="checkbox"/>
		At the hospital/health centre/dispensary	<input type="checkbox"/>
		At the hospital/health centre/dispensary and then they referred me for screening	<input type="checkbox"/>
		During a community meeting	<input type="checkbox"/>
		Through the radio/television	<input type="checkbox"/>
		Through a poster	<input type="checkbox"/>
		Other (specify)	<input type="checkbox"/>
C2 - 1.14 QUAL	What information have you received about this research study and its purpose?	<i>Type the response here.</i>	
		I have never heard about this study	<input type="checkbox"/>
C2 - 1.15	Where do you live relative to one of the research clinics or relative to this research clinic where you are now?	5 – 15 minutes on foot	<input type="checkbox"/>
		16 – 30 minutes by foot	<input type="checkbox"/>
		>30 minutes by foot	<input type="checkbox"/>
		5 – 15 minutes in a bus/taxi/daladala/matatu	<input type="checkbox"/>
		16 – 30 minutes in a bus/taxi/daladala/matatu	<input type="checkbox"/>
		>30 minutes in a bus/taxi/daladala/matatu	<input type="checkbox"/>
C2 - 1.16	Does this research study offer any other services to the community that you know of?	I don't know	<input type="checkbox"/>
		Treating adults/or children who are sick	<input type="checkbox"/>
		Assisting the community in other ways	<input type="checkbox"/>
		Teaching local community about health related issues	<input type="checkbox"/>
		Conducting health related research	<input type="checkbox"/>
		Other (specify)	<input type="checkbox"/>

C2 - 1.17	How well known is this study in the community where you live?	YES	<input type="checkbox"/>
		NO	<input type="checkbox"/>
C2 - 1.18	Do you think it's important for the study to inform certain people in the community while it is conducting research in or near your community?	YES	<input type="checkbox"/>
		NO	<input type="checkbox"/>
C2 - 1.19 QUAL	Please share with me whom you think should know more about this study in your community?	<i>Type the response here. Once you have written the response you will be asked to select the post options that best match the answer.</i>	
		POSTCODE	
		INDIVIDUAL RESIDENT IN THE TARGET AREA	<input type="checkbox"/>
		MY FRIENDS AND FAMILY or FRIENDS AND FAMILIES OF PARTICIPANTS	<input type="checkbox"/>
		PEOPLE IN NEED OF THE TREATMENT/CARE/PREVENTION	<input type="checkbox"/>
		ADVOCATE or ACTIVIST	<input type="checkbox"/>
		COMMUNITY BASED ORGANISATION STAFF	<input type="checkbox"/>
		NON GOVERNMENTAL ORGANISATION STAFF	<input type="checkbox"/>
		SCHOOL TEACHER	<input type="checkbox"/>
		YOUTH WORKER	<input type="checkbox"/>
		STUDENTS IN SCHOOLS	<input type="checkbox"/>
		LOCAL HEALTH FACILITY STAFF	<input type="checkbox"/>
		TRADITIONAL HEALER	<input type="checkbox"/>
		LOCAL FAITH BASED LEADER	<input type="checkbox"/>
		LOCAL LEADERSHIP – GOVERNMENT OR ELECTED	<input type="checkbox"/>
		LOCAL LEADERSHIP - TRADITIONAL	<input type="checkbox"/>
		COMMUNITY HEALTH WORKER	<input type="checkbox"/>
		MEDIA PERSONNEL/JOURNALISTS	<input type="checkbox"/>
		LOCAL BUSINESS OWNERS	<input type="checkbox"/>
		LOCAL POLICY MAKERS	<input type="checkbox"/>
LOCAL BUSINESS	<input type="checkbox"/>		
LEGAL EXPERT	<input type="checkbox"/>		
OTHER (specify)	<input type="checkbox"/>		
C2 - 1.20 QUAL	Please share with me why you feel these people should be informed?	<i>Type the response here.</i>	
C2 - 1.21 QUAL	Please can you tell me about any positive messages you have heard in the community about this study?	<i>Type the response here.</i>	
		I have not heard any positive messages	<input type="checkbox"/>
C2 - 1.22 QUAL	Please can you tell me about any negative messages or rumours you may have heard in the community about this study?	<i>Type the response here.</i>	
		I have not heard any positive messages	<input type="checkbox"/>
C2 - 1.23	Is there anything that you do not like about this study or something that worries you about the trial?	YES	<input type="checkbox"/>
		NO (SKIP C2 - 1.26)	<input type="checkbox"/>

<p>C2 - 1.24 QUAL</p>	<p>What do you not like or what worries you about participating in this study?</p> <p>Only if the respondent is not forthcoming you can use some of these as probes;</p> <ul style="list-style-type: none"> • Potential side effects - drug/vaccine • Potential Risks of the intervention - drug/vaccine • Discomfort of Procedures - e.g. blood taking • My health may suffer • The time it takes - Inconvenience • Travel Distance • Cost • Stigma/Rumours 	<p>Write the response word for word</p>																									
<p>C2 - 1.25</p>	<p>What are the 3 most important reasons why you would consider volunteering for this study?</p> <p>(Probe anything else-tick as many as possible)</p>	<p><i>Type the response here. Once you have written the response you will be asked to select the post options that best match the answer.</i></p> <p>POSTCODE</p> <table border="1" data-bbox="722 779 1479 1400"> <tr> <td>Previous experience or reputation of research unit</td> <td><input type="checkbox"/></td> </tr> <tr> <td>Free medical assistance/treatment for participants</td> <td><input type="checkbox"/></td> </tr> <tr> <td>Better treatment/health care services for participants</td> <td><input type="checkbox"/></td> </tr> <tr> <td>The study was well explained with details that convinced me</td> <td><input type="checkbox"/></td> </tr> <tr> <td>The views/influences of key people in the community</td> <td><input type="checkbox"/></td> </tr> <tr> <td>The intervention/drug/vaccine is beneficial</td> <td><input type="checkbox"/></td> </tr> <tr> <td>I wanted to test/check rumours</td> <td><input type="checkbox"/></td> </tr> <tr> <td>Participants get free transport to the facility</td> <td><input type="checkbox"/></td> </tr> <tr> <td>This research will benefit other people</td> <td><input type="checkbox"/></td> </tr> <tr> <td>Participants get reimbursements for time and travel</td> <td><input type="checkbox"/></td> </tr> <tr> <td>The research leads to better health</td> <td><input type="checkbox"/></td> </tr> <tr> <td>Others (specify)</td> <td><input type="checkbox"/></td> </tr> </table>		Previous experience or reputation of research unit	<input type="checkbox"/>	Free medical assistance/treatment for participants	<input type="checkbox"/>	Better treatment/health care services for participants	<input type="checkbox"/>	The study was well explained with details that convinced me	<input type="checkbox"/>	The views/influences of key people in the community	<input type="checkbox"/>	The intervention/drug/vaccine is beneficial	<input type="checkbox"/>	I wanted to test/check rumours	<input type="checkbox"/>	Participants get free transport to the facility	<input type="checkbox"/>	This research will benefit other people	<input type="checkbox"/>	Participants get reimbursements for time and travel	<input type="checkbox"/>	The research leads to better health	<input type="checkbox"/>	Others (specify)	<input type="checkbox"/>
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Participants get reimbursements for time and travel	<input type="checkbox"/>																										
The research leads to better health	<input type="checkbox"/>																										
Others (specify)	<input type="checkbox"/>																										
<p>C2 - 1.26</p>	<p>After todays' visit are you considering volunteering for this research study?</p>	<table border="1" data-bbox="722 1400 1479 1552"> <tr> <td>YES</td> <td><input type="checkbox"/></td> </tr> <tr> <td>NO</td> <td><input type="checkbox"/></td> </tr> <tr> <td>Don't Know</td> <td><input type="checkbox"/></td> </tr> </table>		YES	<input type="checkbox"/>	NO	<input type="checkbox"/>	Don't Know	<input type="checkbox"/>																		
YES	<input type="checkbox"/>																										
NO	<input type="checkbox"/>																										
Don't Know	<input type="checkbox"/>																										
<p>C2 - 1.27</p>	<p>Time Interview Ended</p>	<p><input type="checkbox"/><input type="checkbox"/> HOUR <input type="checkbox"/><input type="checkbox"/> MINUTE</p>																									
<p>C2 - 1.28 QUAL</p>	<p>Observations (Note down any further comments or impressions shared by the interviewee – recording their answers word for word exactly as they state them)</p>																										

Tools – SET D1

SELF ASSESSMENT - For COMMUNITY ENGAGEMENT MANAGER or CLO

When to complete

- Every 6 months.

Target

- To be completed by the persons responsible for community engagement (manager/liaison) and the information entered directly into database during collection/completion. If this is the first self-assessment, you can reflect on the life of the various trials to date, if this is the second assessment, you should reflect on the past 4-6 months only.

Number to complete

- There is no defined sample size – however we suggest that you conduct a minimum of 2 self assessments per year and that all your CLO's and staff in the CSE department do so every 6 months.
- The richer your M&E Data will be and the greater the justification for your work and its potential impact on trial outcomes.

Key terms for this tool

- Post Code: Coding is an analytical process in which both quantitative (such as questionnaires) and qualitative (such as narratives) data are categorised to facilitate analysis. In the case of these questionnaires, you are required to record the narrative of the respondent, word for word and then post code or select the applicable code that corresponds with the response.

Estimated Time

- ½ hour.

TOOL D1 - SELF ASSESSMENT

For COMMUNITY ENGAGEMENT MANAGER or COMMUNITY LIAISON OFFICER

SECTION 1: GENERAL INFORMATION						
D1 - 1.0	SELF ASSESSMENT NUMBER					
D1 - 1.1	NAME OF RESEARCH TRIAL					
D1 - 1.2	NAME OF LOCATION OR RESEARCH SITE					
D1 - 1.3	DATE OF SELF-ASSESSMENT	<input type="text"/> <input type="text"/> DAY	<input type="text"/> <input type="text"/> MONTH	<input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> YEAR		
D1 - 1.4	TIME SELF ASSESSMENT STARTED	<input type="text"/> <input type="text"/> HOUR	<input type="text"/> <input type="text"/> MINUTE			
SECTION 2: SELF ASSESSMENT						
D1 - 1.5	What is your role and title in this research trial?	Community Engagement Manager – In charge				<input type="checkbox"/>
		Community Liaison – In charge				<input type="checkbox"/>
		Community Liaison – Junior				<input type="checkbox"/>
		Other (<i>specify</i>)				<input type="checkbox"/>
D1 - 1.6	How long have you been in this position?	Less than 1 year				<input type="checkbox"/>
		Over 1 year – under 2 years				<input type="checkbox"/>
		Over 2 year – under 3 years				<input type="checkbox"/>
		Over 3 years				<input type="checkbox"/>
				S1	S2	S3
D1 - 1.7	For how long have you been involved in the various trials in which you are involved as a Community Engagement Manager?	I am not involved in this particular study as a CLO	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		From the initial stages of planning/ protocol development	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		From the stages of implementation/ Initiation of recruitment	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		Joined once the trial was already well underway	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		Other - None of these apply	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
D1 - 1.8	Reflecting on the past 6 months of the trial, in your opinion how well known is your research organisation in the immediate local communities where you are conducting your clinical trial?	Very well known throughout				<input type="checkbox"/>
		Well known around trial sites				<input type="checkbox"/>
		Only known by small groups of people				<input type="checkbox"/>
		Only known by research participants & relatives				<input type="checkbox"/>
		In general not known				<input type="checkbox"/>
		I don't know				<input type="checkbox"/>
		Other (<i>specify</i>)				<input type="checkbox"/>
D1 - 1.9	Reflecting on the past 6 months, how well do you think the communities in which you are conducting your clinical trial understand the purpose of the study?	Understand very well				<input type="checkbox"/>
		Understand				<input type="checkbox"/>
		Don't Understand				<input type="checkbox"/>
		I don't know				<input type="checkbox"/>
D1 - 1.10	Reflecting on the past 6 months, how engaged is your CAB in issues relating to your clinical trial (s)?	I don't know – I am not aware – We have not assessed				<input type="checkbox"/>
		Very engaged				<input type="checkbox"/>
		Engaged				<input type="checkbox"/>
		Not engaged				<input type="checkbox"/>
		Indifferent				<input type="checkbox"/>

D1 - 1.11 QUAL	<p>Reflecting on the past 6 months which mechanisms have you as the community stakeholder engagement team used to inform or consult community stakeholders?</p> <p>Write your answer and then select the relevant postcode options if applicable.</p>	<p><i>Write your response and then match your response to a category below – if there is no match to your response, choose other</i></p>		
		POSTCODE		
				<p>RATE HOW OFTEN YOU ADOPT THIS APPROACH 0 = NEVER 1 = OCCASIONAL 2 = FREQUENT 3 = ALWAYS</p>
		I don't know – I am not aware	<input type="checkbox"/>	<input type="checkbox"/>
		CAB & CAB Activities only	<input type="checkbox"/>	<input type="checkbox"/>
		Groups of Community Representatives (non CAB)	<input type="checkbox"/>	<input type="checkbox"/>
		Community Public Meetings Gatherings/Dialogues	<input type="checkbox"/>	<input type="checkbox"/>
		CB0s, FB0s, or other community networks	<input type="checkbox"/>	<input type="checkbox"/>
		Face to face discussions/ home visits	<input type="checkbox"/>	<input type="checkbox"/>
		Interactions at hospitals and health facilities or clinics	<input type="checkbox"/>	<input type="checkbox"/>
		Dissemination of IEC materials	<input type="checkbox"/>	<input type="checkbox"/>
		Press/radio coverage	<input type="checkbox"/>	<input type="checkbox"/>
		Outreach education efforts	<input type="checkbox"/>	<input type="checkbox"/>
		Theatre/music/sport	<input type="checkbox"/>	<input type="checkbox"/>
D1 - 1.12 QUAL	<p>Reflecting on the past 6 months, which mechanisms have you as the community engagement team used to consult with broader stakeholders – beyond the communities where the trial is underway?</p> <p>Write your answer and then select the relevant postcode options if applicable.</p>	<p><i>Write your response and then match your response to a category below – if there is no match to your response, choose other</i></p>		
		POSTCODE		
			Select if relevant	<p>RATE HOW OFTEN YOU DO THIS 0 = NEVER 1 = OCCASIONAL 2 = FREQUENT 3 = ALWAYS</p>
		Through local leadership	<input type="checkbox"/>	<input type="checkbox"/>
		Through the health facility	<input type="checkbox"/>	<input type="checkbox"/>
		Through hosting events – theatre, concerts	<input type="checkbox"/>	<input type="checkbox"/>
		Through small meetings – focus groups	<input type="checkbox"/>	<input type="checkbox"/>
Through community meetings	<input type="checkbox"/>	<input type="checkbox"/>		
Through schools	<input type="checkbox"/>	<input type="checkbox"/>		

	Face to Face Discussions / Home visits	<input type="checkbox"/>	<input type="checkbox"/>		
	Through posters and flyers	<input type="checkbox"/>	<input type="checkbox"/>		
	Through radio and newspaper	<input type="checkbox"/>	<input type="checkbox"/>		
	Through CAB	<input type="checkbox"/>	<input type="checkbox"/>		
	Through a CBO	<input type="checkbox"/>	<input type="checkbox"/>		
	Through NGO advisory Group	<input type="checkbox"/>	<input type="checkbox"/>		
	Through IEC materials	<input type="checkbox"/>	<input type="checkbox"/>		
	Outreach efforts	<input type="checkbox"/>	<input type="checkbox"/>		
	Through theatre/music/sport	<input type="checkbox"/>	<input type="checkbox"/>		
	None of the above	<input type="checkbox"/>	<input type="checkbox"/>		
	Other (<i>specify</i>)	<input type="checkbox"/>	<input type="checkbox"/>		
D1 - 1.13	Reflecting on the past 6 months to 1 year which stakeholders (community or broader as per definitions in the manual) have been involved in any of the following activities relating to this trial?	CSH	BSH	None/ Neither/ Don't Know	
	Formative research activities – discussions before the research begins	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	Stakeholder advisory plans – discussions to plan how all stakeholders and gate keepers are engaged in the study	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	Stakeholder education plan – discussions to plan how to sensitize and inform community and broader stakeholders (as per definition at start)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	Communication plans – discussion on how to communicate and reach out to target communities for trial recruitment and enrolment.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	Issues management plan – discussion on how to address problems that may arise in the community in relation to the research study	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	Site selection – discussion around which research sites to select and why	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	Protocol development – discussion around the development of the research plan and approach	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	Informed consent process - discussion around the informed consent process and forms for prospective trial participants	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	Access to care and treatment for trial participants - discussion about what services trial participants may or may not receive while enrolled	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	Recruitment and retention and follow up – discussion about how to access, retain and support trial participants	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	Trial participant exit from trial - discussion on how to transition participants out of the trial when the trial ends	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	Results dissemination - discussion on research results and how to inform the community stakeholders	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	Post-trial access to care and treatment – discussion on services for trial participants after the research is complete	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
D1 - 1.14	In your assessment, over the past 6 months, how well is your engagement work on this trial aligned with GPP – good participatory practice guidelines?	S1	S2	S3	S4
	Very well aligned – excellent	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Aligned – good	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Poorly aligned	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Not aligned	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	I don't know – Not aware – What is GPP?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

D1 - 1.15 QUAL	Reflecting on the past 6 months what has been the predominant focus of your engagement with the community stakeholders (CSH) and broader stakeholders (BSH)?	<i>Type your response and then match your response to a category below – if there is no match to your response, choose other</i>			
		POSTCODE			
			CSH	BSH	
		ADHERENCE ISSUES	<input type="checkbox"/>	<input type="checkbox"/>	
		COMMUNICATION PLAN	<input type="checkbox"/>	<input type="checkbox"/>	
		COMMUNITY ENTRY/INTRO	<input type="checkbox"/>	<input type="checkbox"/>	
		CT/POST TRIAL ACCESS TO CARE	<input type="checkbox"/>	<input type="checkbox"/>	
		FOLLOW UP ISSUES	<input type="checkbox"/>	<input type="checkbox"/>	
		FORMATIVE WORK	<input type="checkbox"/>	<input type="checkbox"/>	
		INFORMED CONSENT	<input type="checkbox"/>	<input type="checkbox"/>	
		ISSUES MANAGEMENT PLAN	<input type="checkbox"/>	<input type="checkbox"/>	
		MOBILIZATION/SENSITIZATION/EDUCATION	<input type="checkbox"/>	<input type="checkbox"/>	
		PLANNING	<input type="checkbox"/>	<input type="checkbox"/>	
		POST TRIAL ACCESS TO CARE	<input type="checkbox"/>	<input type="checkbox"/>	
		PROTOCOL DEVELOPMENT	<input type="checkbox"/>	<input type="checkbox"/>	
		PROTOCOL REVIEW	<input type="checkbox"/>	<input type="checkbox"/>	
		RECRUITMENT	<input type="checkbox"/>	<input type="checkbox"/>	
		RESOURCE IDENTIFICATION	<input type="checkbox"/>	<input type="checkbox"/>	
		RESULTS DISSEMINATION	<input type="checkbox"/>	<input type="checkbox"/>	
		RETENTION ISSUES	<input type="checkbox"/>	<input type="checkbox"/>	
		ROLE CLARIFICATION	<input type="checkbox"/>	<input type="checkbox"/>	
		SITE SELECTION	<input type="checkbox"/>	<input type="checkbox"/>	
		STAKEHOLDER ADVISORY PLAN	<input type="checkbox"/>	<input type="checkbox"/>	
STAKEHOLDER EDUCATION PLAN	<input type="checkbox"/>	<input type="checkbox"/>			
STUDY BRIEFING	<input type="checkbox"/>	<input type="checkbox"/>			
STUDY INFO UPDATES	<input type="checkbox"/>	<input type="checkbox"/>			
TRAINING	<input type="checkbox"/>	<input type="checkbox"/>			
UPDATE/FEEDBACK	<input type="checkbox"/>	<input type="checkbox"/>			
OTHER (specify)	<input type="checkbox"/>	<input type="checkbox"/>			
D1 - 1.16 QUAL	Please write any key suggestions or any constructive solutions which you are aware the community stakeholders (can include the CAB), have made to any or all of your trials.	Write your response here			
		Did the trial act on these suggestions?	YES <input type="checkbox"/>	NO <input type="checkbox"/>	No suggestions made <input type="checkbox"/>
D1 - 1.17 QUAL	Please write any key suggestions or any constructive solutions which you are aware that any broader stakeholders have made to any or all of your trials.	Write your response here			
		Did the trial act on these suggestions?	YES <input type="checkbox"/>	NO <input type="checkbox"/>	No suggestions made <input type="checkbox"/>

D1 - 1.18 QUAL	<p>If you have acted on suggestions in the past 6 months, please share those actions in detail.</p> <p>If you have not acted on suggestions, can you explain why you think no actions have been taken, as a result of stakeholder participation?</p>	Write your response				
D1 - 1.19	Based on results, over the past 6 months how important has your stakeholder engagement programme been to the clinical trial operations?	Very Important and essential	<input type="checkbox"/>			
		Important but not essential	<input type="checkbox"/>			
		Limited value	<input type="checkbox"/>			
		Not important	<input type="checkbox"/>			
		I don't know – there is no data to show value	<input type="checkbox"/>			
D1 - 1.20 QUAL	<p>Please give concrete examples of how the stakeholder engagement programme has directly benefited the trial over the past 6 months? Note – do not make sweeping statements without concrete evidence.</p>	Write your response				
D1 - 1.21	<p>On average, over the past 6 months, how often have you consulted in person/directly with various stakeholders (SH)?</p> <p>CSH – community SH BSH – broader SH NSH – national SH ISH – international SH</p>		CSH	BSH	NSH	ISH
		Every day	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		Every week at least once	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		Every month at least once	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		Every 3 months at least once	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		At least twice a year	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		Once a year	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		Not sure – very rarely	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		Never	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
D1 - 1.22	Reflecting on the past 6 months, are you very satisfied, satisfied, unsure, dissatisfied, very dissatisfied with your stakeholder engagement outputs?		CSH	BSH	NSH	ISH
		Very Satisfied	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		Satisfied	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		Unsure	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		Dissatisfied	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		Very Dissatisfied	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
D1 - 1.23 QUAL	Please give a examples that illustrate why you are very satisfied, satisfied, unsure, dissatisfied, dissatisfied with stakeholder engagement over the past 6 months.	Write your response				
D1 - 1.24	Over the past 6 months, how would you rate the strength of your research projects' engagement with the stakeholders (for each of the trials underway		S1	S2	S3	S4
		Very Strong The CSH or BSH is/are involved in all (90-100%) aspects of the research, from planning through dissemination of the research.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		Strong The CSH or BSH is/are involved in most (71-89%) aspects of the research but not necessarily all development and planning.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		Medium The CSH or BSH is/are involved in about 60 to 70% of the research process.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		Weak The CSH or BSH is/are involved in very few aspects (40-59%) of the research activities	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

		Very Weak The CSH or BSH is/are involved in less than 40% of the research activities.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>											
		I don't know – Not in a position to judge	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>											
D1 - 1.25	In the past 6 months (or life of trial as per above) have you written any agreements with your community stakeholders ORCABS? (Do not mention those already indicated in previous assessment). Note: if this is the first self-assessment, you can reflect on the life of the trial to date, if this is the second assessment, you should reflect on the past 6 months only.	YES Be sure to upload this agreement at the end of this assessment	<input type="checkbox"/>														
		I DON'T KNOW (SKIP D1 - 1.27)	<input type="checkbox"/>														
		NO (SKIP D1 - 1.27)	<input type="checkbox"/>														
D1 - 1.26	If yes - Please indicate the name(s) of the document(s). Also be sure to attach this document at the end of the self-assessment.																
D1 - 1.27	If yes, does this agreement with the stakeholders address any or all of the following: <ul style="list-style-type: none"> • Ethics? • Roles & responsibilities of all participants? • Data ownership? • Dispute resolution? • Dissemination of results? 	No agreement developed/Or don't know if agreement developed	<input type="checkbox"/>														
		I don't know the content of the agreement	<input type="checkbox"/>														
		Ethics	<input type="checkbox"/>														
		Roles & responsibilities of all participants	<input type="checkbox"/>														
		Data ownership	<input type="checkbox"/>														
		Dispute resolution	<input type="checkbox"/>														
		Dissemination of results	<input type="checkbox"/>														
		Other (specify)	<input type="checkbox"/>														
D1 - 1.28	Reflecting on the past 6 months, on average how often have you engaged with stakeholders of any kind related to any of the trials? (excluding already enrolled trial participants)	I don't know – I'm not involved	<input type="checkbox"/>														
		Every day	<input type="checkbox"/>														
		Every week at least once	<input type="checkbox"/>														
		Every month at least once	<input type="checkbox"/>														
		Every 3 months at least once	<input type="checkbox"/>														
		At least twice a year	<input type="checkbox"/>														
		I don't know	<input type="checkbox"/>														
		Other (specify)	<input type="checkbox"/>														
D1 - 1.29	Currently how many full or part time staff are employed by the research unit to address community engagement?	<table border="1"> <tr> <th colspan="2">Full Time</th> <th colspan="2">Part Time</th> </tr> <tr> <td colspan="2">_____</td> <td colspan="2">_____</td> </tr> <tr> <td colspan="2">Write Number</td> <td colspan="2">Write Number</td> </tr> </table>	Full Time		Part Time		_____		_____		Write Number		Write Number				
Full Time		Part Time															
_____		_____															
Write Number		Write Number															
D1 - 1.30	How much did the community stakeholder engagement (CSE) programme spend in the past 6 months for CSE efforts for each of the trials you are involved in?	<table border="1"> <tr> <th>S1</th> <th>S2</th> <th>S3</th> <th>S4</th> </tr> <tr> <td>\$ _____</td> <td>\$ _____</td> <td>\$ _____</td> <td>\$ _____</td> </tr> </table>	S1	S2	S3	S4	\$ _____	\$ _____	\$ _____	\$ _____							
S1	S2	S3	S4														
\$ _____	\$ _____	\$ _____	\$ _____														
D1 - 1.31 QUAL	Can you share, in detail, what lessons you have learned about how to conduct CSE over the past 6 months?	Write your response															

D1 - 1.32	Over the past 6 months – as the CLO - how supported do you feel by the clinical research team and other members of the research team?	Very supported	<input type="checkbox"/>
		Supported	<input type="checkbox"/>
		Not supported	<input type="checkbox"/>
		I don't know	<input type="checkbox"/>
D1 - 1.33 QUAL	Why do you feel the way you have described above – not supported, supported or very supported?	Write your response	
D1 - 1.34	Reflecting on the past 6 months, can you rate your stakeholder engagement efforts – how well are you achieving your goals?	Excellent - We are achieving our community engagement goals/on target with our work plan	<input type="checkbox"/>
		Good – we are progressing well and steadily – we are nearly on target with our work plan	<input type="checkbox"/>
		Average – we are achieving some of our targets, we are lagging behind on our targets	<input type="checkbox"/>
		Poor – we are not achieving our goals and targets	<input type="checkbox"/>
		I don't know	<input type="checkbox"/>
D1 - 1.35 QUAL	Please comment in detail on your response above and suggest why this is the case?	Write your response	
D1 - 1.36	TIME SELF ASSESSMENT ENDED	<input type="checkbox"/> <input type="checkbox"/> HOUR <input type="checkbox"/> <input type="checkbox"/> MINUTE	
ADD ATTACHMENTS OF DOCUMENTS – referred to in this self-assessment.			

Tools – SET D2

PRINCIPAL INVESTIGATOR or SENIOR RESEARCHER SELF ASSESSMENT

When to complete

- Every 6 months.

Target

- To be completed by the Principal Investigators (PIs) and Senior Researchers within your trial - ideally each PI or Researcher should complete two or three self assessments during the course of a trial.
- If this is the first self-assessment, the PI or Senior Researcher can reflect on the life of the various trials to date, if this is the second assessment, you should reflect on the past 4-6 months only.

Number to complete

- There is no defined sample size – however we suggest that an absolute minimum of 1 self-assessment every 6 months. In the course of the trial every PI and Senior researcher should self-assess a least once, preferably once a year.
- This will engage the views of PIs and researchers more effectively.
- The more committed you are to scheduling time for these self-assessment the more likely you are to collect the reflective data from those running the trials that sheds light on how much they understand CSE efforts and their suggestions.
- Over time you will have a rich data set which will have great value in the long term.
- The richer your M&E Data will be and the greater the justification for your work and its potential impact on trial outcomes.

Key terms for this tool

- Post Code: Coding is an analytical process in which both quantitative (such as questionnaires) and qualitative (such as narratives) data are categorised to facilitate analysis. In the case of these questionnaires, you are required to record the narrative of the respondent, word for word and then post code or select the applicable code that corresponds with the response.

Estimated Time

- ½ hour.

TOOL D2 – CAB - PRINCIPAL INVESTIGATOR or SENIOR RESEARCHER SELF-ADMINISTERED QUESTIONNAIRE

SECTION 1: GENERAL INFORMATION		
D2 - 1.0	INTERVIEW NUMBER	
D2 - 1.1	NAME OF RESEARCH TRIAL	
D2 - 1.2	NAME OF LOCATION OR RESEARCH SITE	
D2 - 1.3	DATE OF INTERVIEW	<input type="text"/> <input type="text"/> DAY <input type="text"/> <input type="text"/> MONTH <input type="text"/> <input type="text"/> <input type="text"/> <input type="text"/> YEAR
D2 - 1.4	TIME INTERVIEW STARTED	<input type="text"/> <input type="text"/> HOUR <input type="text"/> <input type="text"/> MINUTE
SECTION 2:		
D2 - 1.5	What is your position in this trial?	Principal Investigator – International <input type="checkbox"/>
		Senior Researcher – International <input type="checkbox"/>
		Principal Investigator – In country <input type="checkbox"/>
		Senior Researcher – In country <input type="checkbox"/>
		Other (<i>specify</i>) <input type="checkbox"/>
D2 - 1.6	How long have you been in this position?	Less than 1 year <input type="checkbox"/>
		Over 1 year – under 2 years <input type="checkbox"/>
		Over 2 year – under 3 years <input type="checkbox"/>
		Over 3 years <input type="checkbox"/>
D2 - 1.7	For how long have you been involved in this trial as a PI or Senior Researcher?	From the initial stages of planning/protocol development/ review <input type="checkbox"/>
		From the stages of implementation/Initiation of recruitment <input type="checkbox"/>
		Joined once the trial was already well underway <input type="checkbox"/>
		Other - None of these apply <input type="checkbox"/>
D2 - 1.8	Reflecting on the past 6 months of the trial - in your opinion how well known is your research organisation/unit in the immediate local communities where you are conducting your clinical trial?	Very well known throughout <input type="checkbox"/>
		Well known around trial sites <input type="checkbox"/>
		Only known by small groups of people <input type="checkbox"/>
		In general not known <input type="checkbox"/>
		I don't know – I am not involved <input type="checkbox"/>
		Other (<i>specify</i>) <input type="checkbox"/>
D2 - 1.9	Reflecting on the past 6 months (or longer if this is the first self-assessment you are completing), in your opinion, how engaged is your CAB in issues relating to this clinical trial (s)?	I don't know – I am not aware – I am not involved <input type="checkbox"/>
		Very engaged <input type="checkbox"/>
		Engaged <input type="checkbox"/>
		Emerging Engagement – engagement is in early days <input type="checkbox"/>
		Not engaged <input type="checkbox"/>
		Indifferent <input type="checkbox"/>
D2 - 1.10 QUAL	Reflecting on the past 6 months which mechanisms has your research team including your stakeholder engagement team used to inform or consult community stakeholders within the communities where your trial is underway?	Write response here

	Stakeholder engagement team used to inform or consult community stakeholders within the communities where your trial is underway? Write your answer and then select the relevant postcode options if applicable.	POSTCODE			
			Select if relevant	RATE HOW OFTEN YOU ADOPT THIS APPROACH 0 = NEVER 1 = OCCASIONAL 2 = FREQUENT 3 = ALWAYS	
	I don't know – I am not aware		<input type="checkbox"/>	<input type="checkbox"/>	
	CAB		<input type="checkbox"/>	<input type="checkbox"/>	
	Trial Participant Groups		<input type="checkbox"/>	<input type="checkbox"/>	
	Stakeholder meetings		<input type="checkbox"/>	<input type="checkbox"/>	
	Local events		<input type="checkbox"/>	<input type="checkbox"/>	
	Community Dialogues		<input type="checkbox"/>	<input type="checkbox"/>	
	Face to Face Discussions/Home Visits		<input type="checkbox"/>	<input type="checkbox"/>	
	Focus Group Discussions		<input type="checkbox"/>	<input type="checkbox"/>	
	Radio /Press/Media		<input type="checkbox"/>	<input type="checkbox"/>	
	NGO Advisory Groups		<input type="checkbox"/>	<input type="checkbox"/>	
	Theatre/Music/Sport events		<input type="checkbox"/>	<input type="checkbox"/>	
	Groups already established in the area		<input type="checkbox"/>	<input type="checkbox"/>	
National Conferences		<input type="checkbox"/>	<input type="checkbox"/>		
Other (specify)		<input type="checkbox"/>	<input type="checkbox"/>		
D2 - 1.11 QUAL	Reflecting on the past 6 months which mechanisms has your research team/ community engagement team used to consult with broader stakeholders – beyond the immediate communities where the trial is underway?(refer to diagram at the start of interview if you need further clarification).	Write your response here			
		POSTCODE			
				Select if relevant	RATE HOW OFTEN YOU DO THIS 0 = NEVER 1 = OCCASIONAL 2 = FREQUENT 3 = ALWAYS
		I don't know – I am not aware		<input type="checkbox"/>	<input type="checkbox"/>
		Broader Stakeholder Advisory Meetings		<input type="checkbox"/>	<input type="checkbox"/>
		Local Events		<input type="checkbox"/>	<input type="checkbox"/>
		Ongoing dialogue with NGOs or CBOs		<input type="checkbox"/>	<input type="checkbox"/>
		Political Groups		<input type="checkbox"/>	<input type="checkbox"/>
		NGO Advisory Groups		<input type="checkbox"/>	<input type="checkbox"/>
		Social Cultural Groups		<input type="checkbox"/>	<input type="checkbox"/>
		Professional Groups		<input type="checkbox"/>	<input type="checkbox"/>
		CABs		<input type="checkbox"/>	<input type="checkbox"/>
		Groups already established in the area		<input type="checkbox"/>	<input type="checkbox"/>
		Call in Radio Shows /		<input type="checkbox"/>	<input type="checkbox"/>
		News Press		<input type="checkbox"/>	<input type="checkbox"/>
		TV Media		<input type="checkbox"/>	<input type="checkbox"/>
		Theatre/Music/Sport events		<input type="checkbox"/>	<input type="checkbox"/>
		National or International Conferences		<input type="checkbox"/>	<input type="checkbox"/>
None of the above		<input type="checkbox"/>	<input type="checkbox"/>		
Other (specify)		<input type="checkbox"/>	<input type="checkbox"/>		

D2 - 1.12	Reflecting on the past 6 months to 1 year which community or broader stakeholders () have been involved in any of the following activities relating to this trial?		CSH	BSH	None/ Neither/ Don't Know	
	Formative research activities – discussions before the research begins		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	Stakeholder advisory plans – discussions to plan how all stakeholders and gate keepers are engaged in the study		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	Stakeholder education plan – discussions to plan how to sensitize and inform community and broader stakeholders (as per definition at start)		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	Communication plans – discussion on how to communicate and reach out to target communities for trial recruitment and enrolment.		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	Issues management plan – discussion on how to address problems that may arise in the community in relation to the research study		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	Site selection – discussion around which research sites to select and why		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	Protocol development – discussion around the development of the research plan and approach		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	Informed consent process - discussion around the informed consent process and forms for prospective trial participants		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	Access to care and treatment for trial participants - discussion about what services trial participants may or may not receive while enrolled		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	Recruitment and retention and follow up – discussion about how to access, retain and support trial participants		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	Trial participant exit from trial - discussion on how to transition participants out of the trial when the trial ends		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
	Results dissemination - discussion on research results and how to inform the community stakeholders		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
Post-trial access to care and treatment – discussion on services for trial participants after the research is complete		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
			S1	S2	S3	S4
D2 - 1.13	In your assessment, over the past 6 months, how well is your engagement work on this trial aligned with GPP – good participatory practice guidelines?	Very well aligned – excellent	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		Aligned – good	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		Poorly aligned	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		Not aligned	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		I don't know – Not aware – What is GPP?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
D2 - 1.14	In your view what is the purpose of the Community Advisory Board or its equivalent in your institution – please provide as much detail as possible.					

D2 - 1.15 QUAL	Reflecting on the past 6 months what has been the predominant focus of your engagement with the community stakeholders (CSH) and broader stakeholders (BSH)?	Write your response here			
		POSTCODE			
			CSH	BSH	
		ADHERENCE ISSUES	<input type="checkbox"/>	<input type="checkbox"/>	
		COMMUNICATION PLAN	<input type="checkbox"/>	<input type="checkbox"/>	
		COMMUNITY ENTRY/INTRO	<input type="checkbox"/>	<input type="checkbox"/>	
		CT/POST TRIAL ACCESS TO CARE	<input type="checkbox"/>	<input type="checkbox"/>	
		FOLLOW UP ISSUES	<input type="checkbox"/>	<input type="checkbox"/>	
		FORMATIVE WORK	<input type="checkbox"/>	<input type="checkbox"/>	
		INFORMED CONSENT	<input type="checkbox"/>	<input type="checkbox"/>	
		ISSUES MANAGEMENT PLAN	<input type="checkbox"/>	<input type="checkbox"/>	
		MOBILIZATION/SENSITIZATION/EDUCATION	<input type="checkbox"/>	<input type="checkbox"/>	
		PLANNING	<input type="checkbox"/>	<input type="checkbox"/>	
		POST TRIAL ACCESS TO CARE	<input type="checkbox"/>	<input type="checkbox"/>	
		PROTOCOL DEVELOPMENT	<input type="checkbox"/>	<input type="checkbox"/>	
		PROTOCOL REVIEW	<input type="checkbox"/>	<input type="checkbox"/>	
		RECRUITMENT	<input type="checkbox"/>	<input type="checkbox"/>	
		RESOURCE IDENTIFICATION	<input type="checkbox"/>	<input type="checkbox"/>	
		RESULTS DISSEMINATION	<input type="checkbox"/>	<input type="checkbox"/>	
		RETENTION ISSUES	<input type="checkbox"/>	<input type="checkbox"/>	
		ROLE CLARIFICATION	<input type="checkbox"/>	<input type="checkbox"/>	
		SITE SELECTION	<input type="checkbox"/>	<input type="checkbox"/>	
		STAKEHOLDER ADVISORY PLAN	<input type="checkbox"/>	<input type="checkbox"/>	
STAKEHOLDER EDUCATION PLAN	<input type="checkbox"/>	<input type="checkbox"/>			
STUDY BRIEFING	<input type="checkbox"/>	<input type="checkbox"/>			
STUDY INFO UPDATES	<input type="checkbox"/>	<input type="checkbox"/>			
TRAINING	<input type="checkbox"/>	<input type="checkbox"/>			
UPDATE/FEEDBACK	<input type="checkbox"/>	<input type="checkbox"/>			
OTHER (specify)	<input type="checkbox"/>	<input type="checkbox"/>			
D2 - 1.16	Please write any key suggestions or any constructive solutions which you are aware the community stakeholders (can include the CAB), have made to any or all of your trials.	Write your response here			
		Did the trial act on these suggestions?	YES <input type="checkbox"/>	NO <input type="checkbox"/>	No suggestions made <input type="checkbox"/>
D2 - 1.17	Please write any key suggestions or any constructive solutions which you are aware that any broader stakeholders have made to any or all of your trials.	Write your response here			
		Did the trial act on these suggestions?	YES <input type="checkbox"/>	NO <input type="checkbox"/>	No suggestions made <input type="checkbox"/>

D2 - 1.18 QUAL	<p>If you have acted on suggestions in the past 6 months, please share those actions in detail.</p> <p>If you have not acted on suggestions, can you explain why you think no actions have been taken, as a result of stakeholder participation?</p>	Write your response				
D2 - 1.19	Based on results, over the past 6 months how important has your stakeholder engagement programme been to the clinical trial operations?	Very Important and essential	<input type="checkbox"/>			
		Important but not essential	<input type="checkbox"/>			
		Limited value	<input type="checkbox"/>			
		Not important	<input type="checkbox"/>			
		I don't know – there is no data to show value	<input type="checkbox"/>			
D2 - 1.20 QUAL	<p>Please give concrete examples of how the stakeholder engagement programme has directly benefited the trial over the past 6 months? Note – do not make sweeping statements without concrete evidence.</p>	Write your response				
D2 - 1.21	<p>On average, over the past 6 months, how often have you consulted in person/directly with various stakeholders (SH)?</p> <p>CSH – community SH BSH – broader SH NSH – national SH ISH – international SH</p>		CSH	BSH	NSH	ISH
		Every day	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		Every week at least once	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		Every month at least once	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		Every 3 months at least once	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		At least twice a year	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		Once a year	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		Not sure – very rarely	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		Never	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
D2 - 1.22	Reflecting on the past 6 months and thinking about results, are you very satisfied, satisfied, unsure, dissatisfied, very dissatisfied with your stakeholder engagement outputs? (Abbreviations as per previous question).		CSH	BSH	NSH	ISH
		Very Satisfied	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		Satisfied	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		Unsure	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		Dissatisfied	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		Very Dissatisfied	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
D2 - 1.23 QUAL	Elaborate on your answer above as to why you feel this way (very satisfied, satisfied, unsure, dissatisfied, or very dissatisfied) in relation to the different stakeholder engagement efforts undertaken by your trial. Please give a examples that illustrate your stand.	Write your response				

D2 - 1.24	Over the past 6 months, how would you rate the strength of your research projects' engagement with the stakeholders (for each of the trials underway		S1	S2	S3	S4
		Very Strong The CSH or BSH is/are involved in all (90 - 100%) aspects of the research, from planning through dissemination of the research.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		Strong The CSH or BSH is/are involved in most (71 - 89%) aspects of the research but not necessarily all development and planning.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		Medium The CSH or BSH is/are involved in about 60 to 70% of the research process.	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		Weak The CSH or BSH is/are involved in very few aspects (40 - 59%) of the research activities	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		Very Weak The CSH or BSH is/are involved in less than 40 of the research activities	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		I don't know - Not in a position to judge	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
D2 - 1.25 QUAL	In your opinion why does your research engage with community stakeholders (CSH) broader stakeholders (BSH) national stakeholders (NSH) international stakeholders (ISH)	Write your response here				
		In your opinion why does your research engage with community stakeholders?				
		In your opinion why does your research engage with broader stakeholders?				
		In your opinion why does your research engage with national stakeholders?				
		In your opinion why does your research engage with international stakeholders?				
		POSTCODE OPTIONS – YOU MAY CHOOSE UP TO 3 FOR EACH CATEGORY OF SH				
			CSH	BSH	NSH	ISH
		TO GET THE PERMISSIONS NECESSARY TO CONDUCT THE STUDY	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		TO ENHANCE RECRUITMENT AND RETENTION of trial participants	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		TO CONSULT WITH THEM – to gather their opinions/ideas/suggestions on the protocol, informed consent and other processes	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		TO SEEK THEIR APPROVAL – to facilitate/enable the research	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		TO CREATE AWARENESS – to prevent rumours and resistance in the community	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		TO LISTEN TO THE COMMUNITY & GATHER FEEDBACK on how the study is being received in the community	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		TO BUILD TRUST BETWEEN THE STAKEHOLDERS AND THE RESEARCH – to enable future research	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		TO MITIGATE POTENTIAL CONTROVERSY - that may interfere with the research	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		TO PROTECT THE COMMUNITY – from research that is detrimental to the community	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		TO DISCUSS POLICY & POST TRIAL IMPLEMENTATION	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
TO SEEK FUNDING AND CONTINUED SUPPORT	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
TO MOBILIZE AND SENSITIZE ABOUT THE TRIAL PURPOSE	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		
OTHER (specify)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>		

D2 - 1.26	Reflecting on the past 6 months which of the following statements best represent your opinion? You may choose up to two options.	Community Stakeholder & Broader Engagement is a bonus/good for public relations but it is not essential to the success of the trial.	<input type="checkbox"/>		
		Community Stakeholder & Broader Stakeholder Engagement is a waste of time, staff and finances – in reality it does not contribute to the success of the trial.	<input type="checkbox"/>		
		Community Stakeholder & Broader Stakeholder Engagement is valuable in theory, but in reality there is no data to show us that it has a true benefit.	<input type="checkbox"/>		
		Community Stakeholder & Broader Stakeholder Engagement is very important and the trial could not advance without it.	<input type="checkbox"/>		
		Community Stakeholder & Broader Stakeholder Engagement is an ethical requirement and clinical research has responsibility to engage with all levels of stakeholders, regardless of its impact on trial outcomes.	<input type="checkbox"/>		
D2 - 1.27	Do you think that your trial invests sufficient time, staff and finances into community and broader stakeholder engagement?		TIME	STAFF	FINANCE
		YES	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
		NO	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
D2 - 1.28	In your opinion, over the past 6 months, how much value have your community and broader stakeholder engagement efforts added to your research study?	Great value	<input type="checkbox"/>		
		Some Value	<input type="checkbox"/>		
		Questionable/Undetermined value	<input type="checkbox"/>		
		No value	<input type="checkbox"/>		
		I don't know – Not in a position to judge	<input type="checkbox"/>		
D2 - 1.29	TIME INTERVIEW ENDED	<input type="checkbox"/> <input type="checkbox"/> HOUR <input type="checkbox"/> <input type="checkbox"/> MINUTE			
PLEASE ATTACH ANY DOCUMENTS THAT COULD SUPPORT YOUR RESPONSES					