DATABASE TRAINING

17th & 18th September, 2014
A Community & Stakeholder Engagement Monitoring & Evaluation Toolkit
Purpose of Training

• Introduce the ENGAGEMENT database to you as the first set of users;
• Train you to navigate the database;
• Train you how to administer 11 tools;
• Train you how to enter data;
• Introduce you to a part of the outputs menu;
• Review the possibilities for generating reports.
Starting Point

• Cell phones off or silent & out of sight/touch until breaks!
• Set aside your emails & other work until after the session.
• Adopt & expect positive communication.
• After every section there will be a chance to ask your questions – write them down & ask them during question time!

Thank you!
<table>
<thead>
<tr>
<th>Time</th>
<th>Agenda</th>
</tr>
</thead>
<tbody>
<tr>
<td>8:30</td>
<td>Gather for 9am start</td>
</tr>
<tr>
<td>9:00</td>
<td>Introductions</td>
</tr>
<tr>
<td></td>
<td>Background &amp; Overview of the Training</td>
</tr>
<tr>
<td>10:15</td>
<td>Team allocations</td>
</tr>
<tr>
<td></td>
<td>Set up - Database Access for each Institution Team &amp; computers</td>
</tr>
<tr>
<td>10:45</td>
<td>TEA BREAK</td>
</tr>
<tr>
<td>11:00</td>
<td>Navigating the Database - The Tools</td>
</tr>
<tr>
<td></td>
<td>Role Playing Process</td>
</tr>
<tr>
<td>11:30</td>
<td>A SET - Tool AA</td>
</tr>
<tr>
<td>12:00</td>
<td>A SET - Tool A1</td>
</tr>
<tr>
<td>13:00</td>
<td>LUNCH BREAK</td>
</tr>
<tr>
<td>14:00</td>
<td>A SET - Tool A2 &amp; A3</td>
</tr>
<tr>
<td>15:00</td>
<td>B SET - Tool B1 &amp; B2</td>
</tr>
<tr>
<td>16:00</td>
<td>TEA BREAK</td>
</tr>
<tr>
<td>16:20</td>
<td>B SET - Tool B2 &amp; B3</td>
</tr>
<tr>
<td>17:20</td>
<td>Close and Summary &amp; Homework</td>
</tr>
<tr>
<td>Time</td>
<td>Activity</td>
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<tr>
<td>8:30</td>
<td>Gather for 9am start</td>
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<tr>
<td>9:00 - 9:30</td>
<td>Summary and Homework Feedback/Questions</td>
</tr>
<tr>
<td>9:30 - 10:45</td>
<td>C SET - Tool C1 &amp; C2</td>
</tr>
<tr>
<td>10:45 - 11:00</td>
<td>TEA BREAK</td>
</tr>
<tr>
<td>11:00 - 12:00</td>
<td>D Set - Tool D1 &amp; D2</td>
</tr>
<tr>
<td>12:00 - 13:00</td>
<td>Processing the Data</td>
</tr>
<tr>
<td>13:00 - 14:00</td>
<td>LUNCH BREAK</td>
</tr>
<tr>
<td>14:00 - 15:00</td>
<td>Processing the Data &amp; Reporting</td>
</tr>
<tr>
<td>15:00 - 15:30</td>
<td>Processing the Data &amp; Reporting</td>
</tr>
<tr>
<td>15:30 - 16:30</td>
<td>Next steps, Support, Feedback, Closure</td>
</tr>
<tr>
<td>16:30</td>
<td>CLOSE - TEA BREAK</td>
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</tbody>
</table>
Toolkit Trajectory

- Indicator Development - prior to May 2013
- Tool Development - July/August 2013
- Tool Piloting & Presentation – September 2013@ Forum
- Analysis Plan – February 2014
- Database (data entry) Development – June/July/Aug/Sept 2014
- Database (data entry) Testing & Edits - July/August 2014
- First Users Training - September, 2014
- Refinement and Finalization of Outputs & Reports
- Launch – December 2014
- Total of 2.5 months of consultant time and 3.5 months of programming - 6 months to materialize.
Terms & Acronyms

- **M&E**  monitoring and evaluation
- **CSE**  community and stakeholder engagement
- **CAB**  community advisory board
- **CSH**  community stakeholder
- **BSH**  broader stakeholder
- **NSH**  national stakeholder
- **ISH**  international stakeholder
- **SHs**  stakeholders
Stakeholder Onion
Premise

• CSE is an ethical and scientific requirement for all research involving human participants.
Purpose of CSE in Clinical Trials

• Increase knowledge & understanding about the disease and research processes among SHs.
• Obtain & incorporate SH input into trial design.
• Understand & address SH concerns to avoid miscommunication or premature closure of the trial.
• Enhance recruitment & retention, through community informed study designs.
• Improve implementation of the research findings leading to SH acceptance & uptake of trial results if appropriate.
Current thinking around CSE

- Establish norms and formalize budgets for CSE.
- Adopt a CSE approach that goes far beyond the CAB.
- Recognize that CSE is **not only about recruitment & retention**.
- **Carefully identify SH groups** – inclusivity.
- Ensure early & authentic involvement with selected SH groups.
- Plan for & address future access to treatment post trial early on.
- Adopt an attitude of open dialogue.

AND

- Implement M&E and incorporate results into evidence-based planning & approaches!
M&E of CSE

• A need to establish an evidence-base for the role that CSE plays in clinical trials.

• To date very few attempts to do so & most describe CSE versus measure it.

• Measuring the value of CSE could influence researchers’ willingness to properly incorporate CSE practices into clinical research plans.
M&E of CSE

• This is the first attempt to formalize measurement of Community and Stakeholder Engagement in clinical trials.
The ENGAGEMENT&ENT Toolkit

– The Database
  • Data entry component for the 11 tools;
  • Simple descriptive statistics & narrative output component;
  • Capability to export the outputs to a report template;
  • Capability to export all data to a statistics package for sophisticated analysis & evaluation purposes;
  • Potential for a mapping hub programmed already.

  • To train in-house
The Toolkit

- Work planning
- Reporting
- M&E Planning
- The CSE M&E ToolKit
- Results, Analysis & Interpretation
- M&E Implementing
The Tools

A TOOLS
AA
Stakeholder ID & Analysis
DAILY
A1
Engagement Log
DAILY
A2
Compilation of Clinical Data
MONTHLY
A3
Inventory of CSE alongside GPP
MONTHLY
DAILY & MONTHLY

B TOOLS
B1
Community Stakeholder Interview
QUARTERLY
B2
Advisory Group Member Interview
QUARTERLY
B3
Broader Stakeholder Interview
QUARTERLY
QUARTERLY

C TOOLS
C1
Trial Participant Interview
BIANNUALLY
C2
Prospective Trial Participant
BIANNUALLY
BIANNUALLY

D TOOLS
D1
CE/CLO Self-Assessment
ANNUALLY
D2
PI Self-Assessment
ANNUALLY
ANNUALLY
Prerequisites to success

• Commit the time;
  – A maximum of 1 day a month dedicated to M&E and reporting – spread out throughout the month.

• Be regular & consistent.
• Pay attention to detail.
• Keep a detailed diary – where you highlight what needs to be entered into the database.
Interview Skills *for key informant interviews*

- Be very familiar with the interviews prior to use.
- The questionnaires are not to be administered word for word – use your community sensitivities.
- Be clever as you administer them & listen to the responses to see how to adapt the questions to your informant.
- Apply the qualitative skill of recording narrative as spoken.
- Please don’t answer on behalf of the respondent or put words in their mouths!
Sample Sizes

- No defined sample sizes – only suggestions;
- The quality of M&E data depends on your investment in the process;
- Feeding quality data regularly into the system, means sponsor/trial/CSE community will be able to measure the true value of your work.
- You will need to justify your sampling in the report where you present results.
Sampling

– Sampling frame will form part of M&E plan
– Quota sampling
  • Decide in advance which categories of stakeholders (CSH/CAB/BSH) with specific characteristics to sample & caste your net as broadly and inclusively as possible;
  • Aim for a sample of key informants that reflects the stakeholder onion - recognizing your intention is to capture the broadest range of stakeholder input, to shed light on the quality and effectiveness of your CSE.
The Tools

A-Tools:
- AA: Stakeholder ID & Analysis (DAILY)
- A1: Engagement Log (DAILY)
- A2: Compilation of Clinical Data (MONTHLY)
- A3: Inventory of CSE alongside GPP (MONTHLY)

B-Tools:
- B1: Community Stakeholder Interview (QUARTERLY)
- B2: Advisory Group Member Interview (QUARTERLY)
- B3: Broader Stakeholder Interview (QUARTERLY)

C-Tools:
- C1: Trial Participant Interview (BIANNUALLY)
- C2: Prospective Trial Participant (BIANNUALLY)

D-Tools:
- D1: CE/CLO Self-Assessment (ANNUALLY)
- D2: PI Self-Assessment (ANNUALLY)
Navigating the Database

with Kenneth Babigumira of MRC
Introduction to the Database

• A web-based data entry, data analysis and reporting tool;

• Designed to run on most browsers
  – Tested and validated on Internet Explorer (IE 9+), Firefox & Chrome.
Users & Roles

• Certain conditions to participation & access;
• TB Alliance administrator will then set you up as a user on the database & assign some role(s) to your username;
  – Site View Only
  – Site Data Entry
  – Site Data Management
  – Each participating research site will have designated “admin” user(s) with the role of “Site Data Management”
Site Setup

• For the purpose of the training we have already set up your sites and your usernames and assigned you passwords for the training.

• You each have that information in hand ready to enter it into the system.
Web based address

• Training Database:
  http://67.207.154.82/appdev/

• Live Database:
  http://67.207.154.82/app/
The Login Page
Home Screen

This is a Community Stakeholder Engagement (CSE) Monitoring and Evaluation Software. It will be used for data entry, data analysis and reporting.

Getting started

Toolkit Map

AA: Stakeholder ID & Analysis
A1: Engagement Log
A2: Compilation of Clinical Data
A3: Inventory of CSE alongside GPP Guidelines

B1: Community Stakeholder Interview
B2: Advisory Group Member or Community Representative Interview
B3: Broader Stakeholder Interview
C1: Participant Volunteer Exit Interview

DAILY & MONTHLY
QUARTERLY
Adding a research site (1)

- This will be set up by site manager & TB Alliance administrator

Click on the Site setup link on the welcome page. This will redirect you to the site setup screen.
Adding a research site (2)

Click on this button to add a new research site. If the site already exists in the list, then select it instead of creating a new one.
Adding a research site (3)
Managing Site Details (1)

- **Trial Details** – used on all the tools for populating list of research trials applicable to the site.
- **Region/Zone/Ward Details** – used on tool A2
- **Health Facility Details** – used on tool A2
- **Site Personnel Details** – used on most of the tools for populating the list of the person who compiled/entered the data or interviewed.
Managing Site Details (2)

- It is very important that sites enter all site details before they can start entering data using the tools.
Add a Toolkit Entry (1)

• To get started, click on the tool using the left hand menu, or click on the tool on the toolkit map (if on the welcome page).
Add a Toolkit Entry (2)

1. Select the toolkit questionnaire type
2. Select the research site
3. Click the add button. You will be redirected to a blank for data entry
Add a Toolkit Entry (3)

1. Select the questionnaire type

2. The list only shows 10 entries per time. You can adjust them number using the records per page.
   Use the search to look for your form, searching by either the consultation date, tracking number or engagement type.

3. Click on the edit link to open the form and make the changes you want to make.
Setting Up

• Logging you in!
Trying out the tools

- Role play
- Record responses – one step at a time!
Set A Tools

• Core Monitoring Tools
• Daily or Monthly
  – Tool AA – Stakeholder ID & Analysis
  – Tool A1 – Engagement Log
  – Tool A2 – Compilation of Clinical Trial Data
  – Tool A3 – CSE Inventory alongside GPP
Tool AA – Stakeholder ID & Analysis

• When & Why to complete
  o Whenever a new stakeholder is engaged
  o To rate power, influence & participation intermittently so as to decide where to invest time and effort.

• Number to complete
  o No defined sample size
  o ++ Stakeholders consulted = more information in the database to use for effective planning or M&E.

• Estimated Time
  o 10 - 15 minutes maximum
Tool AA – Stakeholder ID & Analysis

• Role Play

• A phone conversation between the CE manager and the chairperson of the Youth with TB Network!

• Featuring, guest stars: LIMAKATSO & HELEN
FORM AA – IDENTIFY THE STAKEHOLDERS

This form is completed whenever a new stakeholder is engaged, updated automatically via A1 and revisited to rate power and engagement intermittently.

<table>
<thead>
<tr>
<th>AA-1.1 SITE:</th>
<th>Clinical HIV Research Unit - Helen Joseph</th>
</tr>
</thead>
<tbody>
<tr>
<td>AA-1.2 REFERENCE (always used for this SH)</td>
<td></td>
</tr>
<tr>
<td>AA-1.3 STAKEHOLDER NAME</td>
<td></td>
</tr>
<tr>
<td>AA-1.4 STAKEHOLDER TYPE</td>
<td>Select...</td>
</tr>
<tr>
<td>AA-1.5 TYPE OF STAKEHOLDER</td>
<td>Select...</td>
</tr>
</tbody>
</table>

Specify in detail
Tool A1 – Engagement Log

• When & Why to complete
  o As soon after ENGAGEMENT of any kind as possible
  o Captures details of 4 engagement mechanisms
    o CONSULTATION – CAB – OUTREACH - MEDIA

• Number to complete
  o One entry per engagement of any kind
  o Entries capture planning and implementation efforts

• Estimated Time
  o 5 – 10 minutes maximum per engagement
Tool A1 Engagement Log - Consultation

• Role Play

• A thinking out loud conversation in your office at the end of the day!

• Featuring, guest stars: SIYA
### Tool A1 Engagement Log - Consultation

#### FORM A1 – COMMUNITY ENGAGEMENT LOG

<table>
<thead>
<tr>
<th>Site:</th>
<th>Kilifi Welcome Trust</th>
</tr>
</thead>
<tbody>
<tr>
<td>Name of Research Trial:</td>
<td>Select...</td>
</tr>
<tr>
<td>Protocol Number</td>
<td>Select one or more protocols</td>
</tr>
<tr>
<td>A1#1 Name of Person Who Did the Engagement:</td>
<td>Select...</td>
</tr>
<tr>
<td>Title/Position of Person Who Did the Engagement:</td>
<td>Select...</td>
</tr>
<tr>
<td>1. Date of Consultation</td>
<td><em>Blank</em></td>
</tr>
<tr>
<td>2. Type of Community Engagement</td>
<td>Consultation</td>
</tr>
<tr>
<td>Name of CAB:</td>
<td><em>Blank</em></td>
</tr>
<tr>
<td>3. Tracking Number</td>
<td><em>Blank</em></td>
</tr>
</tbody>
</table>

A unique consecutive number (generated by software) assigned to this.
Tool A1 Engagement Log - CAB

• Role Play

• A thinking out loud conversation in your office at the end of the day!

• Featuring, guest stars: John
<table>
<thead>
<tr>
<th>Q1-5</th>
<th>Q6</th>
<th>Q7-8</th>
<th>Q9</th>
<th>Q10</th>
<th>Q11</th>
<th>Q12</th>
<th>Q13-15</th>
<th>Related Documents</th>
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<tbody>
<tr>
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<td></td>
<td></td>
<td></td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**SITE:**

**NAME OF RESEARCH TRIAL:**

**PROTOCOL NUMBER**

**A1# NAME OF PERSON WHO DID THE ENGAGEMENT:**

**TITLE/POSITION OF PERSON WHO DID THE ENGAGEMENT:**

**1. DATE OF CONSULTATION**

**2. TYPE OF COMMUNITY ENGAGEMENT**

**Name of CAB:**

**3. TRACKING NUMBER**

A unique consentive number (generated by software) assigned to this.
Tool A1 Engagement Log - OUTREACH

• Role Play

• A thinking out loud conversation in your office at the end of the day!

• Featuring, guest stars: Ella
Tool A1 Engagement Log - OUTREACH

FORM A1 – COMMUNITY ENGAGEMENT LOG

| SITE: | Kilifi Welcome Trust |
| NAME OF RESEARCH TRIAL: | Select... |
| PROTOCOL NUMBER | Select one or more protocols |
| A1#1 NAME OF PERSON WHO DID THE ENGAGEMENT: | Select... |
| TITLE/POSITION OF PERSON WHO DID THE ENGAGEMENT: | Select... |

1. DATE OF CONSULTATION

2. TYPE OF COMMUNITY ENGAGEMENT
   - OUTREACH

3. TRACKING NUMBER
   - A unique identifier number (generated by software) assigned to this...
Tool A1 Engagement Log - MEDIA

• Role Play

• A thinking out loud conversation in your office at the end of the day!

• Featuring, guest stars: Vela
**Tool A1 Engagement Log - MEDIA**

**FORM A1 – COMMUNITY ENGAGEMENT LOG**

<table>
<thead>
<tr>
<th>SITE:</th>
<th>Kilifi Welcome Trust</th>
</tr>
</thead>
<tbody>
<tr>
<td>NAME OF RESEARCH TRIAL:</td>
<td>Select...</td>
</tr>
<tr>
<td>PROTOCOL NUMBER</td>
<td>Select one or more protocols</td>
</tr>
<tr>
<td>A1#1 NAME OF PERSON WHO DID THE ENGAGEMENT:</td>
<td>Select...</td>
</tr>
<tr>
<td>TITLE/POSITION OF PERSON WHO DID THE ENGAGEMENT:</td>
<td>Select...</td>
</tr>
<tr>
<td>1. DATE OF CONSULTATION</td>
<td></td>
</tr>
<tr>
<td>2. TYPE OF COMMUNITY ENGAGEMENT</td>
<td>MEDIA</td>
</tr>
<tr>
<td>Name of CAB:</td>
<td></td>
</tr>
<tr>
<td>3. TRACKING NUMBER</td>
<td>A unique consecutive number (generated by software) assigned to this...</td>
</tr>
</tbody>
</table>
Tool A2 – Compilation of Clinical Trial Data

• When to complete
  - Monthly – as close to the same day each month.

• Number to complete
  - All clinical trial data required for each month.

• Estimated Time
  - 15 – 30 minutes
Tool A2 – Compilation of Clinical Trial Data

• Role Play

• *Its mid morning and you have a monthly meeting with your Data Manager to compile the data required for Tool A2.*

• *Featuring, guest stars: John & Siya*
Tool A2 – Compilation of Clinical Trial Data

FORM A2 – CLINICAL TRIAL DATA EXTRACTION FORM

SECTION 1: GENERAL INFORMATION

Instructions on completing this form

⚠️ Please ensure that you have set up the Regions and Health Facilities using the Site Setup screen before completing this form.

Current setup:
- 0 Regions
- 0 Health facilities

<table>
<thead>
<tr>
<th>A2-1.0</th>
<th>NAME OF TRIAL:</th>
<th>Select...</th>
</tr>
</thead>
<tbody>
<tr>
<td>A2-1.1</td>
<td>Protocol Number</td>
<td>Select...</td>
</tr>
<tr>
<td>A2-1.1</td>
<td>Site:</td>
<td>IAVI</td>
</tr>
</tbody>
</table>

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.
Tool A3 – CSE Inventory alongside GPP

• When to complete
  o Retrospective
  o Monthly – as close to the same day each month.

• Number to complete
  o Reflect on current stage of research life

• Estimated Time
  o 15 – 30 minutes
Tool A3 – CSE Inventory alongside GPP

• GPP categories
  o Formative Work
  o Trial Protocol Development
  o Informed Consent Forms & Processes
  o Trial Results Dissemination
  o Development of Issues Plan
  o Procedures for Participant Exit from Trial
  o Intervention & Trial Product Dissemination
Tool A3 – CSE Inventory alongside GPP

• Group work exercise

• Reflect on the stage of the trial you are given & answer as if that stage is underway and suggestions have emerged through your CSE systems.

• Featuring, guest stars: You all!
# Tool A3 – CSE Inventory alongside GPP

## FORM A3 – INVENTORY OF CSE ALONGSIDE GPP GUIDELINES

### SECTION 1: GENERAL INFORMATION

<table>
<thead>
<tr>
<th>A3-1.0</th>
<th>NAME OF TRIAL:</th>
<th>Select...</th>
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</thead>
<tbody>
<tr>
<td>A3-1.1</td>
<td>Protocol Number</td>
<td>Select one or more protocols</td>
</tr>
<tr>
<td>A3-1.1</td>
<td>Site:</td>
<td>Kilifi Welcome Trust</td>
</tr>
<tr>
<td>A3-1.2</td>
<td>MONTH BEING COMPILED (all data will be collected about this month):</td>
<td>Select...</td>
</tr>
<tr>
<td>A3-1.3</td>
<td>YEAR:</td>
<td>Select...</td>
</tr>
<tr>
<td>A3-1.4</td>
<td>YEAR OF TRIAL:</td>
<td>Select...</td>
</tr>
<tr>
<td>A3-1.5</td>
<td>NAME OF PERSON COMPILING</td>
<td>Select...</td>
</tr>
</tbody>
</table>

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### Related Documents

- [Tool A3 - CSE Inventory alongside GPP](#)
Set B Tools

- Stakeholder Informants
- In time for Quarterly review

- Tool B1 – Community Stakeholder - CSH
- Tool B2 – Advisory Board or CAB
- Tool B3 – Broader Stakeholder - BSH
Tool B1 – Community Stakeholder

• When & Why to complete
  o Ideally schedule 1 a month, 3 per quarter.
  o Use it as an opportunity to reach new stakeholders

• Number to complete
  o No defined sample size
  o ++ Stakeholders consulted = more information in the database to use for effective planning or M&E.

• Estimated Time
  o 30 minutes maximum
Tool B1 – Community Stakeholder

• Role Play

• You have scheduled an interview with a key informant, a leader of a church in one of the communities from which you are recruiting participants.

• Featuring, guest stars: Laia & Nombuyiselo
# Tool B1 – Community Stakeholder

## FORM B1 – COMMUNITY STAKEHOLDER INTERVIEW

**Instructions:** This questionnaire should be completed with community stakeholders – these include community based organisations (CBOs), the families and friends of trial participants, schools, trial site staff, local religious institutions, traditional leaders, community advisory boards and local health service providers, home care workers etc. Ideally you should try to reach a minimum of 2 broader stakeholders 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 policymakers, politicians, local media and medical professionals.

### SECTION 1: GENERAL INFORMATION

<table>
<thead>
<tr>
<th>B1-1.0</th>
<th>INTERVIEW NUMBER</th>
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<tbody>
<tr>
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<table>
<thead>
<tr>
<th>B1-1.1</th>
<th>NAME OF RESEARCH TRIAL(S).</th>
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</thead>
<tbody>
<tr>
<td></td>
<td></td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>B1-1.2</th>
<th>SITE.</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Tembisa Clinical Research Site</td>
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</tbody>
</table>

<table>
<thead>
<tr>
<th>B1-1.3</th>
<th>DATE OF INTERVIEW</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
</tr>
</tbody>
</table>
Tool B2 – CAB Member Interview

• When & Why to complete
  - Ideally schedule 1 a month, 3 per quarter.
  - Use it as an opportunity to reach new stakeholders

• Number to complete
  - No defined sample size
  - ++ Stakeholders consulted = more information in the database to use for effective planning or M&E.

• Estimated Time
  - 30 minutes maximum
Tool B2 – CAB Member Interview

• Role Play

• You have scheduled an interview with a key informant, who is a CAB member. She is a head nurse in the zone.

• Featuring, guest stars:
Tool B2 – CAB Member

FORM B2 – ADVISORY GROUP MEMBER OR COMMUNITY REPRESENTATIVE INTERVIEW

Instructions: This questionnaire should be completed with community stakeholders’ – these include community based organisations (CBOs), the families and friends of trial participants, schools, trial site staff, local religious institutions, traditional leaders, community advisory boards and local health service providers, home care workers etc. Ideally you should try to reach a minimum of 2 broader stakeholders 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 policymakers, politicians, local media and medical professionals.

SECTION 1: GENERAL INFORMATION

<table>
<thead>
<tr>
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<tbody>
<tr>
<td>B2-1.1</td>
<td>NAME OF RESEARCH TRIAL(S):</td>
</tr>
<tr>
<td></td>
<td>PROTOCOL NUMBER</td>
</tr>
</tbody>
</table>
Tool B3 – Broader Stakeholder Interview

• When & Why to complete
  o *Ideally schedule 1 a month, 3 per quarter.*
  o *Use it as an opportunity to reach new stakeholders*

• Number to complete
  o *No defined sample size*
  o *++ Stakeholders consulted = more information in the database to use for effective planning or M&E.*

• Estimated Time
  o *30 minutes maximum*
Tool B3 – Broader Stakeholder Interview

• Role Play

• *You have scheduled an interview with a key informant, a leader of a church in one of the communities from which you are recruiting participants.*

• *Featuring, guest stars:*
Tool B3 – Broader Stakeholder

FORM B3 – BROADER STAKEHOLDER INTERVIEW

Instructions: This questionnaire should be completed with broader stakeholders’ members – these include non-governmental organisations (NGOs), local health department directors, managers or policymakers, politicians, local media and medical professionals. Ideally you should try to reach a minimum of 2 broader stakeholders from each relevant location or zone represented in your trials’ catchment area – or as seen appropriate by your team. Be reminded that this Interview is not targeting community stakeholders – which include community based organisations (CBOs), the families and friends of trial participants, schools, trial site staff, local religious institutions, traditional leaders, community advisory boards, local health service providers.

SECTION 1: GENERAL INFORMATION

<table>
<thead>
<tr>
<th>B3-1.0</th>
<th>INTERVIEW NUMBER</th>
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<tr>
<td>B3-1.1</td>
<td>NAME OF RESEARCH TRIAL(S):</td>
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<td></td>
<td>PROTOCOL NUMBER</td>
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<tr>
<td>B3-1.2</td>
<td>NAME OF LOCATION OR RESEARCH SITE</td>
</tr>
<tr>
<td>B3-1.3</td>
<td>DATE OF INTERVIEW</td>
</tr>
</tbody>
</table>

Tembisa Clinical Research Site
End of Day 1

• Your Questions!

• Home work – experiment with the tools and come back with your favorite tool and a reason for your choice.
Processing the Data & Reporting

• The Indicators - Areas of Desired Impact
  • Formative research plans
  • Trial protocol development
  • Informed consent forms and processes & participant understanding
  • CSE mechanisms
  • Communications plans
  • Pertinent issues management plans
  • Recruitment approach
  • Participant retention levels
  • Participant adherence to trial regimens & procedures
  • Levels of trust among community and among stakeholders
  • Research literacy
Processing the Data & Reporting

• Disease risk perception issues
• Avoidance of volunteer harms
• Avoidance of rumors about trial
• Participant experience at clinic visits
• Participant access to package of products and services
• Participant exit from trial
• Focus of research agenda
• Policy discussions on intervention
• Trial results dissemination
• Participant access to services post trial
• Healthcare and/or research capacity