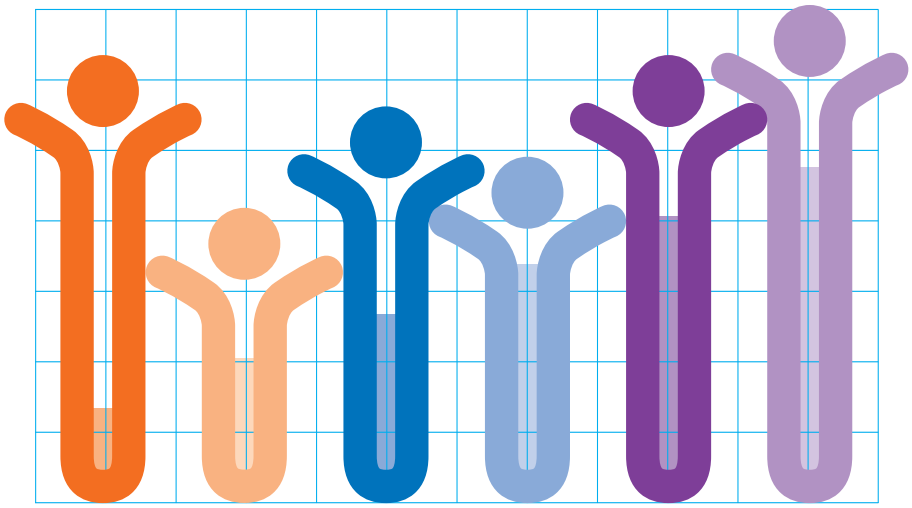

ENGAGEMENT FOR IMPACT

A manual to support the use of the

M&E for Community Stakeholder Engagement in Clinical Trials Database

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Definition of Terms

Advocate: A person or group that acts on behalf of individuals or groups.

AVAC: Global Advocacy for HIV Prevention: An international, non-profit Organization that uses education, policy, analysis, advocacy and community mobilization to accelerate the ethical development and eventual global delivery of AIDS vaccines and other new HIV prevention options as part of a comprehensive response to the pandemic.

CAB: Community advisory boards (CAB): Also referred to as community advisory groups. A formal stakeholder advisory mechanism composed of community members or representatives that meet regularly with research team representatives. Community advisory boards or groups act as an independent advisory voice; a community advisory board provides feedback to research teams about community norms and beliefs, as well as community views and concerns around specific trials.

Formative research activities: Activities that enable research teams to gain an informed understanding of the local population, sociocultural norms and practices, local power dynamics, community perceptions, channels of communication and decision-making, and history of research in the area, as well as an informed understanding of the needs and priorities of the people living in the trial catchment area.

Good clinical practice: Internationally recognized guidelines for designing, conducting, recording, and reporting clinical trials in which humans participate. Following the guidelines helps to ensure that the participants are protected and that the data collected are accurate.

Good participatory practice: Internationally recognized guidelines for effective stakeholder engagement that builds mutually beneficial, sustained relationships between trial funders, sponsors, and implementers and other stakeholders that are transparent and respectful and ultimately work to address the interests of community stakeholders.

Protocol: A document that details the goals, design, methodology, statistical considerations, and organization of a study or clinical trial. The clinical trial protocol will have a study plan that describes what types of people may participate in the trial, the schedule of tests, procedures, medications and dosages, and the length of the study. The plan is carefully designed to safeguard the health of the participants as well as to answer specific research questions. A large trial may have sub-studies or protocols.

Research life-cycle: The entire process of the study, starting from developing the concept and continuing through to the completion of the study and dissemination of results.

CSE Team: The group of staff within a trial responsible for implementing the community and stakeholder engagement program.

Stakeholders: Individuals, groups, organizations, governments, or other entities that are affected by the outcome of a trial or that can influence the outcome of proposed research through their input and actions. These can be local, regional (broader), national or international stakeholders.

Community: Groups who share a common sense of belonging and where there is a level of trust between members. This can be defined as - Geographical – based around where people live, such as neighborhood, suburb or town; Interest – based around common interests, such as conservation, social justice or sporting interest or Identity – based on sharing a common identity such as age, culture or lifestyle.

Community engagement: Mutual communication and deliberation that occurs between an implementing institution and a defined community.

Goal: A broad statement of a desired, usually longer-term, outcome of a program. Goals express general program intentions and help to guide the development of the program – in this case a community and stakeholder engagement program. Each goal has a set of related; specific objectives that if met will collectively lead to the achievement of the stated goal.

Indicator: A quantitative or qualitative variable that can provide a measure of achievement, assess performance or reflect on changes connected to an intervention. Single indicators are limited in their use. Indicator data should be collected and interpreted as part of a set of indicators.

Logical Framework: A management tool sometimes used to improve the design of program interventions. It involves identifying strategic elements (inputs, outputs, activities, outcomes, impact) and their causal relationships. It thus facilitates planning, execution and monitoring and evaluation of a program.

Monitoring: A routine tracking and reporting system typically focused on priority information about a program. This includes inputs and intended outputs, outcomes and impacts.

M&E Plan: An implementation strategy (often multiple years) for the collection, analysis and use of data needed for program management and accountability purposes. The plan describes the data needs, linked to a specific program, the M&E activities that need to be undertaken to satisfy the data needs, the specific data collection tools and procedures; the standardized indicators; the components of the M&E system; the roles and responsibilities of different individuals; how data will be used for management and accountability. The plan also includes resource requirement estimates.

M&E Workplan: An annual and budgeted M&E Plan that describes the priority M&E activities for the year and the roles and responsibilities of various individuals or groups; the cost of each activity and the funding identified; a timeline for delivery or all outputs. The work plan is used for coordinating M&E activities and assessing progress of M&E implementation throughout the year.

Stakeholders: Individuals and/or groups with an interest in an activity and/or outcome. Stakeholders may be internal or external to the organization and may be direct or indirect beneficiaries.

Stakeholder engagement: Stakeholder engagement is a way of thinking about external audiences and their relationship to organizational outcomes. It implies a longer term relationship where both parties have a mutual interest in, and ability (planned or unplanned) to impact upon, the project outcomes.

Objective: A statement of the desired program, which meets the criteria of being SMART – specific, measureable, achievable, realistic and time phased.

Quantitative Data: Data collected using quantitative methods and measured on a numerical scale, can be analyzed using statistical methods and can be displayed using tables, charts, histograms and graphs.

Qualitative Data: Data collected using qualitative methods, such as interviews, focus groups, observation and key informant interviews. Qualitative data can provide an understanding of social situations and interaction, as well as people's values, perceptions, motivations and reactions. Qualitative data are generally expressed in narrative form – providing a complete detailed description.

Introduction

"…[Community and Stakeholder] engagement in research is a process of inclusive participation that supports mutual respect of values, strategies, and actions for authentic partnership of [the] people affiliated with or self-identified by geographic proximity, special interest, or similar situations to address issues affecting the well-being of the community of focus [in the research]."
(Fawcett, PaineAndrews et al. 1995)

Community and Stakeholder Engagement (CSE) is considered an ethical and scientific requirement for all research involving human participants. Community and stakeholder engagement in research is required to:

"Ensure the ethical and scientific quality of proposed research, its relevance to the affected community, and its acceptance by the affected community, community representatives should be involved in an early and sustained manner in the design, development, implementation, and distribution of results…"
(UNAIDS. 2007)

Community and stakeholder engagement in the clinical trial process aims to enhance collaboration, partnership and dialogue between trial sponsors, trial researchers (international and national), and individuals at various levels who have a stake in, or are directly affected by the disease or condition being studied and/or in the implementation and outcomes of the clinical or biomedical research. Community and stakeholder engagement requires representatives of the research team to become part of the community and community members to become part of the research team, creating a unique working and learning environment before, during, and after the research.

Typically CSE strategies implemented within and around clinical trials should attempt to:

- Increase knowledge and understanding about disease, research processes and/or health products under study among the relevant stakeholders including the relevant community representatives ;
- Obtain and incorporate stakeholder and community input into the clinical trial design;
- Understand and address stakeholder and community concerns in the research process so as to avoid disruption or premature closure of the trial;
- Enhance facilitation of recruitment and retention, as a result of culturally appropriate/ community informed study designs; and
- Improve implementation of the research leading to stakeholder and community acceptance and uptake of health products under study if appropriate.

Many clinical research groups may still have a limited understanding of what CSE entails, despite having dedicated CSE teams. In practice, significant confusion often persists around the definition of community and stakeholder engagement in research, and many researchers continue to use the terms 'community stakeholder engagement' very loosely.

Community engagement is versatile, mutable and adaptable. It plays a slippery role, it plays a lot of useful roles for us, but it is difficult to grasp. Like a bar of soap it slips out of our hands."
Daniel Glaser - (WellComeTrust 2011)

In a busy trial, with a tight timeline, clinical researchers are often keen to find out how CSE can benefit the trial's progress and may ask questions like: *'How can we solicit meaningful input from these stakeholders in order to benefit the trial?'* Or perhaps *'How or will community and stakeholder engagement positively impact on our trial outcomes?'* There is growing recognition that before a trial can benefit from CSE, the stakeholders need to have been engaged in a fair and appropriate manner that is closely monitored. Each trial needs a CSE team that is dedicated to engagement for the right reasons and has a strong monitoring and evaluation framework in place at the start of each trial that can track and inform the stakeholder and community engagement process throughout the lifecycle of the trial.

This manual presents some background and a set of tools to set in motion a culture of monitoring the CSE programs affiliated to HIV and TB related clinical trials. This guide accompanies the database and represents the first CSE M&E toolkit of its kind. The toolkit developers will welcome constructive feedback for subsequent revisions.

The manual is divided into sections intended to facilitate use by CSE program teams. The manual begins with a *Background and an introduction to the concept of Stakeholders* and an *Overview of CSE and M&E* followed by the preliminary *Indicator Framework* developed by the working group that formed the basis for the database, some basic fundamentals of *Work Planning* and its inseparable connection to effective M&E. We then introduce the *M&E tools* that feature in the database, followed by explanation of each tool including its purpose and when and how to enter the data. You will then be introduced to the *Quarterly Report* template and be shown how to generate a set of basic results that your sponsors wish to see feature in your quarterly report. This manual also takes you step by step through using the database and also FAQs that highlight the way in which the database can be exploited by trial statisticians for more sophisticated analysis.

Background

The need for more structured community and stakeholder engagement in clinical trials was spurred on over the past 15 years by vocal activists and the recognition that community and stakeholder inclusion in clinical research is an ethical responsibility, and that not involving stakeholders and the community in clinical research threatens the viability of trials (UNAIDS 2006).

Guidelines for Good Participatory Practice (GPP) in HIV trials emerged as a result of these serious controversies, first arising from the oral tenofovir (an essential HIV antiretroviral drug) trials in Cameroon and Cambodia in 2003. Activists in the trial countries and some international groups criticized the trials as unethical— particularly related to access to ongoing care for trial participants and about lack of sufficient community and stakeholder engagement. These issues led to the shutdown of the tenofovir trial in Cambodia and Cameroon. These obstacles resulted in a period of reflection among donors, advocates, and scientists to determine what went wrong and discussion on what needed to change to prevent this reaction and emerging mistrust of clinical research. UNAIDS in 2005 assembled a global consultation to search for a way forward (UNAIDS 2006). Out of the process emerged the GPP, a product jointly developed by UNAIDS and AVAC. The development of GPP had two goals:

1. To establish clear, global standards for community participation and input in HIV prevention trials.
2. To publish guidelines with the intent of seeking eventual endorsement by the International Council on Harmonization (ICH)(Bass November 27, 2007).

Subsequently, in 2012 the GPP for TB Trials were released. The Good Participatory Practice (GPP) guidelines for TB Drug Trials were a collaborative product between AVAC and the Stakeholder and Community Engagement Workgroup of the Critical Path to TB Drug Regimens. These guidelines, in turn, offer trial funders, sponsors, and implementers' some systematic guidance on how to engage stakeholders and communities throughout the research lifecycle, specific to TB research.

This toolkit is closely aligned with the GPP guidelines and dedicates an entire tool to the monitoring of GPP features as they apply throughout the lifecycle of the trial.

The Stakeholders

The stakeholders are everywhere! But, precisely who are they?

It is essential for your CSE team to hold itself to the challenging standard of articulating who the stakeholders in your trial really are and then the circumstances of your trial will then dictate which stakeholders must be engaged, and to what extent.

The general definition of stakeholders proposed in the GPP guidelines for TB and for HIV includes: all individuals, groups, organizations, government bodies, and communities who have an interest in the conduct and outcomes of a specific trial.

They may include:

- current and prospective trial participants;
- families of trial participants;
- individuals residing within, or surrounding, the area where research is conducted;
- people affected by the disease being studied;
- community engagement coordinators;
- health service providers, such as community health workers;
- community-based organizations (CBOs);
- community or interest groups;

- non-governmental organizations (NGOs);
- advocates and activists;
- religious or faith based groups;
- educators;
- local politicians and chiefs;
- key opinion leaders;
- media;
- national and local healthcare authorities;
- governments;
- research teams;
- academic institutions;
- companies; and
- public-private/ product development partnerships.

Figure 1: Stakeholder Onion - from TB-GPP.

As depicted in Figure 1, various subsets of stakeholders exist:

Community Stakeholders - refer to those individuals and groups that are either directly affected by the conduct of a drug trial or that represent the interests of parties that are. Examples of community stakeholders include participants and their relatives; communities where the trial is conducted; and local advocates and activists. The other stakeholders depicted in Figure 1 also have significant interests and potential impact on the conduct of trials (GPP TB, 2012).

Broader Stakeholders/Mid-Level Stakeholders – refer to those operating just outside the community sphere. They are not part of the community where the trial is operating or targeting participants. Broader or Mid-Level Stakeholders are local professionals – for example local NGOs, Local Policy Makers, Local Media and Local Health Practitioners. These Broader Stakeholders are very familiar with the context where the trial is operating, but they are engaged at a professional level, rather than a personal level. They think about the community more broadly (GPP TB, 2012).

National Stakeholders - refer to those addressing the issues under investigation at a national or federal level in the countries where trials are underway. These stakeholders are typically far removed from the communities where the trial is underway, their priority is more regulatory and policy focused. At this level we are referring to – Ministries of Health, Members of Parliament for the areas under study, National NGOs, National Media and National Sponsors. The CSE team is not always involved with this level of stakeholder – typically the trial administrators or PIs work with this level (GPP TB, 2012).

Global/International Stakeholders - refer to those at the top of the stakeholders who are located outside the target country. These stakeholders may be those who fund the trials or provide the practice guidelines or who design the multi-site protocols, secure international approval. These may include trial sponsors and networks, UN or WHO related groups, multi-lateral donors, large international NGO's and donors (GPP TB, 2012).

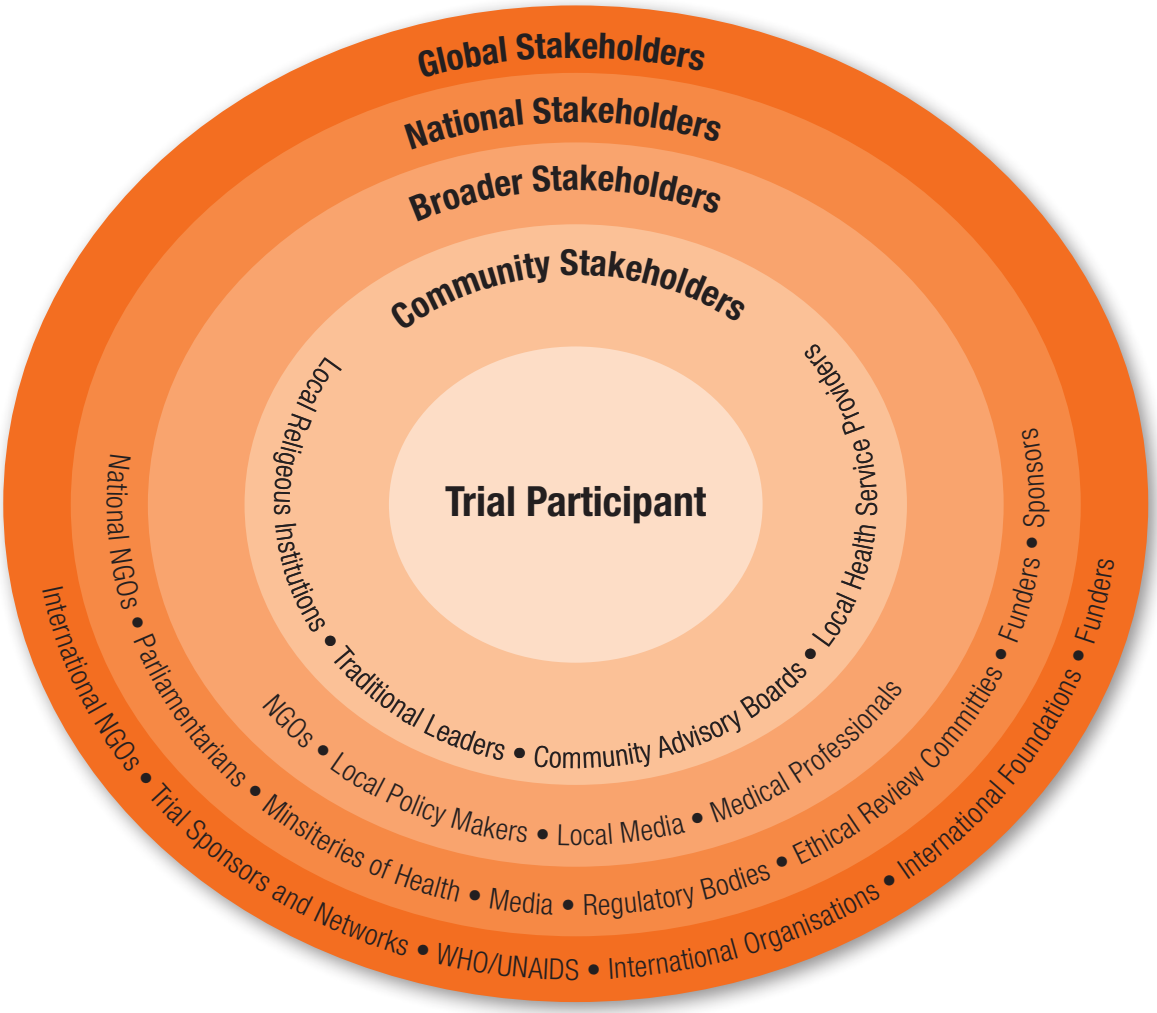


Figure 2: Layers of Biomedical HIV Prevention Trial Stakeholders - from HIV GPP.

Community and Stakeholder Engagement

Having defined your specific stakeholders, the question remains: what is community and stakeholder engagement for you and your trial? Stakeholder engagement broadly speaking can refer to any form of consultation, collaboration, and partnership put in place to enable a dialogue between all parties having a stake in a specific trial with the goal of reaching a point where that project is understood, acceptable, and meaningful to all (Stakeholder-Community-Engagement-Workgroup-Critical-Path-TB-Drug-Regimens-Initiative. 2011). Stakeholder engagement is inherently multi-directional – hence when it is well implemented, it should entail genuine dialogue and not one way information giving.

For some trials community stakeholder engagement (CSE) refers to the process in which trial funders, sponsors, and research teams develop meaningful relationships with specific subsets of stakeholders in relation to various aspects of the clinical trial research process; such as design and implementation, dissemination of results, and the development of strategies for access to trial products. Since this kind of CSE is widely acknowledged as best practice in clinical trials, it is now becoming a standard expectation of many donors as well as communities and various stakeholders wherever clinical research is conducted.

In the past the most widely accepted best practice for CSE in health have been the development of community advisory boards (CABs), also referred to as community advisory groups (CAGs) or community forums; community education and research literacy training and the development of networks for patient and community leaders, NGOs and health care providers. However, over-reliance on CABs as a CSE mechanism has raised questions about its true value. These are other CSE mechanisms that can be used when clinical research teams think more expansively about how communities and stakeholders can be genuinely engaged in the research process. Some of the current thinking around CSE principles and strategies are described in Table 1.

Table 1: Current Approaches to CSE in Clinical Trials

1. Establish norms and formalize budgets for Stakeholder and Community Engagement

Single mechanism one-size-fits-all approaches do not work. It is important to maintain a range of strategies for engaging stakeholders and the community (Heise, 2007), while working to establish norms around the principles and purpose of the engagement. GPP for HIV and TB prevention and treatment trials are one step in this direction but a lot more needs to be done to formalize the goals operationally. It is recommended that new norms for community engagement should include clear guidance on reasonable budgets and these budgets should be controlled at a site level (Slevin West K, Ukpong et al. 2008).

2. Beyond the CAB

CABs and other similar structures can play an important role in the engagement process. Experience indicates however, that CABs often suffer from serious limitations. Researchers should employ a diverse range of approaches beyond the CAB and sponsors should require the creation and implementation of more creative less prescriptive one size fits all approaches, instead of relying solely on CABs.

> **"CABs should not be the only mechanism used to engage and solicit input from the community stakeholders. Questions regarding the extent to which a CAB can truly and actively represent the community, the perceived autonomy of an advisory body organized by the research institution, and a CAB's reliance on volunteers who have competing priorities are examples of some of these limitations."**
> **(Heise, 2007)**

> **"…by focusing on a CAB as the primary mechanism for implementing community involvement, the whole enterprise is subject to the success or failure of one strategy."**
> **(Global-Campaign-for-Microbicides. 2004)**

3. Early Involvement

As important as the how to engage stakeholders and communities is the when to engage them. Involving communities in the decisions about if, where, and why research will take place helps to establish trust and a sense of ownership over the research. Early investment in the capacity of communities to engage in the research process helps to build a strong base of support and can help to avoid future misunderstandings that may threaten the viability of trials (Global-Campaign-for-Microbicides. 2004).

4. Planning for Future Access

Beyond the successful implementation of research trials, community support is vital for the successful introduction and future acceptance of study products should they prove effective. Engaging communities and stakeholders early can help to build authentic 'buy in' and ensure the strategies for introduction are contextually appropriate and acceptable to the community.

5. Open Dialogue

Coordinated efforts to share lessons learned and best practices are vital, as are questions of how to monitor and evaluate such strategies and measure their success. Research institutions need to recognize and support the importance of opportunities for ongoing professional dialogue on these emerging issues.

6. Documenting Monitoring Results and Evidence-Based Approaches

There is need for quantitative and qualitative evidence to support increased investment in community engagement in clinical trials. All new and creative strategies and practices should be monitored, documented and evaluated in order to build a body of evidence to inform authentic and effective community engagement and to shed light on its impact on clinical trial outcomes (Slevin West K, Ukpong et al. 2008).

Amidst the various CSE approaches in operation, it is generally believed that CSE is essential to the clinical research process; and that in theory CSE builds a more positive and beneficial relationship between clinical research and communities – which may or may not have the potential to achieve better research results and outcomes. The latter has yet to be proven.

Guidelines on CSE (UNAIDS/AVAC 2011) and ethical standards for community participation in research (UNAIDS/WHO 2007) have have been published and in addition to addressing ethics generally, they offer recommended best, activites and strategiesfor CSE in health research. However, these existing guidelines provide little insight into the expected outcomes of CSE, indicators of successful CSE programs, or appropriate monitoring and evaluation tools for assessing the impact of CSE on clinical trials processes and outcomes as well as on communities. This toolkit provides some of the 'tools' needed to begin this process.

ENGAGING with the concepts of ENGAGEMENT

Engagement is not about getting public buy-in for a research program or technology through lobbying or campaigning, and it is beyond simple health promotion. It is about starting a two-way interaction between research and the worlds of the public or policy.

Engagement is about 'exchange'. It is not just about providing information or disseminating ideas or results. Engagement challenges the notion of communities as 'recipients' and has the potential for community members to become politically and critically aware and in turn involved in scientific processes.

Communities can also drive the engagement process, holding scientists and science accountable for their ethics. Engagement is about finding formal and informal ways to bridge the divide between two or more knowledge systems and cultures; for example, between scientists, policy makers and community members. Power and how it operates is central to how scientists and communities engage with one another. A researcher's priority is to do the science but scientists need to assess how power and politics affect the quality of their science, and whether engagement might improve research excellence.

Whether to engage with communities or not is an ethical question. Engagement is not a benchmark for ethics. Ethics does not stop when community engagement takes place. Engagement itself has ethical implications. Engaging with communities in creative ways, collaborating with artists and using participatory methodologies are real options for scientists. Creative methodologies can be particularly helpful to nurture genuine expression, subvert power and catalyse discussion.

Community engagement practices need to be evidence based. Evaluating and monitoring community engagement processes and outcomes are important. Anyone planning an evaluation should be aware of whose agenda is being promoted, and on whose terms the evaluations take place.

(Wellcome Trust - Under the Microscope - 12–15 June 2011, third in a series of conferences organised by the Wellcome Trust to examine public engagement within health research)

Monitoring & Evaluation of Community & Stakeholder Engagement Programs

Amidst the recognition that CSE has great value, there is a growing need, within clinical research areas, to begin to establish an evidence-base for the role that CSE plays in clinical trial research processes and outcomes. It has been implied that if the value of CSE could be measured, this could greatly influence trial sponsor and researchers' willingness and ability to properly incorporate CSE practices into clinical research plans, as well as bring additional donor resources to the field. The need to provide evidence of the measurable role that CSE plays in clinical trials and possibly its impact requires the development of monitoring and evaluation tools followed by systematic data capture allowing monitoring to take place in the short term and evaluations in the longer term.

The availability of tools specific to the task of monitoring the value the CSE to clinical trial outcomes is limited. The few attempts to measure, as opposed to describe CSE in clinical research have either been limited to particular research communities who have yet to disseminate their approach, or tend to focus very specifically on community engagement in HIV/AIDS trials, leaving out other key prominent areas of research such as tuberculosis (TB) and malaria.

The M&E tools for CSE programs that have been developed over the last decade (King, Servais et al. 2009) have tended to focus on NGO programming or health service delivery rather than on clinical research and trials. Unlike health service delivery or the implementation of validated interventions, clinical research often involves the testing of a treatment or prevention product whose efficacy has not yet been determined. Trial participation may require enrollment for periods extending from 1-5 years (including follow-up), and may involve potential risks as well as benefits to individuals and to communities. Furthermore, clinical research can include hard-to-reach and/or stigmatized target populations, trials across multiple regions or countries, and can be subject to requirements to comply with international ethical standards and practices for recruitment, enrollment, and access to products. The research context raises many challenges for CSE implementation and measurement.

To deal with the multifaceted nature of CSE within clinical trials, implementers, program managers, and clinical research staff need a launch pad of practical tools and resources that are easy to use, adapt, and are appropriate for use by CSE program and research staff at the clinical trial site-level.

Defining M&E

Monitoring and Evaluation are related. Monitoring is the first part of Evaluation, and involves setting targets which form part of a work plan and aim to measure on-going progress and determine whether the program activities are producing the intended or 'planned for' outcomes. Evaluation is also a structured process but on the other hand its role is to assess the midterm or eventual success of a program in meeting its goals and reflect on the lessons learned.

Table 2: Relationship between Monitoring & Evaluation
(Global-Fund-for-Fight-Against-AIDS-Tuberculosis-and-Malaria. 2011)

DIMENSION	MONITORING	EVALUATION
FREQUENCY	Periodic, occurs regularly	Episodic
FUNCTION	Tracking and Oversight	Assessment
PURPOSE	To improve efficiency; provide information for re-programming to improve outcomes.	Improve effectiveness, impact, and value for money, future programming, strategy and policy making.
FOCUS	Inputs, outputs, processes, work plans for operational implementation.	Effectiveness, relevance, impact, cost-effectiveness, trial effects.
METHODS	Routine review of reports, registers, administrative database and field observations.	Scientific, rigorous, complex and intensive design.
INFORMATION SOURCE	Routine or surveillance, field observation, reports, rapid assessments, program review meetings.	Same sources used for monitoring plus special studies, surveys etc.
COST	Consistent, recurrent costs spread across implementation period.	Episodic often focused at the midpoint and the end of the implementation period.

An effective M&E within a CSE program could have the potential to do the following:

- Assess the results of the CSE program to determine if planned objectives have been met;
- Assist in quarterly planning and target setting ;
- Determine if the CSE program planning was appropriate;
- Justify the resources invested in the CSE program or raise questions thereon;
- Determine which of the different CSE methods or phases are more effective than others;
- Improve CSE practice highlighting the success of CSE methods while learning from mistakes or less useful methods;
- Identify strengths, weaknesses, and areas for improvement for the CSE program;
- Demonstrate the impact of a CSE strategy on the levels of community awareness and understanding;
- Gain credibility and support over time for varied and effective CSE approaches;
- Demonstrate the value that the CSE program has added to the clinical trials process.

Table 3: Example of an M&E Framework

COVERAGE	MONITORING	EVALUATION
Outputs (Products, Services, Deliverables, Reach)	How many people or communities were reached? Were the targeted numbers reached?	**How adequate** was the 'reach' of our program? Did we reach enough people? Did we reach the right people?
Process (Design & Implementation)	How was the program implemented? Was implementation in accordance with our work plan design and ethical professional specifications?	**How well** was our program implemented? Fairly, ethically, legally, culturally appropriately, professionally, efficiently? For outreach, did we use the best avenues and methods we could have? How well did we access hard-to-reach and vulnerable populations?
Outcomes (things that happen to people or communities)	What has changed since (and as a result of) program implementation? How much have outcomes changed relative to targets?	**How substantial** and valuable were the outcomes? How well did they meet the most important needs and help realize the most important aspirations? Should they be considered truly impressive, mediocre, or unacceptably weak? Were the outcomes worth achieving given the effort and investment put into obtaining them?

Monitoring and Evaluation of CSE therefore requires a systematic approach in order to analyze progress and effectiveness of a program. The M&E system and processes must be built into the program from the design phase and carried out throughout the lifecycle of the trial.

The CSE Monitoring Toolkit

The Toolkit introduced in this manual provides a tailor made database designed to support CSE teams working on clinical trials to capture their monitoring data on a day to day, month to month, quarterly and biannual basis.

The data collection tools were developed hand in hand with CSE teams and attempt to capture key data that can be used by CSE programs over time to track their progress. The field testing and tool development process involved asking some of the following questions:

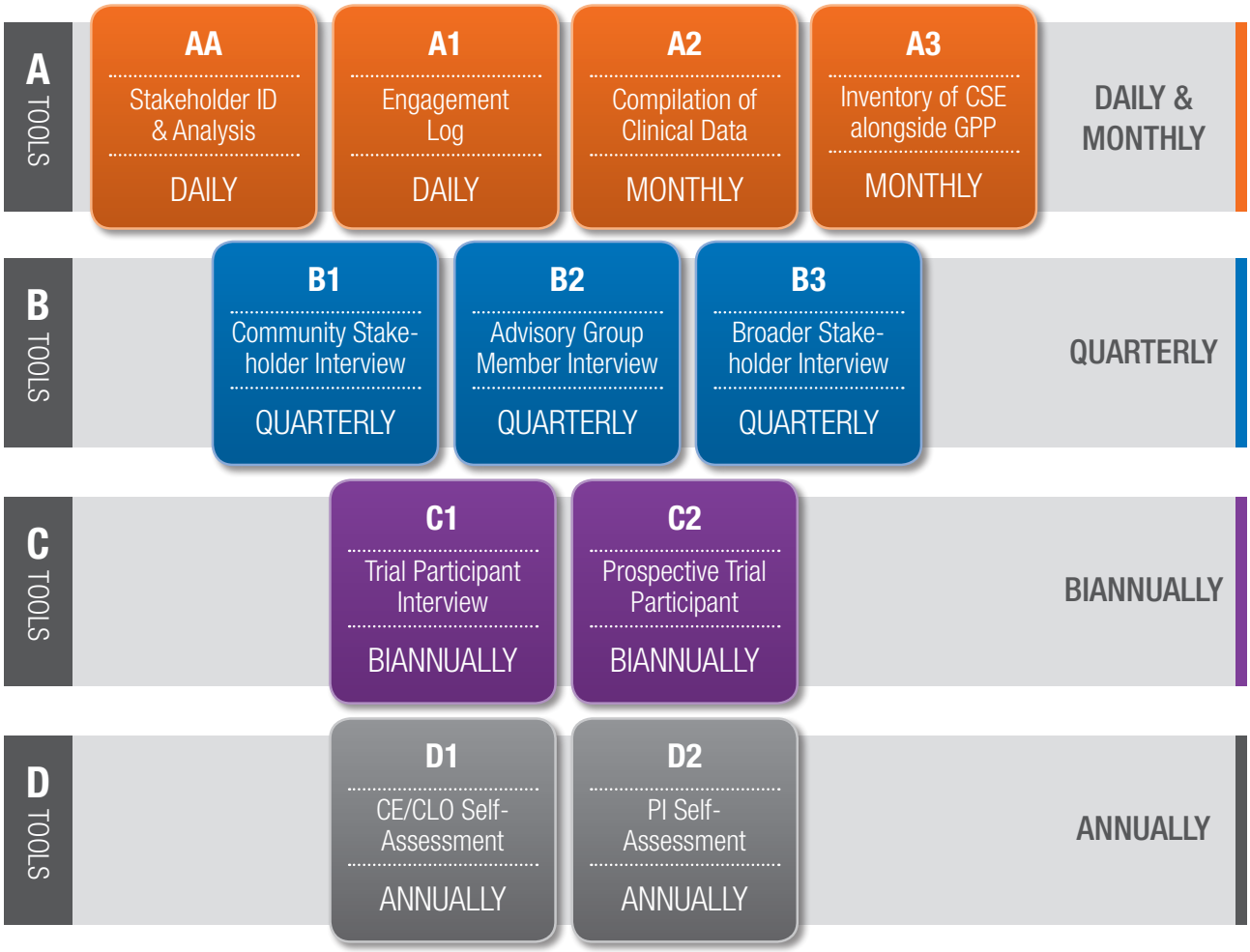
- What do different CSE programs look like?
- What are the (potential) different engagement mechanisms within a CSE program?
- What kind of data already exists within a CSE program that could serve as monitoring data?
- What additional data needs to be captured beyond routine program data to answer key monitoring questions?
- Do CSE programs conduct stakeholder analyses before engaging stakeholders?
- What kinds of simple stakeholder analyses could enhance a CSE program and how could this analysis be monitored over time?
- How do different CSE programs define CSE program success?
- How do CSE programs currently report on their programming and how could this be enhanced?
- What kind of data from CSE activities could inform future practice and can this data be captured?
- How could CSE monitoring outputs be linked directly or indirectly to clinical trial outcomes?

The tools were developed and piloted at sites selected by TB Alliance and AVAC and modified based on feedback from CSE managers and PIs. The daily and monthly tools were designed to support CSE programing and as far as possible not encroach on programming resources and time. There was recognition that monthly/quarterly or biannually entered data would need dedicated time. In general CSE managers requested that the data capture process be user friendly and easy and quick to complete. The idea of a web based database was conceived, where data could be entered directly onto a server, eliminating the need for hard copy questionnaires or forms and data entry or double data entry steps were removed. The concept was supported by field teams.

The tools in the toolkit collect both qualitative information, including community and stakeholder, and even researcher perceptions and experiences in the form of self-assessments, as well as quantitative information, such as number of engagements, time dedicated to different forms of engagement, as well as clinical trial enrollment and retention data, to name a few.

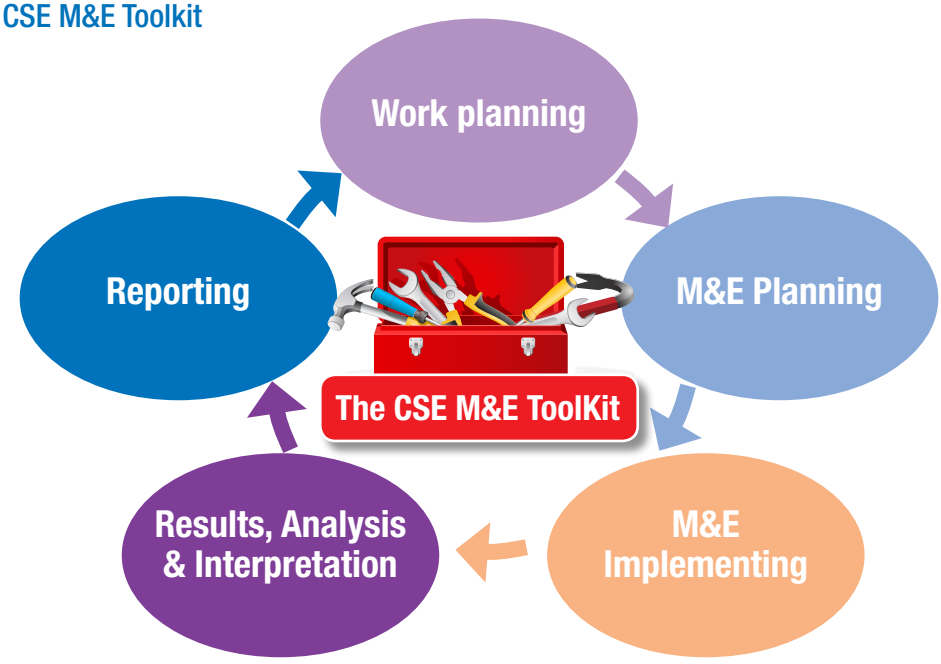
The diagram below is the structure of the M&E Database and the 11 tools that are currently located within the toolkit. In the section Implementing the Toolkit each tool is described – including its purpose and how it can be used and what preprogrammed outputs have so far been developed to support your quarterly reporting as well as some other outputs the data could generate, were you to invest time in analysis.

Figure 3: Structure of the M&E Toolkit



The toolkit is a tracking and M&E framework. An M&E toolkit is only of value once the CSE teams have: (i) a detailed quarterly or annual Work Plan (goal and objective setting) and (ii) a clear M&E Plan and (iii) have been trained to use the database correctly.

Figure 4: The CSE M&E Toolkit



Once all this is in place, CSE teams will be in a position to enter the data on a daily, monthly and biannual basis and generate the 'pre-programmed' quarterly report for the sponsors. You will also be able to extract the data and generate reports for other audiences, and generally track and interpret the results over time, which can inform your work plan for the subsequent quarter. You will always have the option to use the data for more elaborate multivariate analysis to answer specific questions you and your clinical trial team may have in relation to the CSE program.

Indicators

An Indicator is a simple brief and concise expression used to determine the degree of adherence to a set standard. It provides evidence that a certain condition now exists or that certain results have or have not been achieved. Indicators enable one to assess progress – as such, they are a critical part of results-based CSE programs. They are therefore most often quantitative, but they may also be coined in qualitative terms.

Indicators are standardized measures that allow for comparisons over time, over different geographical areas and across different programs. Ideally, indicators should eventually have a proven track record - having demonstrated that they are useful before being broadly deployed. However when there are no indicators to measure something – as is the case of CSE in clinical trials – then the indicators represent a starting place for further development and testing.

Prior to the development of the toolkit, a set of CSE indicators of success (see Indicator section), were developed by the CSE working group. These yet to be validated indicators represent a preliminary indicator framework for CSE which can grow as the database is used and improved.

It is important to note that since the toolkit and database are in their infancy stage of implementation, these indicators have yet to be validated.

You can choose those indicators that respond to the questions you have raised in your M&E plan. You will find the tools that complement each indicator in the Table 6. Remember the "rules-of-thumb" when reviewing indicators. First, do not favor too many indicators. This can result in information overload. Second, note that the indicator will not state the target achievement. The indicator is simply a measurement and, as such, will be non-directional (e.g. neither positive nor negative). Third, the simplest indicators are often the best.

The indicators listed in this toolkit try to meet the following criteria:

- Measurable;
- Can be collected within the time frame and resources available;
- Clear and easily understood by the intended audience;
- Accurately and reliably indicate what they are supposed to show;
- Issues are raised as a result of collecting data on the indicator;
- The tool is available and users have been trained to collect the data.

As a rule, indicators should reflect the stated goals of your CSE program, allowing you, as managers to track your progress towards your benchmarks. Each CSE program will have its own defined set of goals. The indicators you choose or those you develop independently will measure dimensions of quantity or quality or cost, and should help you to assess the progress your program achieves over time or the lack of progress. For this toolkit, TB Alliance and AVAC and their working group developed four sets of indicators.

Table 4: Sets of Indicators

Set 1: Indicators of research site planning or preparedness and CSE mechanisms
Set 2: Indicators of trial conduct and community stakeholder engagement
Set 3: Indicators of research outcomes
Set 4: Indicators of community benefits

Set 1: Research and Site Planning or Preparedness and CSE Mechanisms in place focuses on indicators to assess: (a) the development of formative research plans; (b) the development of trial protocols; (c) the establishment of informed consent forms and processes; (d) the identification and creation of effective CSE mechanisms; (e) the development of sound communications plans; and (f) the development of pertinent issues management plans.

These indicators are captured primarily by Tool AA, A1 and A3 – which are either completed daily or monthly. These data can be triangulated with the responses from the key informant interviews (B through D) using more sophisticated analysis in a statistical package.

Set 2: Trial Conduct & CSE Implementation focuses on the processes, procedures, and experiences of implementing the clinical trial at the site and the process of engaging the community and stakeholders. This area includes indicators to assess: (a) the efficient, timely, and sensitive recruitment of trials participants; (b) the retention of participants on the trials; (c) the adherence to trial regimens and procedures and the honest reporting of adherence; (d) the perception of disease risk on the part of the part of the trial participants and the community; (e) the avoidance of harms to trial volunteers; (f) the avoidance of external misconceptions and/or rumors about the trial; (g) the trial participant understanding of informed consent; and (h) the trial participant experience at clinic visits.

These indicators are captured primarily by Tool AA, A1 and A2 – which is completed monthly and relies heavily on triangulation of data from various key informant interviews B1, B2 and B3 and C1 and C2.

Set 3: Research Outcomes and CSE Outcomes focuses on the processes and expectations related to the results of the trial. This area includes indicators to assess: (a) the dissemination of non-controversial trial results; (b) the procedures for participant exit from trial; (c) the reflection of stakeholder concerns and priorities in the research agenda or next steps of the science; (d) the policy discussions on intervention/product implementation; and (e) participant access post-trial to trial product, interventions, and services.

These indicators are captured primarily by Tool AA, A1 and A2 – which is completed monthly and depend heavily on triangulation of data from various key informant interviews B1, B2 and B3 and C1 and C2, D1 and D2.

Set 4: Community Stakeholder Benefits and Response focuses on the impact of the research on the community and its stakeholders. This area includes indicators to assess: (a) the trust in the community and among stakeholders for research process; (b) the capacity built around healthcare and/or future research; and (c) research literacy in the community and among stakeholders.

These indicators are captured primarily by Tool AA, A1 and A2 – which is completed monthly and require triangulation of data from various key informant interviews B1, B2 and B3 and C1 and C2, D1 and D2.

Over time, as this toolkit is strengthened, it will be important to strengthen the **Indicator framework**.

For each indicator you will need:

- Baseline values – if available (not available as the toolkit is being launched)
- Targets according to frequency of measurement
- Data collection method(s) for the indicator
- Frequency of data collection – monthly, quarterly, annually
- The person or group responsible for data collection and reporting

Table 5: Example of Data Collection Table

TOOL	INDICATORS	FREQUENCY

Table 6: List of Indicators, Areas of Impact and Relevant Tools

Set 1: Community and Stakeholder Engagement (CSE) Indicators for Research and Site Preparedness

AREA OF DESIRED IMPACT OF CSE	MEASURABLE INDICATORS	TOOLS
Formative research plans	Proportion and type of community members/ stakeholders consulted	AA, A1
	Number and frequency of community members/ stakeholders meetings held to review	A1
	Proportion of contributing community members/ stakeholders who agree their input was informed and meaningful	A1
Trial protocol development	Number and type of community member/stakeholder suggestions incorporated	A1, B1, B2, B3, C1, C2
	Perceived satisfaction of community members/ stakeholders with input process	B1, B2, B3, C1, C2
	Level of engagement of community members/ stakeholders during periods of input	A1, B1, B2, B3, C1, C2
	Perceived value added of community member/ stakeholder input on the part of research staff	AA, A1, D1, D2
Informed consent forms and processes	Percentage and reasons of drop out of stakeholders working in advisory capacity	CAB Log of Members
	Proportion of dissatisfactions of community members/ stakeholders during input	B2
	Level of understanding demonstrated by consenting or dissenting trial participants	C1, C2
	Amount of time allocated for community member/ stakeholder input	A1

CSE mechanisms	Number and type of advisory mechanisms in place for research site.	A1, A3
	Number of different sectors represented on research site's primary advisory mechanism (e.g. CAB).	A1, B2
	Number of stakeholders who report ability to operate independently from the research site.	B1, B2, B3
	Frequency of stakeholder meetings with research team.	A1
	Proportion of resource devoted to type of advisory mechanisms in place for research site.	A1, D1, D2
	Appropriateness of mechanism chosen for range of community members/stakeholders	B1, B2, B3, C1, C2
	Level of buy-in from community members/ stakeholders	B1, B2, B3, C1, C2
	Number and type of community-driven engagement exercises	B1, B2, B3, C1, C2
	Level of understanding of community members/ stakeholders of the purpose and objectives of CSE mechanisms	B1, B2, B3, C1, C2
	Perceived satisfaction of community members / stakeholders with the functioning of CSE mechanisms	B1, B2, B3, C1, C2

Communications plans **Issues management plans**	Perceived quality of plans developed.	D1,D2
	Amount of time allocated for development of plans	D1,D2
	Reach and impact of communications plans	A1

Set 2: Community and Stakeholder Engagement (CSE) Indicators for Trial Conduct

AREA OF DESIRED IMPACT OF CSE	MEASURABLE INDICATORS	TOOLS
Nature of recruitment	Percent of expected participants enrolled on protocols during specified period	A2
Participant retention levels	Percent of expected participants retained on protocols during specified period	A2
	Percent of trial participants that reflect demographics of the epidemic in respective communities	A2
Participant adherence to trial regimens and procedures / honest reporting of adherence	Percent of patients lost to follow-up	A2
	Percent of records reviewed without consent or enrollment violations	A2
	Percent of records reviewed without missed Serious Adverse Effects (SAEs) or missed clinical endpoints	A2
Disease risk perception issues	Proportion and type of community members/ stakeholders consulted	A1, AA
Avoidance of volunteer harms	Number and type of community member/stakeholder suggestions incorporated	A1
	Perceived value added of community member/ stakeholder engagement efforts on the part of research staff	D1, D2, AA
Avoidance of external misconceptions/rumors about trial	Extent issues were addressed through community member and stakeholder engagement efforts	A1, B1, B2, B3, C1, C2
Participant understanding of informed consent	Number of participants reporting high levels of understanding of informed consent	C1, C2
	Perceived level on the part of researcher of participant understanding of informed consent	D1, D2
	Number and type of education mechanisms/initiatives focused on relaying information to participants on informed consent	C1, C2, D1, D2
Participant experience at clinic visits	Number of participants reporting positive experience at clinic visits	C1, C2
	Perceived satisfaction of participants with clinic visits	C1, C2
	Perceived quality of participant experience at clinic visits	C1, C2
	Extent participant experience at clinic visits is reviewed and used by research team	C1, C2

Participant access to package of products and services	Number of participants reporting access to quality package of products and services	C1, C2
	Perceived satisfaction of participants regarding access to quality package of products and services	C1, C2

Avoidance of external misconceptions/rumors about trial	Number and type of high quality information resources distributed externally	A1, C1, C2
	Number and type of education mechanisms/initiatives to address misconception/rumors	A1, C1, C2
	Number of stakeholders who report negative messages in community	B1, B2, B3, C1, C2
	Extent issues were addressed through community member and stakeholder engagement efforts	A1, B1, B2, B3, C1, C2

Set 3: Community and Stakeholder Engagement (CSE) Indicators for Research Outcomes

AREA OF DESIRED IMPACT OF CSE	MEASURABLE INDICATORS	TOOLS
Participant exit from trial **Focus of research agenda** **Policy discussions on intervention/product implementation**	Proportion and type of community members/ stakeholders consulted	A1
	Number and type of community member/stakeholder suggestions incorporated	A1
	Perceived value added of community member/ stakeholder engagement efforts on the part of research staff	D1, D2
	Extent issues were addressed through community member and stakeholder engagement efforts	A1
	Perceived satisfaction of community members/ stakeholders with input process	B1, B2, B3
	Amount of time allocated for community member/ stakeholder input	A1
	Number of community member/stakeholder meetings held to review	A1
	Level of engagement of community members/ stakeholders during periods of input	A1
	Number of community members and stakeholders who agree their input was informed and meaningful	B1, B2, B3

Non-controversial trial results dissemination	Number and types of distribution channels used for results dissemination	A3
	Frequency that trial results are disseminated	A1, A3
	Awareness among community members and stakeholders of specific non-controversial trial results	A3
Participant access to trial product, intervention, services post-trial	Number of participants reporting access to trial product, intervention, services post-trial	A3
	Perceived satisfaction of participants regarding access to trial product, intervention, services post-trial	
Participant access to quality package of products and services	Number of participants reporting access to quality package of products and services	C1, C2
	Perceived satisfaction of participants regarding access to quality package of products and services	C1, C2

Set 4: Community and Stakeholder Engagement (CSE) Indicators for Community Benefits

AREA OF DESIRED IMPACT OF CSE	MEASURABLE INDICATORS	TOOLS
Healthcare and/or research capacity built	Number and type of linkages with existing community-based structures	A3
	Number and type of sustained community educational mechanisms/initiatives	A3
	Extent of networking with diverse sectors	AA, A1, A3
	Number and type of new opportunities for additional study/research	
	Number and type of new opportunities for additional health services/care	
	Number and type of new opportunities for additional community and stakeholder engagement	AA, A1, A3
	Perceived level on the part of community members and stakeholders of utilization of knowledge in the community	B1, B2, B3
	Perceived level on the part researchers of utilization of knowledge in the community	D1, D2
	Perceived level on the part researchers of healthcare and/or research capacity	
	Areas of healthcare and/or research capacity identified for improvement	A3

Levels of trust in community and among stakeholders for research process	Number of participants reporting high levels of trust for research process	C1, C2
	Perceived satisfaction of community members and stakeholders with research process	B1, B2, B3, C1, C2
	Perceived level on the part of researchers of trust in community and among stakeholders for research process	D1, D2

Levels of research literacy in community and among stakeholders	Number of trainings conducted	A3
	Number of information resources distributed and engagement activities around research.	A1, A3
	Number of post-test training scores higher than pre-test training scores	
	Number of community members and stakeholders trained as trainers	
	Number of community members and stakeholders who report ability to independently speak on research agenda or trials	B1, B2, B3
	Number of instances of community members and stakeholders making informed statements on research/trial	A1, B1, B2, B3
	Perceived level on the part of researchers of research literacy in community and among stakeholders	D1, D2
	Number and type of community members/ stakeholders consulted	AA, A1
	Perceived value added by researchers of community members/stakeholders input	D1, D2
	Perceived satisfaction of community members/ stakeholders with input process	B1, B2, B3
	Level of engagement of community members/ stakeholders during periods of input	A1
	Amount of time allocated for community member/ stakeholder input	A1
	Number of community members and stakeholders who agree their input was informed and meaningful	B1, B2, B3

Work Planning - Developing a CSE Work Plan

The manual will provide some very basic frameworks to enhance work planning for those CSE teams in need of a planning framework and don't already have something in place.

One proposed model, as depicted in Figure 2, shows a cycle of planning, implementation, and monitoring and evaluation, with multiple stages.

Table 5: Example of Data Collection Table

Steps for Program Management

- *Plan and describe the program*
- *Clarify program objectives and goals*
- *Develop strategy and plans*
- *Identify indicators of success*
- *Design an evaluation that is needed and appropriate*
- *Set up a timeline for evaluation activities*
- *Carry out activities*
- *Collect evaluation data*
- *Analyze and report data*
- *Makes changes to the program based on the data*
- *Carry out new or repeated programs*
- *Evaluate again*

Figure 6: A very simple Program Management Model

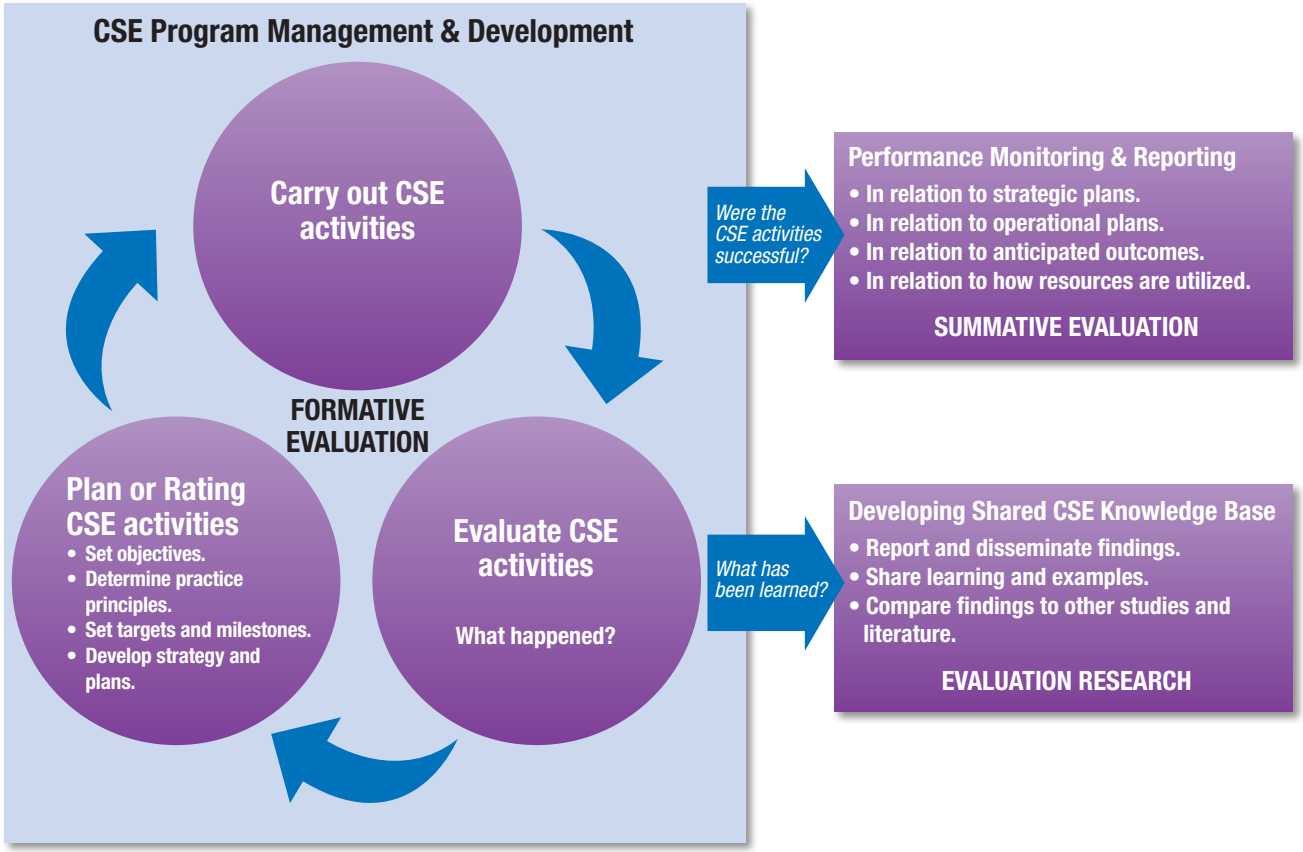
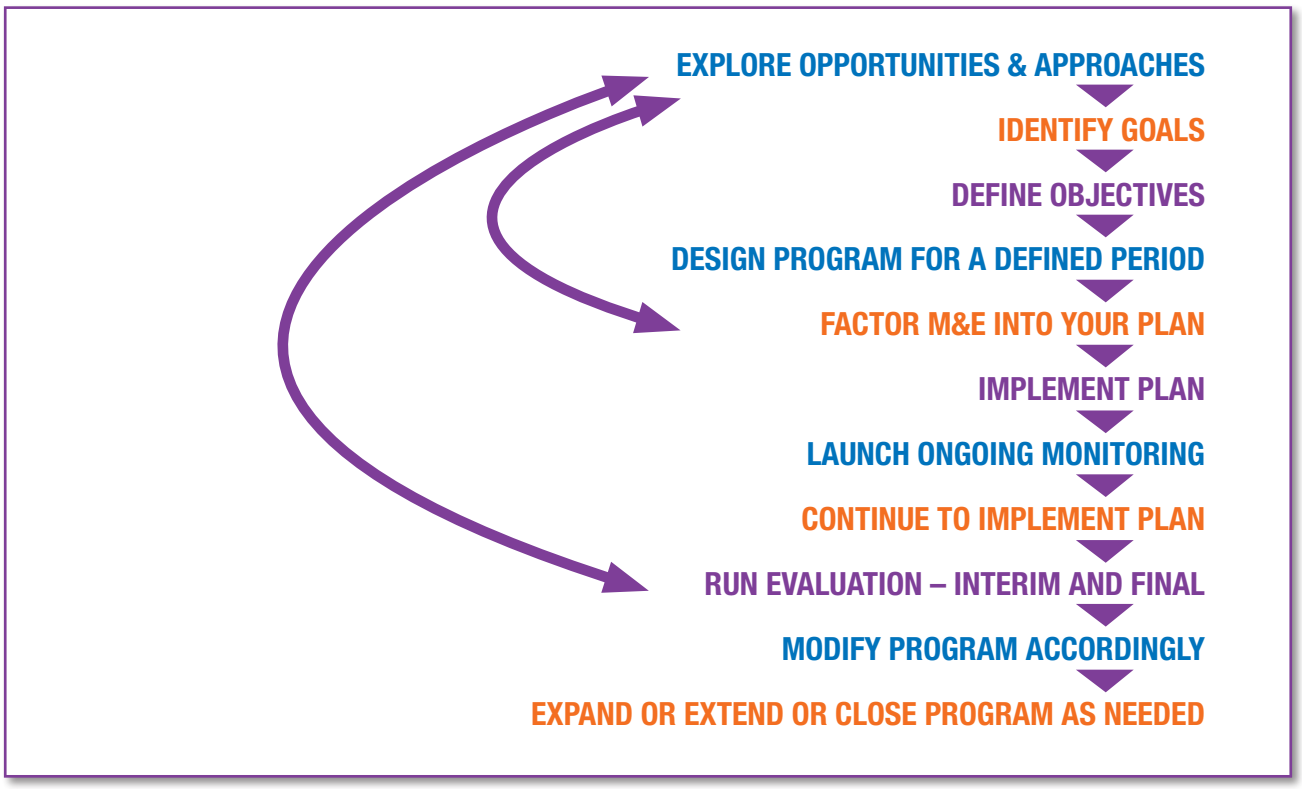


Figure 7: Flow of Events in your planning



Work Planning - Identify Goals and Formulate Objectives for CSE Program

If you have not already done so, the first step in your work planning process is to take your program apart and, together with key people in your CSE M&E team, answer some key questions.

Vision Statement

First of all you need to articulate the Vision Statement for your CSE program. This is likely to be documented when the CSE Program was initially set up. If you're not sure of your program's vision statement, go and find it out! Is there one? Does it still apply? Do you or your team think it needs revisions? The Vision Statement will clearly state what CSE means to your team and your trial. As you are now aware, CSE means different things to different research groups. Your vision will need to reflect your interpretation of CSE very clearly.

Describing your Program

Once you've written the Vision statement down, you can move on to describing your Program. This is your opportunity to describe briefly what your CSE program does. Some CSE programs support the trial teams to decipher what the community stakeholders may find troubling about the research and design and run community forums. They are not at all involved in trial recruitment. Other CSE programs are heavily implicated in trial operations and spend their time working with the CAB and supporting recruitment efforts. As you describe your program in one paragraph, you will need to provide examples of the kind of CSE work that you are doing. Always keep it in line with your Vision Statement.

Describe the Goal of your Program

After describing your program you need to define the goal of your CSE program. This is the main overarching goal that drives all of the activities and related sub-activities. Following the goal are the objectives, or the specific steps for you to accomplish your program's desired goal.

Describe Activities

Finally, you will brainstorm around your activities you need to do in order to carry out your program's objectives. Within each set of activities, there will be plenty of sub activities that must be accomplished in order to achieve your main objectives.

Table 7: Definitions of Program Goal & Objectives

Program Goal: Is a quantified statement that describes what you wish your program to be in the future. This will likely require time to accomplish and therefore the goal is the long-term direction for your CSE program. Goals are written for the overall program and not for your single activities, program goals include words such as: ***improve, promote, prevent, reduce, and increase***. Program Goals are written in general terms, free of details, and provide a specific long-term direction for your program. Goals are found in the long term outcome section of your logic model. An example of a program goal for a CSE program might be: Ensure community representatives successfully provide input on 100% of all study protocols implemented initiated at this site.

Objective: Is a detailed step to be taken to achieve a goal. An objective is more precise than a goal and needs to be measurable. An objective should be written so that:

- It can be clearly understood, detailing what needs to be accomplished;
- It should be implemented in such a way that the monitoring data can be used to determine if it has been accomplished.

Objectives are important because they represent what your CSE program will implement and in turn what you will monitor and ultimately evaluate. In logic models they are found in the intermediate and short term outcome section. You can use a series of questions to guide the development of your objectives such as:

Does my objective describe how things will change in the community or in the trial?
In what ways will the community be "different" when the CSE program has implemented its program?

As you think about the development of objectives for your CSE program, it may be helpful to use the **SMART** (Specific, Measurable, Achievable, Realistic, and Time-oriented) acronym, which is often used for monitoring and evaluation purposes[1].

1 Centers for Disease Control and Prevention. Introduction to program evaluation for public health programs: a self-study guide. 2005. Retrieved from: http://www.innonet.org/resources/files/Introduction_to_program_eval_pub_health.pdf.

Table 8: SMART – one approach to formulating objectives

Specific: Your objectives should specify what you want to achieve!

A specific objective has a higher likelihood of being accomplished than a general one. An objective should clearly state specific reasons, purposes, or benefits of accomplishing the objective, and by whom. An objective that is specific will usually have a single result, which means there will be an observable action, behavior, or achievement that can be described or measured.

Measurable: You should be able to measure whether or not you are meeting your objectives!

The key to determining the progress toward meeting each objective will be to know whether the objective has been achieved. You can ask yourself: how will I know if I have been successful? What will the data tell me? You can link your objectives to the database outputs and determine what results will reveal your success or failure. Just because something is measurable, however, does not mean that it is worth measuring. The outputs generated by the database are measurable and relevant. But there may be other outputs that you need your statistician to generate from the database - be careful that the capacity to measure does not start to dominate at the expense of relevance.

Achievable: Your objectives should be attainable!

Making sure your objectives are achievable is critical to demonstrating success. In considering whether each objective is achievable, you should think about the barriers that stand between you and achieving your objective. Objectives should be ambitious, but they should also be consistent with your expectations for accomplishment. Objectives that are too ambitious will reflect poorly on your CSE program.

Realistic: You should be able to realistically achieve your objectives with the resources you have!

For your objectives to be relevant, they must be something that can actually be done given the resources available for the specified activity. This includes financial, personnel, and time resources. Your objectives should be plausible given these constraints.

Time bound: You should specify when you want to achieve your objectives!

Each one of your objectives needs to be allocated a time period for its achievement. Specifying a date as to when the objective is to be accomplished is only part of addressing the time element. It is important to ask whether you have left enough time to get everything else done. Will other competing demands on your time cause delay? Addressing these questions helps to ensure that the objectives will account for the fundamental link between time and achievability.

Logic Model

Now that you have 'dissected your program' and articulated its vision, goal, objectives and activities, you are in a position to develop a plan for your program. A logic model is one such approach that guides implementation. There are many others that you may prefer. The logic model outlines: what you hope to achieve (your intended results) and how you will do this (your planned work). The logic model identifies the linkages between the activities of the CSE program and the outcomes. It does so by giving you the opportunity to succinctly list a set of activities that make up the program and a sequence of outcomes that will flow from these activities.

The logic model provides steps to achieve the immediate, intermediate and final outcomes of a CSE program and the relationship between the different activities, as well as the justifications and assumptions of the program alongside the program goals and objectives. The logic model makes sure you stick to your pre-determined CSE recipe most of the time.

The logic models is not intended to be fixed or static, therefore it can serve as a dynamic representation of your CSE program while supporting your planning, management, evaluation, communication and M&E. There is always opportunity to factor into the unexpected.

There are two parts of a logic model.

- First, there is the logic component. This is the section with the reasoning behind your proposed CSE actions and should describe the relationship between the parts and the whole.
- Second, there is the model component which provides the conceptual framework. The model represents reality and shows in a linear fashion, the expected steps needed to reach your intended results. Together the model and the logic represent the roadmap for your CSE program.

Figure 8: Additional Elements of your Logic Model

If-Then

A common problem for CSE programs is that activities and strategies may not always lead to the desired outcomes. A logic model makes the connections explicit. A series of "if-then" statements can be linked together to form the foundation of a logic model: if resources are available to the CSE program, then the CSE program activities can be implemented; if program activities are implemented successfully, then certain outputs and outcomes can be expected. In developing your logic model, check your "if-then" statements to ensure that they make sense and lead to the outcomes you want to achieve.

Assumptions

The assumptions that underlie a program's theory are conditions that are necessary for its success, and that you believe to be true. Your program needs these conditions in order to succeed, but you believe these conditions already exist; they are not something you need to bring about through your program activities. Assumptions are the beliefs you have about the program, the participants, and how the program will work.

Inputs

The inputs are the available resources for your program such as funding, facilities, staffing. Identifying these helps you determine the extent to which you will be able to implement the program and achieve your intended outcomes.

Activities

Activities are the actions that are needed to implement your program. They are what you will do with program resources in order to achieve your program outcomes, and ultimately, your goals.

Outputs

Outputs are the measurable, tangible, and direct products or results of your program activities. They lead to your desired outcomes (usually "counts, "numbers", or "frequencies"), such as number of community based organizations sensitized or number of outreach sessions hosted or number of trial participants who bring their families for sensitization but they are not themselves the changes you expect the program will produce. Outputs do help you assess how well you are implementing the program.

Outcomes

Outcomes express the results that your program intends to achieve if implemented as planned - they are a direct result of the program activities. Outcomes are the changes that occur or the difference that is made. For example – an overall increase in the recognition of the trial within the communities where you are working during or after your CSE program. Outcomes indicate a measurable change and are usually written "to increase" or "to decrease".

Contextual Factors

Contextual factors are issues that may or may not be under your control, but could affect your program's implementation or the achievement of your outcomes. Examples of contextual factors that may affect the outcomes of your CSE program include social, political, cultural and economic conditions. If there are unexpected riots around your research facility in relation to another trial, this may affect your program implementation.

By the time you prepare your logic framework/model, you will be clear about the intended goal of your CSE program and you will have specified your program's objective. Having this clear, you can then begin to fill in the spaces in the Table below. You need to begin by inserting your activities. Once your activities are listed, you can work backwards and forwards to fill in the other spaces.

Table 9: Elements of the Logic Model/Framework

Begin by inserting activities

Input	Activity	Output	Outcomes	Impact
Quantifiable resources going in to your activities - the things you budget for.	1) What you do to accomplish your objectives? 2) What else do you do to accomplish these objectives? Are there any sub-objectives that should be measured? In most cases each activity should have its own set of inputs and outputs.	Immediate results from your activity, e.g.: - individuals reached - individuals sensitized - individual trained - outreach events planned - outreach events carried out according to plan	Longer-term expected results related to changes in knowledge, attitude, and behavior. Outcomes usually give an indication whether program goals are being achieved	Long-term, significantly positive effect on levels of awareness about the trials. Long-term, effect on clinical trial outcomes – recruitment and retention. This should ultimately relate to a program or organization vision.

Indicators can accompany your logical framework and help you to measure progress towards a specific objective or goal. After you've laid out the various levels (input, output, outcome, impact) for each of your activities above, you can then begin to decide how to measure progress towards achieving your objectives and goals by selecting appropriate indicators. The indicators that have already been identified by TB Alliance and AVAC and their working group can be revisited in Table 6 whenever necessary. You can choose these and link them to the database or create your own indicators too as you become more familiar with the data being captured and what it is teaching you about your CSE work.

	Input	Activity	Output	Outcomes	Impact
Level	Quantifiable resources going in to your activities - the things you budget for.	1) What you do to accomplish your objectives? 2) What else do you do to accomplish these objectives? Are there any sub-objectives that should be measured? In most cases each activity should have its own set of inputs and outputs.	Immediate results from your activity, for example: - individuals reached - individuals sensitized - individual trained - outreach events planned - outreach events carried out according to plan	Longer-term expected results related to changes in knowledge, attitude, and behavior. Outcomes usually give an indication whether program goals are being achieved.	Long-term, significantly positive effect on levels of awareness about the trials. Long-term, effect on clinical trial outcomes – recruitment and retention. This should ultimately relate to a program or organization vision.
Indicator (example)	- # of training manuals designed & produced - amount of money spent on the training workshop	**Training**	# of people trained # of trainings conducted	Measure of change in levels of awareness/ understanding among Traditional Leadership around the clinical trial.	Awareness of Study Scale Level 8/10

M&E Planning

Once you have a sound logical framework, that you regularly update, you are in a position to construct your M&E plan. You will now have the M&E Database at your disposal which, if correctly used, will help you capture and collate your data and facilitate generating outcomes. Before embarking on using the M&E Database, it is essential that you develop your M&E Plan and clearly define what you want to get out of using the database. This will differ between CSE teams and may also be determined by the nature of the research. The database is a generic tool developed to support the vast array of CSE programs – you will need to tailor how you use the database to meet your M&E goals.

Why do M&E?

- It is like a diagnosis!
- Without a diagnosis you cannot make a plan!
- Without a plan you don't know where you are coming from and where you are going!

Your M&E Plan needs to have the capacity to:

- Structure the numerous M&E activities that will take place;
- Outline the roles and responsibilities – who does what M&E task and when;
- Provide an organized plan on how to track your progress across various studies;
- Allow your CSE team to work more effectively and efficiently – since you will know what your quarterly M&E goals are and how you will capture and analyze the data;
- Outline how you will respond to various findings and how you will react to the findings and how this will inform decision making/planning;
- Ensure that M&E is fully understood and integrated into part of everyone's' job.

Components of the M&E Process

As you prepare your M&E plan, consider the different aspects of the M&E continuum, outlined in Table 10. Using these sections is the simplest way to build your M&E plan.

Table 10: The M&E Process

Step 1 Source of Data	**Step 2** Collection of Data	**Step 3** Collation and Storage	**Step 4** Analysis	**Step 5** Reporting the Results	**Step 6** Using or Applying the Results
What are we collecting and why?	Who collects this data, from where, and how often? Who checks the quality of the data?	How are data aggregated? Where are the data stored? Who has access, how and why?	There are certain preprogrammed outputs for descriptive statistics. Beyond these outputs there is great potential to transform the data into meaningful outputs to answer your specific M&E questions. Elaborate on these questions and how you will plan for the analysis and interpretation.	To whom will the results be reported? How often? To what end? Who will report? Who will review?	How will the information be used to make informed decisions? Will quarterly M&E & work planning meetings be held? List specific opportunities for use. Complete the Data Use Template.

Step 1 - Source of the Data

The source of the data that you will enter into your M&E database is outlined in the Table 11 below.

Table 11: Source of Data

Tool Code	Tool Name	Source of Data
AA	Identify & Analyze the Stakeholders	Notes following conversations with stakeholders with whom you engage
A1	Daily Activity Compilation Log	Notes from engagement activities
A2	Clinical Trial Data Extraction	Trial data center
A3	Inventory of CSE alongside GPP Guidelines	Your notes throughout the month, including meeting minutes, schedules and plans
B1	Community Stakeholder Interview	Scheduled Interview
B2	Advisory Group Member Interview	Scheduled Interview
B3	Broader Stakeholder Interview	Scheduled Interview
C1	Participant Volunteer Exit Interview	Scheduled Interview
C2	Prospective Volunteer Exit Interview	Scheduled Interview
D1	Community Engagement Manager Self-Assessment	Scheduled Interview
D2	Principal Investigator Self-Assessment	Scheduled Interview

Step 2 - Collection of the Data

As indicated above, the toolkit contains 11 tools. The main element of your M&E plan involves who will collect the data and when and how you will manage the quality of the data.

The AA and A1 forms require that the person completing the form does so, based on notes or memory recall as close to the event as possible. If absolutely necessary, you can plan to print off the forms so that you can enter the data by hand and then enter the data into the database at a later date. The tools are available in a separate document accompanying this manual. Preferably, and in the interest of time and data quality, if you have internet access, you can enter the data directly into the database immediately after the engagement activity, conversation or the GPP related activity.

The A2 form may be completed online or by printing off the form and completing it with the trial data team and then transferring the data into the database when you have ensured that it is correct. Form A2 can also be easily completed directly online. A3 is completed on a monthly basis and requires that you reflect on the activities of the month – you may need to refer to your notes as you complete this form.

The B and C interviews and the D self-assessments can be filled in directly online as you conduct the interview, if you have access to the internet at that time. Otherwise the forms can be printed off and used and then data entered later. Please note, that entering data directly can save you a lot of time and can prevent the data entry errors that can occur when you are copying data from a form. Please consider inviting your stakeholders for the B and C interview to your office and completing the forms directly online.

The D self-assessments can be completed online by you and researchers in their office. You will need to schedule all these data entry activities as part of your work plan.

It is important to identify and manage any potential risks to the quality of your M&E data collected. If the quality of the data being entered into the M&E database is compromised you will waste time and resources and not benefit from this process. The quality of your data is of utmost importance to your CSE program success.

Table 12: Data Quality Management Plan

Name of Indicator	Data Quality Issues	Actions Taken or Planned to Address this Limitation	Additional Comments
(list by indicator)	List possible risks to the quality of data collected. Consider the five criteria for data quality: validity, reliability, integrity, precision, and timeliness.	How will the identified possible risks to the quality of data be managed?	

There are key dimensions of data quality that must be maintained throughout the M&E process. Your CSE team should develop a CSE M&E data entry protocol that is respected by all team members.

Box 1: Dimensions of Data Quality

(Global-Fund-for-Fight-Against-AIDS-Tuberculosis-and-Malaria. 2011)

Accuracy – How correct are the data?

The data are accurate if they measure what they are intended to measure.

Timeliness – How current are the data?

Data are timely when they are up to date and current and when the information is available and entered into the system on time.

Completeness – How much of all the expected data are present/available? The data are complete when the results are complete – you must complete each tool in its entirety. Leaving data out weakens the outputs significantly and often means conclusions cannot be drawn.

Integrity – How protected is the data from deliberate bias or manipulation? Can anyone make up the data and how will this be verified? Data integrity is guaranteed when there are procedures or protocols that don't change according to the user or when or how the data is entered. This allows for consistent collection, measurement and reporting of data. You need to be sure that you can trust the data entered.

Step 3 - Collation and Storage

The data once entered into the database is collated and stored on a server. You do not need to keep hard copies of your forms unless you wish to do so. However, it may be useful to open a hard copy file for each of the stakeholders you engage and maintain copies of their regularly updated AA forms for quick reference – this also means that if more than one member of your team is updating files, everyone can refer to the hard copy whenever they enter new data.

Step 4 - Analysis

Beyond the limited pre-programmed outputs, the dataset is available to site statisticians in CSV format for further analysis based on the data needs of each site, along with the necessary data dictionary and pdfs of the actual questionnaires. Working with the statistician to answer your key M&E questions will allow you to exploit the full value of the database.

Step 5 - Reporting the Results

You can choose how you would like to report on the data. A quarterly pdf template, which could be used for donor and grant reporting, is available on the database for your convenience. This report template currently enables you to report simple descriptive bivariate outputs from the A set of tools. You will need to relate these requested outputs to your quarterly work plan and logical framework. For bigger end of year and end of trial reports, you can create your own template and export the raw data from the database to an analysis software program of your choice for further multivariate analysis and generation of outputs.

Step 6 - Applying the Results

The intention of this database is to support, strengthen and give added value to your CSE work. When you draw up your M&E plan, you will need to describe how you intend to use or apply the results. This will vary by trial and by CSE team. Before you begin using the toolkit you and your team need to know how you intend to use the information collected to make informed program decisions and what steps can help ensure that data collected gets to the right person in the right time in the right format.

Table 13: Data Use Template

Indicator	Uses	Stakeholders	Mechanism	Format	Next Steps
List by indicator	What are the multiple uses for the information generated from this indicator?	Who will you want to communicate this information to?	How will you communicate this information?	How should this information be formatted to best reach the intended user?	What steps must be taken to ensure that this information is used? Any follow up needed? Feedback?

We suggest that your M&E plan include a matrix of what you will report, to whom, and when. You will need to describe what information products will come out of the M&E (e.g., reports, bulletins, graphics, and newsletters) and which ones will be for your benefit and which ones will go further afield. It is important to document all these choices in a table such as the one below.

Data element	Information Product	Recipient	Date
(What you've been collecting)	(Specific report(s) based on a data element or grouping of data elements, indicators)	(MOH, MOA, development partner(s), implementing stakeholder(s))	(Date each report is due)

As part of your planning, complete the Table below, where you identify the audiences for your M&E findings, alongside their interest in the M&E results.

Audience	Interest in the M&E results

M&E Team

As you develop your M&E plan, in addition to the 6 steps above, it is important to know who is on your M&E team. Monitoring and evaluation is most successful when there are defined roles in the M&E plan. Setting up an M&E Team can be helpful. You may want to invite a senior researcher or PI to be on the team along with someone from the trials data capture department and perhaps a CAB member or design your team as you see fit. This team, if it exists, should meet on a regular basis, we propose monthly, to check work plan progress, check the data entry status report (what you have entered into the system to date), to review the quarterly reports and work to apply the results to inform decision making within the program.

Team Member	Role / Responsibility

Scheduling

The toolkit is designed so that it can be completed quickly without taking you away from other tasks for too long. If however you choose to wait to enter your data until the end of the quarter, you will struggle to find sufficient time and the quality of the data will be poor. As you begin to use the toolkit a big part of your M&E plan will be to arrange your schedule carefully and factor in two hours a week to M&E activities. For the B through D tools, you may also need to line up your key informants or schedule time with the trial data department to ensure that the tools are completed according to your agreed planning framework.

Your M&E plan must factor in the time and resources required for *Planning and Design, Monitoring Activities* and R*eporting, Learning and Decision Making* and finally *Adjusting* your program based on your M&E results and also adjusting your M&E approach. The disk below illustrates these key features of your when planning M&E.

Figure 9: M&E Cycle

M&E Implementation

This section introduces you to the intricacies of implementing the toolkit. It introduces sampling of respondents for key informant interviews, it discusses permission and informed consent, interview technique, documenting and coding , triangulation of data, data access and then works through each of the data collection tools – 'tool by tool' and reviews them in detail.

Sampling

Tools B, C and D require a sampling frame. A sampling frame defines the members of the target population who, it is decided, are eligible to be included in your enquiry. Basically, a sampling frame is a complete list of all the members of the particular population that you wish to consider. In the case of C1 interviews, the sampling frame would be all trial participants. From that sampling frame you will then have criteria that allow you to sample your respondents or you may choose to make a random selection. Either way, your CSE M&E team must be able to explain the use the sampling approach. Poor description or justification of your sampling design can lead to criticism of your findings.

An alternative to random sampling approach would be a purposive sampling strategy. The key informant interviews are designed to enhance understandings of a selected group of stakeholders' experience (s) with or around the engagement activities of the trial. If your team's preference is 'purposive sampling' you will typically select "information rich" cases, in other words, individuals, groups or organizations that provide the greatest insight into the monitoring and evaluation questions. How you choose to sample your respondents is entirely up to your M&E team, however, one approach is to choose an equal number of respondents from 3 categories of informants who are likely to give you the greatest payoff in terms of feedback, this is useful considering that your samples will be small. The categories are (i) typical cases or those who are "normal" or "average" for a particular group of informants; (ii) "deviant" or extreme cases or for example, those who represent unusual manifestations of the stakeholders; and (iii) "negative" or disconfirming cases, or those who might represent "exceptions to the rule"(Miles and Huberman 1994). Accessing key informants, as with all qualitative research approaches requires the development and maintenance of relationships with key informants and their communities. Developing and maintaining good relationships with key informants and their organisations will ensure effective sampling and enhance the credibility of the M&E enquiry.

Table 14: Example of a Purposive Sampling Frame for B & C Key Informant Interviews

Purposive Sample Category	Typical / Normal/Average				Deviant/ Extreme/Unusual				Exceptions/Outliers			
Key Informant Interview	# of Interviews to be held per Quarter											
B1 – Community Stakeholder	QTR 1	QTR 2	QTR 3	QTR 4	QTR 1	QTR 2	QTR 3	QTR 4	QTR 1	QTR 2	QTR 3	QTR 4
B2 – Advisory Group Member												
B3 – Broader Stakeholder												
C1 – Trial Participant												
C2 – Prospective Trial Participant												
TOTALS												

Permission & Informed Consent

Be sure that you have introduced the purpose of the interview exercise, slowly and carefully to the respondent. This is not a research study but an M&E exercise and therefore formal informed consent may or may not be required depending on your institutions' regulations. Be sure that you have written approval from your trial coordinators to conduct these M&E interviews. Your respondent needs to be informed of the purpose and process of the interview, the time required and how the information that you are collecting will be used. Below is a script that will help you plan how you intend to introduce the M&E interviews to your key informants.

Box 2: Opening Script for Key Respondent Interviews

Thank you for taking the time to participate in this interview. We are conducting ongoing monitoring of community and stakeholder engagement (CSE) here at _____site. The overall goal of monitoring and evaluating the CSE program is to better understand the benefits and drawbacks of the CSE program and whether our efforts are yielding the outcomes we planned for and possibly better research outcomes.

In conducting these interviews, we hope to learn more about the perceptions and experiences of community members and stakeholders around the trial. Your viewpoint is critical to helping us understand the processes and outcomes of the CSE program developed for this site.

This interview should take about _____minutes. I will ask you some structured questions as well as some open-questions about your experiences. I will enter your responses directly into the database here and also take notes during the interview to record your responses. Your responses will be kept confidential, and only aggregated responses will be shared. Do you have any questions before we begin?

Interview Technique

A large proportion of the tools in the toolkit involve semi-structured interviews.

Box 3: Characteristics of Semi-Structured Interviews (Robert Wood Johnson Foundation 2008)

- The interviewer and respondents engage in a formal interview.
- The interviewer uses an 'interview guide.' This is a list of questions and topics that need to be covered during the conversation, usually in a particular order.
- The interviewer follows the guide, but is able to follow topical trajectories in the conversation that may stray from the guide when this is appropriate.
- Semi-structured interviews also allow informants the freedom to express their views in their own terms.
- The semi-structured interview guide provides a clear set of instructions for interviewers and can provide reliable, comparable data.

It is very important that you are very familiar with the flow of each interview before you administer it and that you don't read the questionnaire without making regular eye contact with your respondent. You may be using a questionnaire on a screen, but remember that you are still conducting an interview and your voice should try to inspire the interest of the respondent.

When you welcome a respondent for an interview, do not begin interviewing right away. Begin with friendly greeting and explanations. Most likely, you will find that you already have a relationship with the respondents – perhaps they are a trial participant or a CAB member. It will be difficult for them to look at you as a neutral interviewer. You will need to overcome this by establishing 'cultural ignorance' – this means communicating the message that as the interviewer you are learner and that what they have to share has great value. Listen and express interest in what the informant tells you by using friendly conversation, without diverging from the interview guide. Be sure to remain neutral in your tone of voice and your facial expressions and try not to show approval or disapproval. In addition try not to say too much, or you may find that you will mould the responses.

Box 4: Key Reminders

- Use open-ended questions.
- Avoid finishing sentences for the informant. Allow people to answer in their own terms voicing their own views, values and experiences. Avoid suggesting a particular answer or implying that one answer is expected or more correct.
- Don't say too much! Encourage an informant to produce more information but don't say too much or you will only get a reflection of yourself in the data.

Documenting Narrative and Coding

The key informant questionnaires in the toolkit administered by you as a semi-structured interview are used to investigate attitudes, beliefs, perceptions, feelings, opinions, knowledge and some aspects of behavior. The coded questions attempt to measure or quantify these attributes. Using questionnaires to collect this data is the quickest way of gathering the M&E information you require, with relatively good response rates.

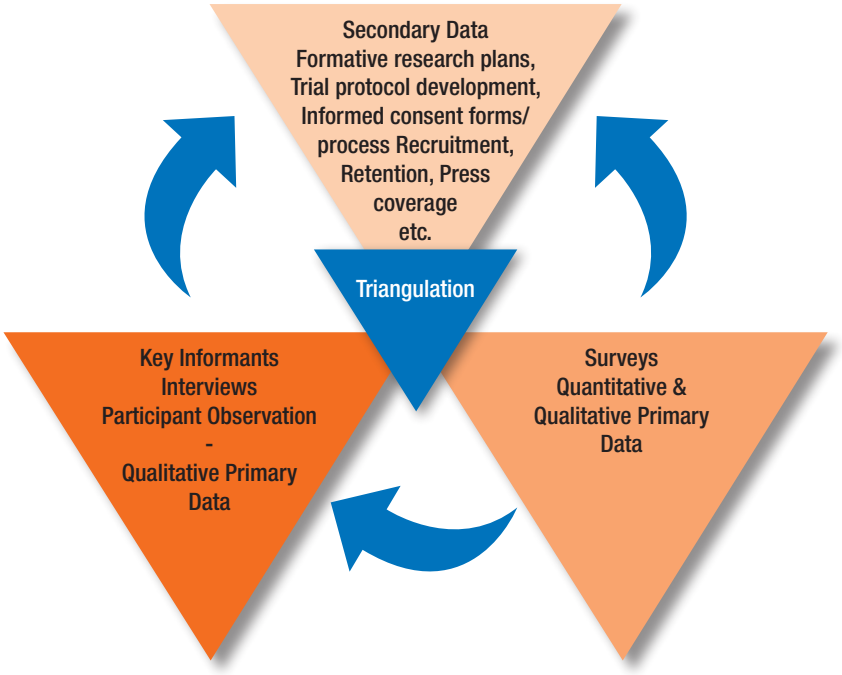
Many of the questions in the semi-structured interview allow for narrative and then an opportunity to convert the response into numbers or codes. You code the response by choosing the most appropriate answer from a list of pre-set choices. The pre-set answers were determined during pre-testing of the tools, however, it is impossible to anticipate all the answers to a question and there will be some answers that get allocated the code for 'other' which could be coded at a later stage.

Since you will select the closest fit from the list of coded responses, be sure not to edit or clean up what the respondent says. As far as possible record the narrative using the informants own words in the narrative.

Triangulation

"The greater the triangulation, the greater the confidence in the observed findings."
(Norman Denzin)

The toolkit has been built to ensure various forms of data triangulation. Triangulation is where we use different methods to approach the same issue, using both qualitative and quantitative data, in order to reveal complementary aspects as well as places where issues diverge. It also means we can compare different points of view between different sources of information (Patton 2001).



Data Access

How to set up users is outlined in the Database User Guide section. However, this section addresses the hierarchy of access to the data and how it has been constructed to ensure secure access.

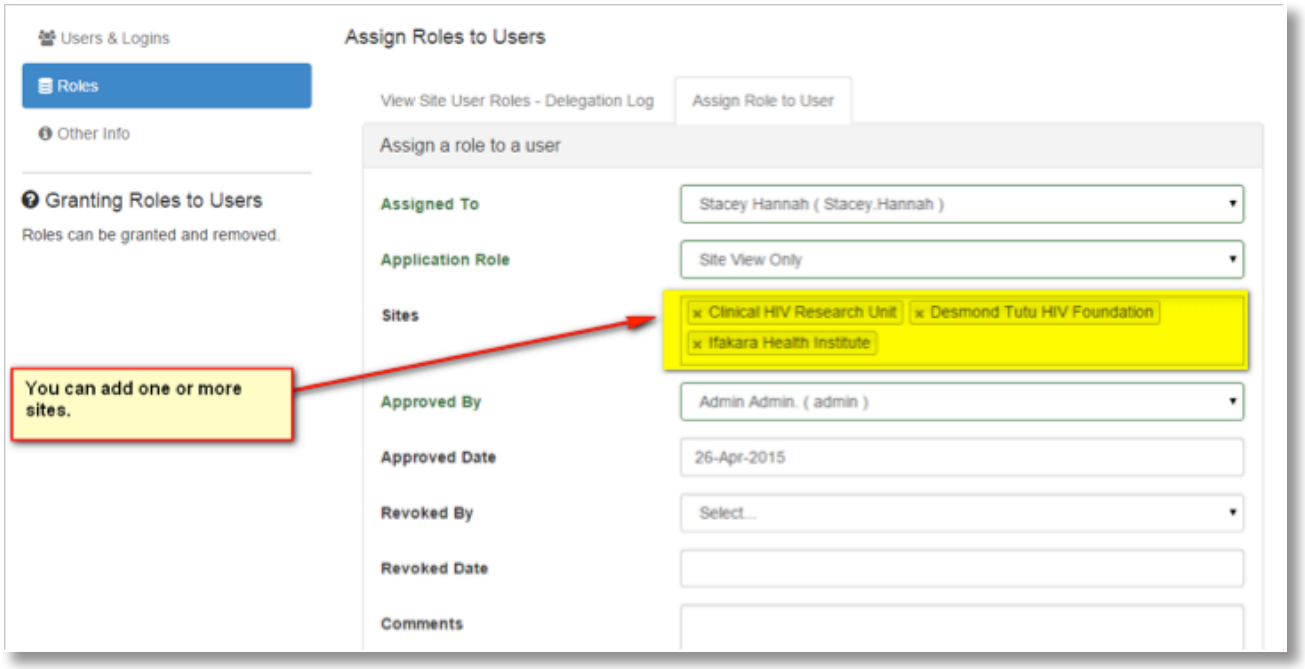
It is very important for you to understand that a user account has to be created for every user who needs to access the database. Creating the account is just the first step and this allows the user to log into the database but at this stage they cannot access any data. The next step is then to define what this user account can do within the database. This is done using a delegation log in the site setup section. In the delegation log, you select the user account, select one or more sites that the user should have access to and also assign a role to the user.

The database supports three site roles namely:

- **Site View Only** – can view toolkit forms (AA, A1, A2, A3, B1, B2, B3, C1, C2, D1, and D2) but cannot add or modify existing forms on the database. This role is for users who need to view the data but not make any changes.
- **Site Data Entry** – can view, add and modify toolkit forms (AA, A1, A2, A3, B1, B2, B3, C1, C2, D1 and D2). However, a user with this role cannot add new site users.
- **Site Data Management** – has all the permissions of the Site Data Entry role plus being able to manage site users, that is, adding new users and assigning/revoking permissions from the users.

Typically all CSE program site users will be set up to access data for only one site. However, it is possible to select more than one site when granting permissions. Donors and sponsors could therefore have access to more than one site, but be restricted and not have access to other sponsors' sites.

Below is an example of how a User can be assigned access to more than one site.

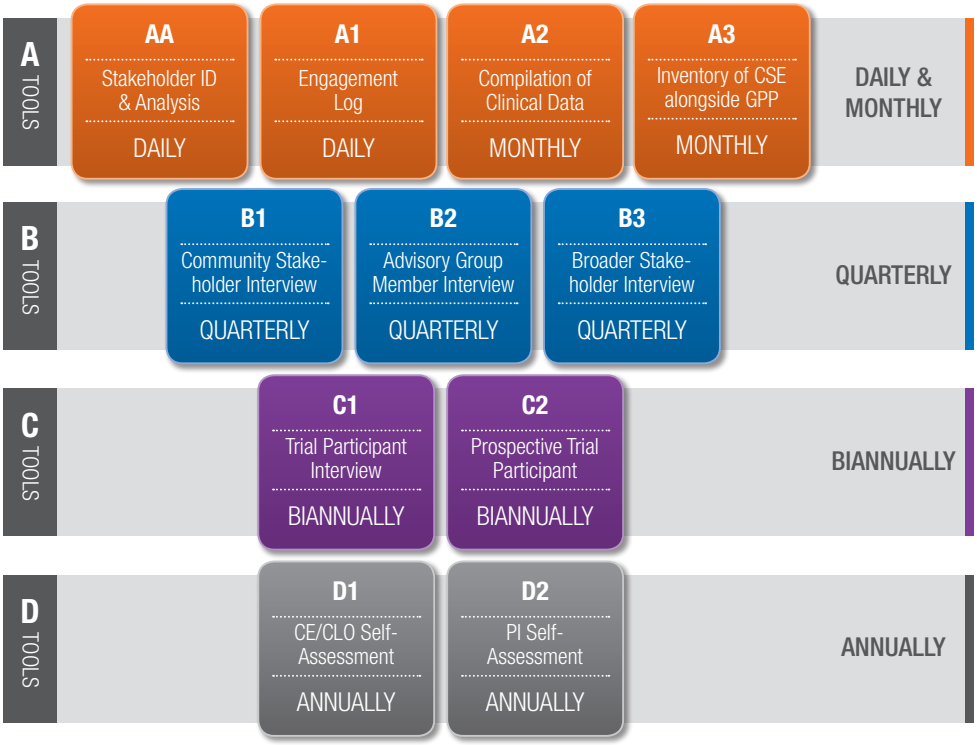


In more complex scenarios such as sites that two sponsors/funders, user access control would need to be further refined to the level of trials. The database access control is not currently programmed to handle such trials but this could be planned for in the future.

Data Collection and Tools

In this section each tool or groups of tools (B, C, D) in the database will be presented in detail. You will find an introduction including justification for its use and where necessary a breakdown of the components of the tool and how to use the tool(s). The figure below reminds you of the structure of the tool matrix.

Figure 10: Tool Matrix



Tool AA – Identify the Stakeholders

In this section each tool or groups of tools (B, C, D) in the database will be presented in detail. You will find an introduction including justification for its use and where necessary a breakdown of the components of the tool and how to use the tool(s). The figure below reminds you of the structure of the tool matrix.

"By ignoring who holds the balance of power, scientists risk the research they do. If you do community engagement and you do not acknowledge power – who is included and excluded in the community – you will end up with biased community engagement."
(WellComeTrust 2011)

A fundamental part of any CSE program is to have accurately identified and understood the stakeholders and their relationship with your program and your program's relationship with them. These relationships are dynamic and shifting.

Having a good understanding of your stakeholders at various points throughout your trial will reduce the risk of avoidable obstacles and can also ensure that you don't miss opportunities that could enhance your CSE and in turn the trial.

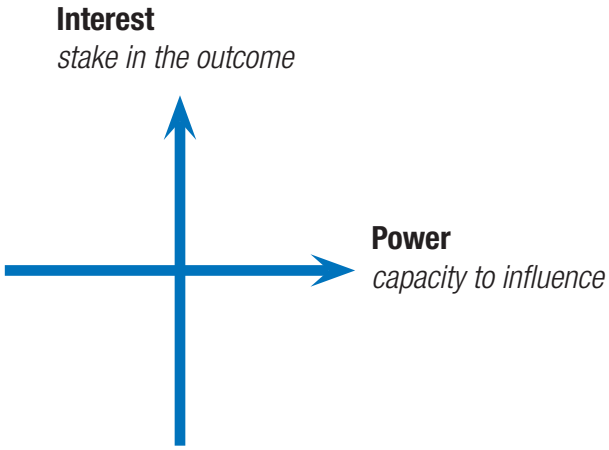
Different groups will have differing stakes in the research or the disease under study or the community or ministry involved. Primary stakeholders include those who, because of power, authority, responsibilities, or claims within the community affected are central the study's CSE. The outcome of any action will likely affect them directly, therefore their participation or that of a carefully selected representative is critical. This primary group of stakeholder also includes, by virtue of the power they wield, those who have the capacity to influence collaboration outcomes, but who may not themselves be directly affected by them. This group can include politicians and officials at the local, national, and regional levels, and international agencies (such as multilateral donors) who control policies, laws, or funding resources.

Stakeholder identification or mapping is therefore the first tool in the Toolkit. A full stakeholder analysis is an extensive process. The AA tool is brief and gives you an opportunity to 'log' all your primary stakeholders and to generate a list of stakeholders over the life span of your trial. As you log your stakeholders, you will become more proficient at rating their level of interest/determination to be involved and their sphere of influence at any point in time. You will also reflect and document if you perceive a logged stakeholder to be resistant or supportive at various points in your trial. You will also rate the power that this stakeholder holds within his or her sphere of influence. You can update your AA entries over time, since your relationships with key stakeholders will inevitably strengthen, weaken or neutralize and you will be able to revisit these relationships. A stakeholder's relationship to the trial and participation in the trial may evolve over time, if you rate them at various points during your trial you can witness how this can change over time. By reviewing your initial stakeholder analysis and updating your plan over the lifespan of the trial you will ensure that your CSE program invests in stakeholder relationships that that will reap the needed rewards for your trial and the community or ideally both and not those that are convenient or habitual.

Note that when you log a stakeholder into the AA form and then you subsequently engage with them, you will be asked in the database to link the AA for to the A1 engagement log as well as to any key informant interviews (B1, B2, B3, C1, C2, and D2).

To reap the full benefit from the AA tool, you will be encouraged to justify your choice to engage this stakeholder in the form of a narrative. You will be limited to a certain number of characters – so you will need to be concise and in one sentence summarize why you have chosen to engage this stakeholder. Longer narratives will congest the database and limit the value of the summaries. You will also be asked to complete the AA form in its entirety. Note that leaving blanks significantly limits the value of the data outputs.

In AA there are sections where you are asked to rate the interest and power of the stakeholder.



You can initially rate interest by reflecting if you perceive that the stakeholder you are logging currently resists or has any conflict of interest or is disinterested in the trial issues you are addressing, or whether he or she is interested, collaborative or supportive.

RESISTANT/CONFLICT	☐
COLLABORATIVE/SUPPORTIVE	☐

You can rate the power of a stakeholder by looking at six attributes and then at three perceptions and rating these as high medium or low/absent.

AA - 1.9 Personally rate the power this stakeholder or stakeholders holds in the area where he or she has a sphere of influence	High	Med	Low/None
KNOWLEDGE & SKILLS – *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?*	☐	☐	☐
COMMUNICATION CONTROL WITH PARTICULAR GROUPS – *does this stakeholder have access to important groups who should be reached to open lines of communication from and to the trial?*	☐	☐	☐
AUTHORITY – REGULATORY – *does this stakeholder hold influence or power over authorization or regulations in the community or more broadly?*	☐	☐	☐
PRESTIGE/STATUS – *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?*	☐	☐	☐
SOCIAL TIES/CONNECTIONS – *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?*	☐	☐	☐
ECONOMIC – FINANCIAL – does this stakeholder have economic or financial influence locally or more broadly?	☐	☐	☐
In your opinion does this stakeholder have a **PERCEIVED RIGHT** to be involved in the trial or components of the trial?	☐	☐	☐
In your opinion does this stakeholder have a **PERCEIVED RESPONSIBILITY** to be involved in the trial or components of the trial.	☐	☐	☐
In your opinion does this stakeholder have a **PERCEIVED RESOLVE** or **DETERMINATION** to be involved in the trial or components of the trial.	☐	☐	☐

You will then be asked to identify where, the stakeholder sits on the continuum of engagement.

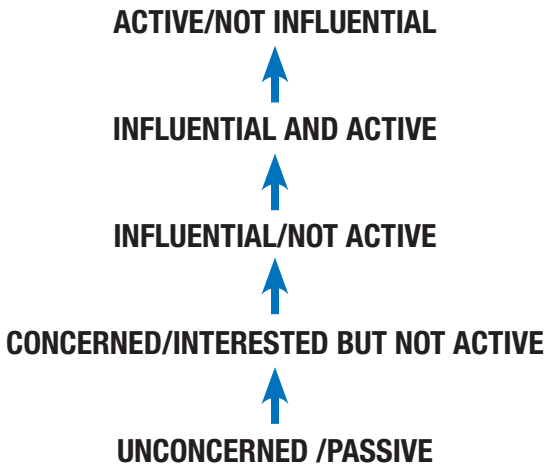
Box 5: Form AA - Continuum of Engagement

INFORMED >> CONSULTED >> INVOLVED >> COLLABORATING >> EMPOWERED

AA-1.11 Select the extent of the stakeholders' relationship with the trial at this point in time.
INFORMED –stakeholder has been provided with information.
CONSULTED – stakeholder is regularly approached for feedback on certain key issues as they arise.
INVOLVED – stakeholder is working directly and actively with the trial or representatives to ensure that public concerns and aspirations are consistently understood and considered.
COLLABORATING – stakeholder is in regular partnership at some level, wherever relevant overlaps exist between their work and the trial interests.
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.

Similarly the final section of the tool asks you to rate the stakeholders' current level of participation in the trial.

Box 6: Form AA - Rating Level of Participation



The AA form is ideally completed whenever you log a new stakeholder or when you revisit a stakeholders' profile and update it. You can link the AA form to other forms and interviews.

Box 7: AA Form - The When and How

When to Complete

- Daily or Weekly
- To be completed whenever a new stakeholder or organisation is added
- To be completed whenever interest/power and engagement require intermittent updating

Number to Complete

- There is no defined sample size
- The more stakeholders you log, the more information you will have in your database to allow you to understand your stakeholders and your engagement approach

Estimated Time

- 5 - 15 minutes

Tool A1 – Daily Activity Compilation Log

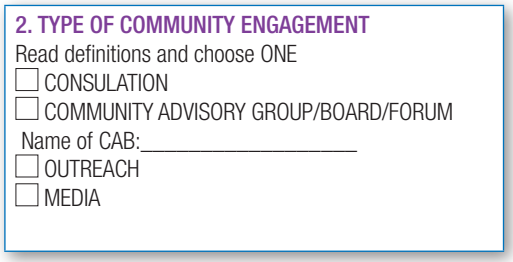
As a CSE Manager you are constantly working on engagement related activities. Many of these activities may not be accounted for in your records. For example, you may spend a week preparing a media release event or formalizing the process for recruiting a new CAB member. You may only document this activity once the media event is implemented successfully or once the new CAB member is recruited. These engagement activities are significant and need to be recorded in order to document the sometimes intricate process behind your daily engagement efforts.

Form A1 is your daily engagement log and captures most of your efforts relating to Consultation, Community Advisory Groups, Outreach and Media. Some examples of what might be captured are included in the Table 14 below.

Table 15: Kinds of Stakeholder Engagement Mechanisms

CONSULTATION – with individuals and small groups	These are conversations and meetings and check ins you may carry out with specific stakeholders to address a wide variety of issues. Consultations may include any meetings with community stakeholders. This may includes discussions around community entry, mobilizations, senstizations and education. It may also include participation recruitment in relation to community engagement, as well as updates and feedback during and after the trial. You can also include phone calls with stakeholders or a visit to the clinic to touch base or update. Consultations logged can be scheduled or unscheduled.
COMMUNITY ADVISORY GROUP/ BOARD/FORUM	These include any or 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.
OUTREACH – to large groups	These include outreach related to any health calendar events, screening days, community meetings, dialogues, theatre or music events, education sessions in institutions (schools, clinics, and universities), and 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.
MEDIA	These include radio, flyers, posters, newsprint, television, press releases and social media.

At the start, as you complete form A1, you will decide which 'type' of engagement your activity relates to. If you've selected the CAB category, then you will need to choose the focus of the engagement. For example, if you are planning a CAB meeting and the CAB meeting relates to training, then you may select both 'Planning' and 'Training' as the focus of your engagement.


2. TYPE OF COMMUNITY ENGAGEMENT
Read definitions and choose ONE
☐ CONSULATION
☐ COMMUNITY ADVISORY GROUP/BOARD/FORUM
Name of CAB:_____
☐ OUTREACH
☐ MEDIA

You have spent two hours planning this meeting, so you would allocate two hours to the activity by choosing the start and finish time for the activity.

Depending on the type of engagement you selected above, you will then choose the form that your engagement took. For example, it may take the form of a unscheduled meeting with key CAB members, or perhaps if your type of engagement was 'Consultation' and you were doing so through email, then you would log the form of engagement accordingly. The lists provided may not be fully inclusive, so you can always choose **other** and specify the form your engagement took.

4.FOCUS OF ENGAGEMENT *(can choose many)*

- ☐ Planning
- ☐ Training
- ☐ Implementation
- ☐ Communication
- ☐ Follow up

5.TIME SPENT ON THIS SPECIFIC ENGAGEMENT ACTIVITY BEING LOGGED

Start: __ __ __ __ Finish: __ __ __ __

Total: __ __ __ __

6.FORM OF ENGAGEMENT

CONSULTATION

- ☐ EMAIL
- ☐ ONE TO ONE MEETING (NOT CAB)
- ☐ ROUTINE/ SCHEDULED MEETING (NOT CAB)
- ☐ UNSCHEDULED OR EMERGENCY GROUPMEETING (NOT CAB)
- ☐ SMALL SUBCOMMITTEE MEETING (NOT CAB)
- ☐ OTHER _____SPECIFY

CAB

- ☐ ROUTINE/ SCHEDULED CAB MEETING
- ☐ UNSCHEDULED OR EMERGENCY CAB MEETING
- ☐ EXECUTIVE COMMITTEE CAB MEETING
- ☐ OTHER _____SPECIFY

OUTREACH

- ☐ GLOBAL HEALTH EVENT
- ☐ HEALTH or RESEARCH EDUCATION
- ☐ HEALTH SCREENING
- ☐ GENERAL COMMUNITY MEETING
- ☐ PEER EDUCATION
- ☐ HEALTH WORKER TRAINING
- ☐ THEATRE/MUSIC EVENT
- ☐ SPORT EVENT
- ☐ OTHER _____SPECIFY

MEDIA *choose those relating to this engagement log*

- ☐ LOCAL RADIO ADVERTISEMENT
- ☐ LOCAL RADIO INTERVIEW
- ☐ REGIONAL/NATIONAL RADIO ADVERTISEMENT
- ☐ REGIONAL/NATIONAL
- ☐ RADIO INTERVIEW
- ☐ TELEVISION ADVERT
- ☐ TELEVISION INTERVIEW
- ☐ LOCAL NEWSPRINT ARTICLE
- ☐ LOCAL PRESS RELEASE
- ☐ NATIONAL NEWSPRINT
- ☐ NATIONAL PRESS RELEASE
- ☐ SOCIAL MEDIA UPDATE
- ☐ INTERNET PLATFORM
- ☐ POSTERS
- ☐ FLYERS
- ☐ BILLBOARDS
- ☐ OTHER _____SPECIFY

Over time it will be very helpful to account for all the groups of people you and your program have reached over the course of your engagement. You will be able to plot when you were most successful at engaging and if this correlated with other events in the trial conduct, for example.

Therefore, you will be requested to indicate the number of people reached, exactly or approximately. The more precise your figures are, the more valuable your data will be. When you are running a media campaign, you may not know the exact number of people the flyers will reach, but you can indicate the expected number, by using figures on readership or the number of youth in a particular location.

7. ATTENDANCE OR REACH

NOTE: Enter the exact number of people in attendance or reach though 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.

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

_____

If any of your engagement activities involving 'training' of any kind, you should document this in question eight and specify the kind of training that took place. For example, during outreach, in addition to engaging interest around the trial, your outreach workers may also be conducting TB Prevention training, you would select this accordingly.

8. TRAINING

DID ANY TRAINING TAKES PLACE AT MEETING:

☐ YES
☐ NO

Specify kind

☐ RESEARCH LITERACY
☐ GPP
☐ GCP
☐ TB PREVENTION AND TREATMENT
☐ HIV PREVENTION AND TREATMENT
☐ OTHER _____SPECIFY

When you are entering Media related outputs, there is an entire section dedicated to the 'Specifics of Media Engagement' – this applies only to Media type engagements. You are asked to specify the name of the radio station or newspaper. Always provide the necessary detail to ensure that your data is valuable.

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)

In the remaining sections of A1 you will identify the purpose of your engagement or the issues addressed. The list is relatively long and as time passes you will become more familiar with the issues listed. You can choose multiple issues, many of which are aligned with the GPP requirements. A few of these issues are listed to the right, the remaining issues can be found in the accompanying document containing all the tools in detail.

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

In question twelve of form A1 you will be asked to highlight the group or groups of stakeholders that have been reached through this engagement currently being logged. Note this is different to where you are asked to do so in AA. A brief example of the proposed options is listed below. If you are holding a CAB meeting, which stakeholders attended? If you are initiating a media event, who were you targeting? You will be able to select more than one and you can specify if the stakeholder group does not feature on this list! If you choose general public – you will be also be asked to specify particular groups within the general public, including their gender and age.

12. COMMUNITY STAKEHOLDERS INVOLVED/REACHED/TARGETED

Choose multiple

- ☐ ADVOCATES & ACTIVISTS OTHER _____ *(specify)*
- ☐ 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 GOVERNEMENT 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

The last section of Form A1, question thirteen requires that you define the outcome of your engagement. This means you can later reflect on the value of your engagements. Be focused in your narrative and note that you have limited space.

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?

You can go on to rate the value of the engagement in question fourteen, followed by next steps and any further comments. You will then have the opportunity to upload any relevant documents, related to this specific engagement.

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

Tool A2 - Clinical Trial Data Extraction

The A2 form is an opportunity for the CSE team to extract clinical trial data on recruitment, retention and adherence data that could, in time, be correlated with CSE efforts.

Section 2 of the form highlights the stage that the trial has reached. Section 3 of the form only applies if your trial is either **Recruiting** (REC) or focused on **Retention and Adherence** (RET-ADH) or on participant follow up (PFU). By completing Section 2 of the form each month, the database will have the information needed to plot your trial timeline.

There are permission issues relating to this tool and you will need to get prior written approval from your clinical trial supervisors to capture this data and enter it into the database.

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

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

In Section 3, there are sections where you can attribute the data to either regions/locations/districts (whatever sub categories you wish) and or health centers. This means you can generate outputs specific to a particular recruitment facility or a sub-location or other sub-category.

Tool A3 – Inventory of CSE alongside GPP & Linkages

Form A3 supports tracking the eight stages of a trial where GPP expects to see a trial capturing feedback from stakeholders. This tool supports the CSE team to track from which kind of stakeholder suggestions were received and how the trial handled the suggestions. The eight categories are listed below in Box 10.

Box 10: GPP Guidelines - Tracking Stakeholder Input/Suggestions

1	SUGGESTIONS RECEIVED FROM CSE REGARDING FORMATIVE RESEARCH PROCESS
2	SUGGESTIONS RECEIVED FROM CSE REGARDING TRIAL PROTOCOL DEVELOPMENT
3	SUGGESTIONS RECEIVED FROM CSE REGARDING INFORMED CONSENT FORMS AND PROCESSES
4	SUGGESTIONS RECEIVED FROM CSE REGARDING COMMUNICATIONS PLAN
5	SUGGESTIONS RECEIVED FROM CSE REGARDING TRIAL RESULTS DISSEMINATION
6	SUGGESTIONS RECEIVED FROM CSE REGARDING DEVELOPMENT OF ISSUES PLAN
7	SUGGESTIONS RECEIVED FROM CSE REGARDING PROCEDURES FOR PARTICIPANT EXIT FROM TRIAL
8	SUGGESTIONS RECEIVED FROM CSE REGARDING INTERVENTION AND TRIAL PRODUCT IMPLEMENTATION

This tool, which is compiled monthly, requires that you keep records of when and how your stakeholders are engaging in these eight categories and to keep count of these. For example, if this month stakeholders were engaged in the formative research process of an upcoming trial, you will need to know if these were community stakeholders or broader stakeholders, as per the definitions presented at the beginning of this manual. You will then be asked to specify where this engagement was managed, internationally, nationally, regionally (sub-Saharan Africa for example) or locally. Formative research is often managed internationally, and you may sometimes not be aware of this taking place. With time, you will want to find ways to remain current on the evolution of trials, so that you can capture the data. If there has been engagement, how did it take place? Did a member of a community scientific sub-committee travel overseas to contribute to the formative process? If so, you will need to follow up on this process and be aware of any suggestions that may have been made and confirm whether they were indeed acted upon. All this information needs to be entered into the database to collect meaningful information that can align the trial with the GPP expectations. It is unlikely that you will have more than one stage on going each month for one trial, but you may have more than one trial being tracked at one point in time. Be sure to enter as many A3 forms as needed, for all the trials, monthly.

At the end of form A3 there is a section on Linkages. You will simply reflect on the previous month and establish if any NEW linkages were formed with CSH or BSH structures. If *New Linkages* have been forged, you will be asked to rate the strength or nature of the linkage. Finally, you will be asked to reflect on the previous month and document any training that has taken place, label the training, Research Literacy or TB Awareness, for example and then list the number of trainings held and brief details of who was reached and for how long.

Tool B1 – Community Stakeholder Interview

Tool B1 is one of the three B interviews. B1 targets any community stakeholder who is not an advisory board member (i.e. not on the CAB or CAG or equivalent) and who is not a Broader Stakeholder or a Trial participant or prospective participant. So for B1 you would anticipate interviewing anyone that features in the second ring of Figure 2 – members of CBOs, participant's family, friends, members of staff a local schools, local religious or faith based groups, traditional healers, local health service providers. You will complete this monthly or quarterly and schedule these interviews into your workplan. We anticipate that if you do two per month, you will have sufficient meaningful data at the end of the year. The focus of these interviews is to establish what community stakeholders know about the trial under enquiry and how they were reached and how they would like or not like to be reached in the future. You will also enquire about positive and negative messages about the trial circulating in the community and determine whom they think should be reached and how.

Tool B2 – Advisory Group Member or Community Representative Interview

This tool is focused only on those stakeholders who are already engaged with the study through an advisory mechanism. This is an opportunity to give these representatives a chance to raise their concerns or experiences in a safe and non-judged arena. A CAB member may never have been consulted independently and this is a chance to better understand their interpretation of their role as a CAB member and their experience with being recruited as one. You will determine if they are content with their level of involvement and how satisfied they are with the way the trial engages with them. You can aim to have interviewed each CAB member at least once per year. This means that one B2 interview can be scheduled per month.

Tool B3 – Broader Stakeholder Representative Interview

This tool is reaching out to Broader Stakeholders. This is the second layer of stakeholders in the stakeholder onion in Figure 1 and Figure 2. Broader Stakeholders include NGOs, local policy makers, local media and medical professionals. The interview tries to establish how far your CSE efforts are reaching and if these BSH have ever been informed about the trial, assuming they are relevant and operate in the area being targeted by the trial. You will have sampled the BSH based on a comprehensive list of BSH operating in the area. The interview, where one interview takes place per month, will expand your understanding of levels of awareness in the zones where you work and allow you to factor the findings into your workplan in order to better reach those who aren't being reached and should be being reached.

Tool C1 – Participant Volunteer Exit Interview

The C set of tools focus either on the trial participant or on a prospective participant. The main focus of this key informant interview is to establish how the participant was initially reached by the trial and whether that process was a positive one and whether now, while enrolled, if the quality of the service is acceptable, the informed consent process experience, who else the participant thinks should know about the trial, the reasons for participation and things that could be improved in the way the participant and his or her community are engaged in the trial. There is no sample size, but we suggest one such interview per month, to allow you to keep a finger on the pulse of participants in the trial.

Tool C2 – Prospective Volunteer – Post Screening Interview

The value of interviewing a prospective volunteer, who has not yet been enrolled, is that the experience is very acute. A trial participant may have been enrolled quite some time ago and so their experience may not be very 'up to date'. On the other hand, a prospective participant has recently been sensitized and is likely very perceptive to the way the trial is being received amongst the target population. You can gather valuable insights into the CSE process among this group of key informants. Again, there is no sample size, but we recommend one interview per month.

Tool D1 – Community Engagement Manager Self-Assessment

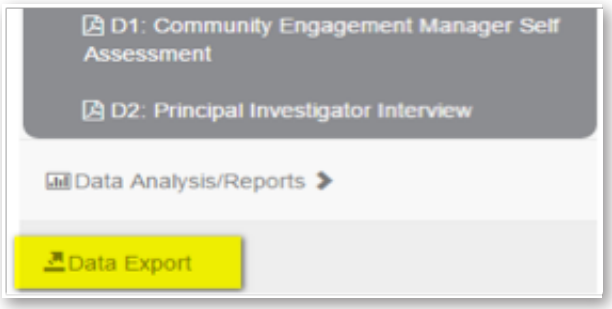
This tool -which may be challenging for CSE teams - requires each member of the CSE group to reflect on the work being done and without accessing the data, reflect o n the past six months It is an opportunity to track your own perception of your progress and it will be valuable for you to track these perceptions over time and compare them with the actual logged findings. Be as honest as possible, as your perception will have the possibility to be triangulated with the quantitative data entered into the other tool sets. If each member of your CSE team can complete the self-assessment twice per year, this would be ideal.

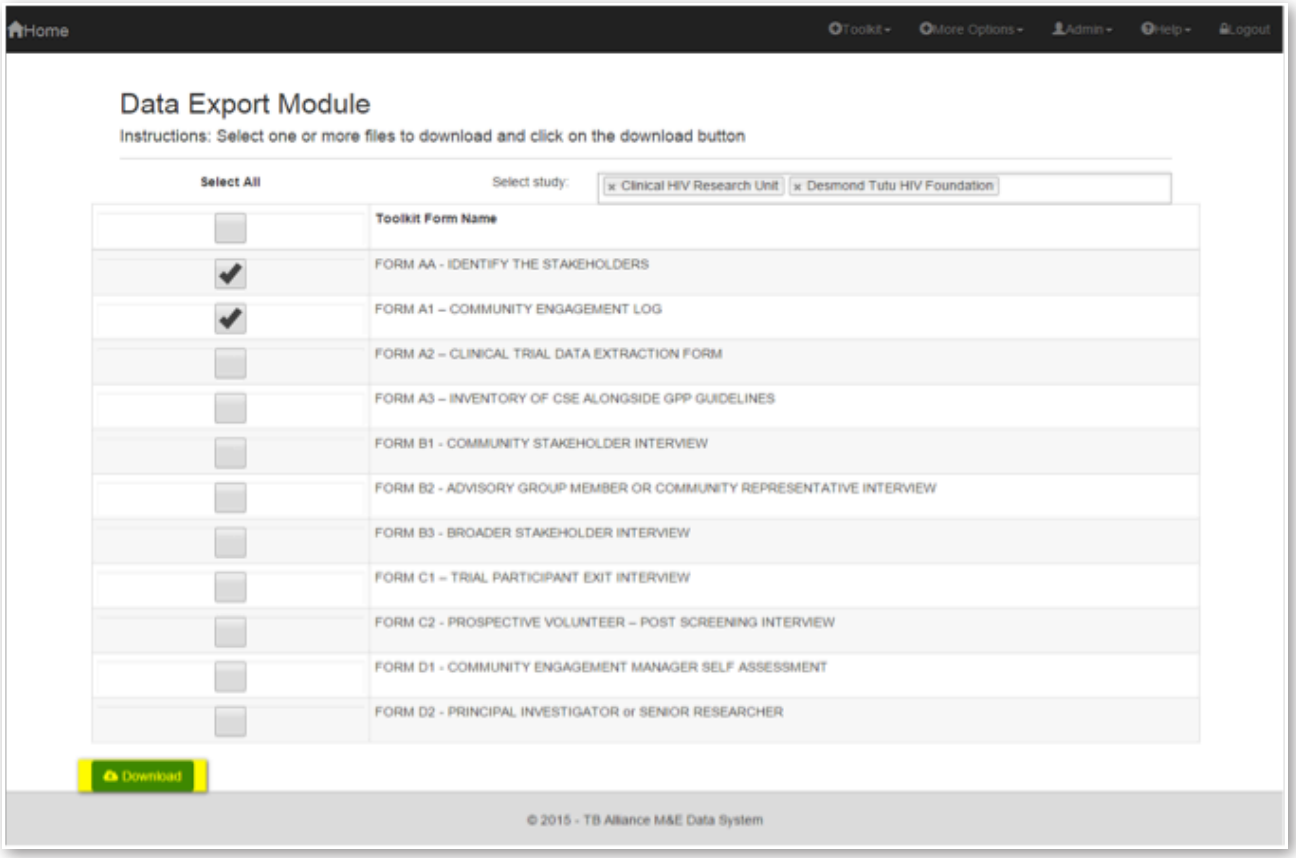
Tool D2 – Principal Investigator Interview

CSE teams can sometimes work in isolation and the 'research' teams may not be involved in your CSE activities. This may mean that the right hand does not know what the left hand is doing. The value of finding out how 'tuned in' the PI or Senior Researchers are into the CSE efforts of the trial, may help to highlight areas for improvement, where the trial can enhance how it communicates with the target community. The D2 self-assessment is for senior research staff to complete every six months.

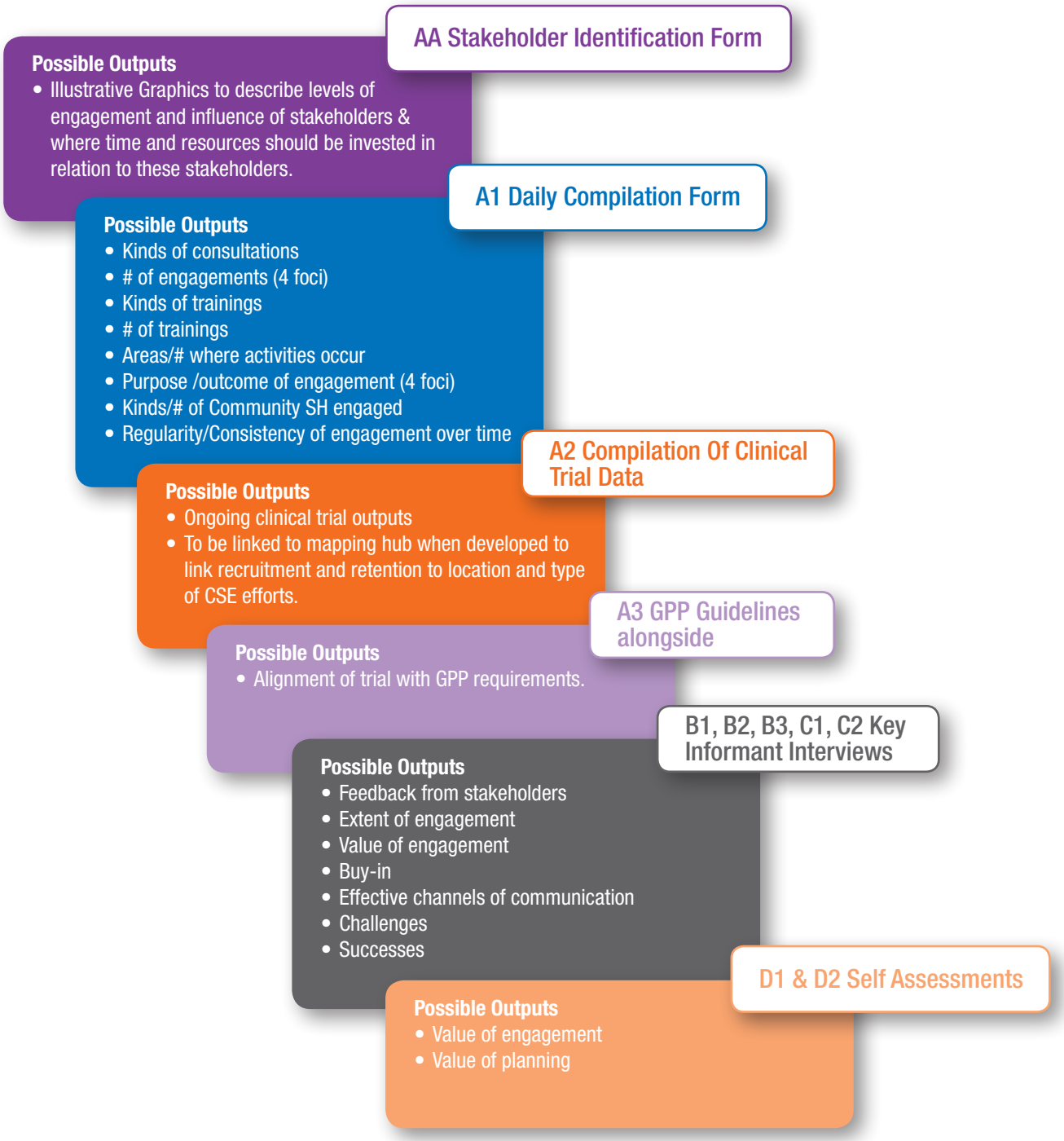
Analysis

The database is primarily a space to capture data and the pre-programmed outputs are an opportunity to track simple descriptive univariate results on a quarterly basis. These outputs will change as we adapt and make the default reports more sophisticated. The bank of pre-programmed outputs will increase over time as they are programmed. Beyond the limited pre-programmed outputs, the dataset is available to site statisticians for further analysis based on the data needs of each site. A statistician can export all the data entered into the database and will get a zipped file that contains a data dictionary and the raw data which he or she can work with in conjunction with the pdfs of the actual questionnaires. The data dictionary describes the questions – including question type, coding and variable type. The dictionary is very important as it is the basis for the coding. The exported raw data is in CSV format. CSV is a plain text file with data in a comma delimited format. The advantage of this format is that it can be imported into most statistical packages as the CSV format is a widely accepted format for data exchange. Users can export one or more tools exporting all the data for their site. Please note that the export does not contain the uploaded documents.





As you grow familiar with the toolkit and the data, you will be able to generate very valuable results and evaluate your entire CSE program at various points during your trial. To date you have not had a vessel in which to organise your CSE data. This is the first outcome of this endeavour. Subsequent steps will include your CSE team using the data for planning and monitoring. The figure below is an introduction to the simple outputs that will emerge from this database and that you can use in the early stages.



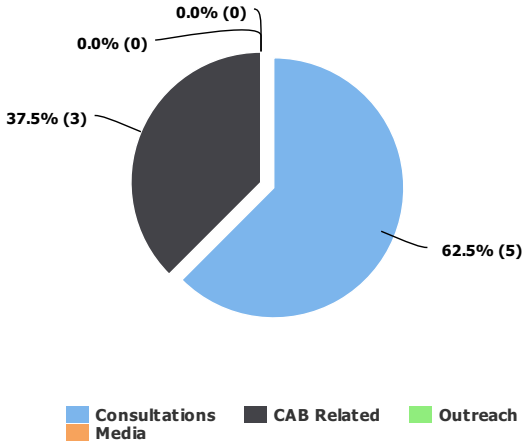
Reporting and Key Outputs

Below is an example of the key outputs from A Tool Set with dummy data. These are pre-programmed outputs. These outputs will feature in the automatic pdf quarterly report that you can submit to your sponsors or partners. Over time this set of outputs will be expanded.

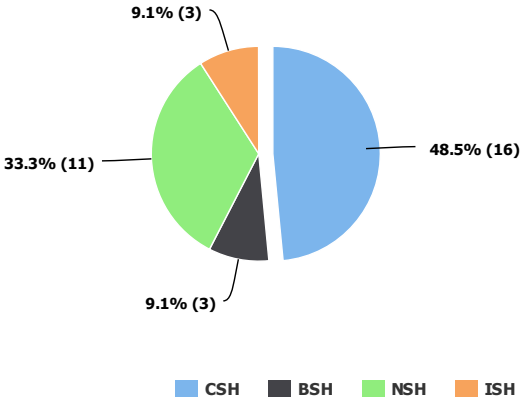
Site Quarterly Report: Q4/2014

Selected Site: <Site Name>

1. Type of Engagements - source A1



2. Category of Stakeholders Engaged/Updated - source AA

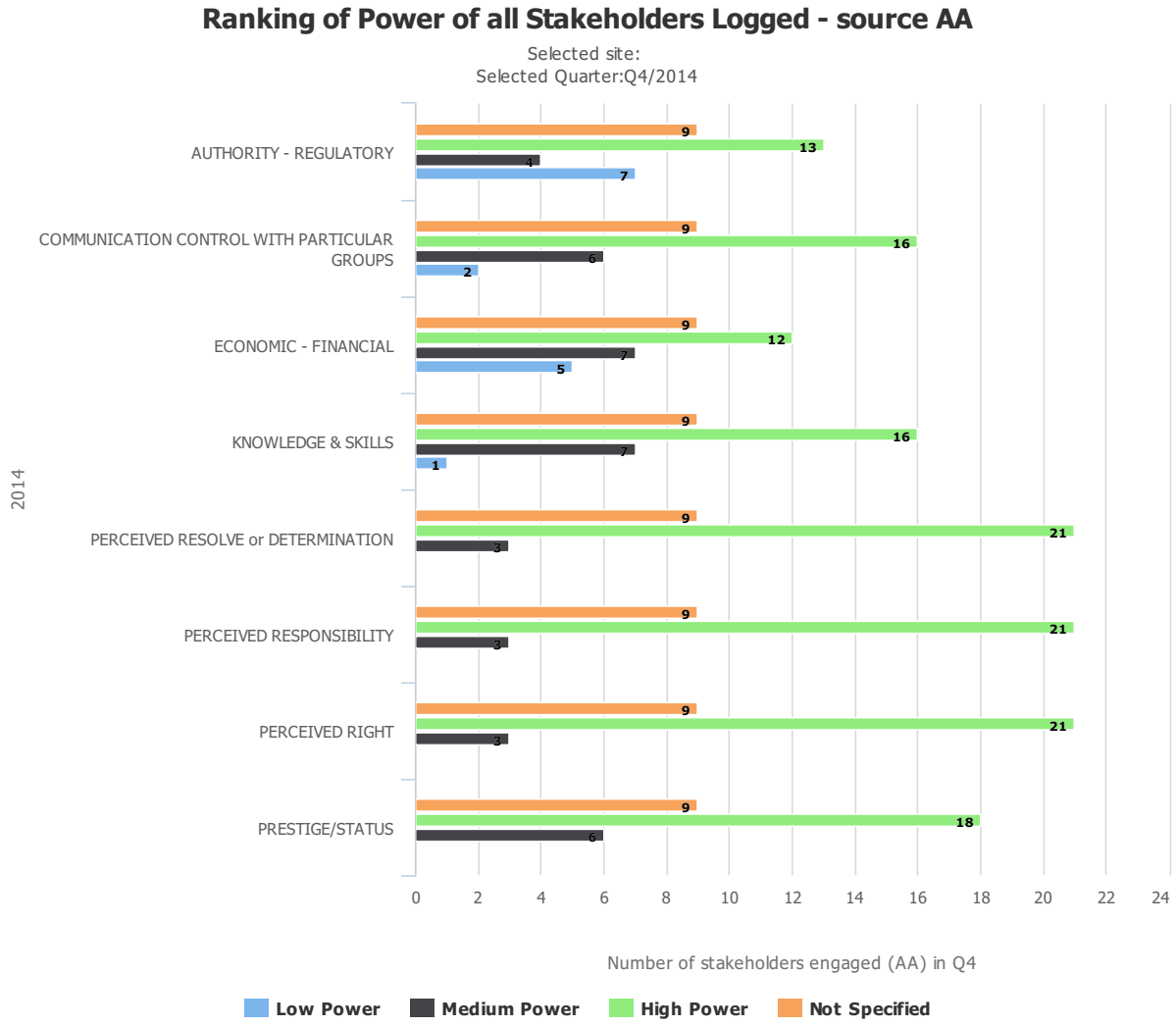


3. List of all Stakeholders - those engaged and not engaged

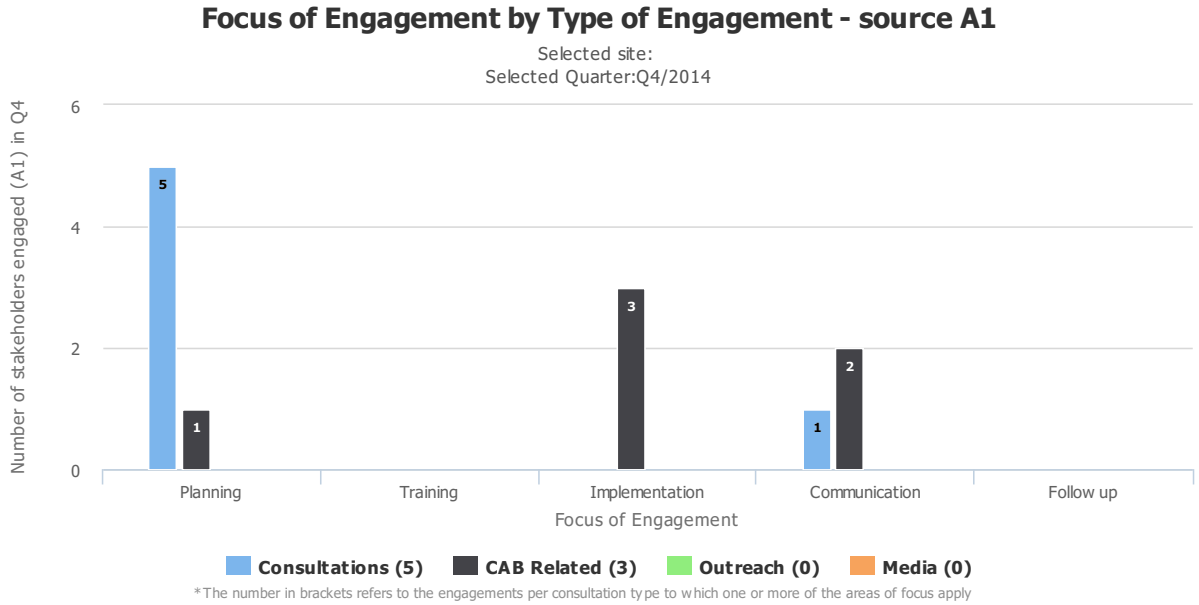
Specific Stakeholder Categories engaged	#
ADVOCATE or ACTIVIST	9
COMMUNITY BASED ORGANISATION STAFF	7
LOCAL LEADERSHIP – GOVERNMENT OR ELECTED	4
OTHER	4
LOCAL FAITH BASED LEADER	3
LOCAL HEALTH FACILITY STAFF	3
DONOR	1
INTERNATIONAL ADVISORY BOARD	1
LEGAL EXPERT	1
COMMUNITY HEALTH WORKER	0
INDIVIDUAL RESIDENT IN THE TARGET AREA	0
LOCAL BUSINESS	0
LOCAL BUSINESS OWNERS	0
LOCAL LEADERSHIP – TRADITIONAL	0
LOCAL POLICY MAKERS	0
MEDIA /JOURNALISTS	0
NGO STAFF	0
SCHOOL TEACHER	0
SPONSOR/COORDINATOR	0
TRADITIONAL HEALER	0
YOUTH WORKER	0
Total	33

Reasons for Engaging Specific Stakeholders - source AA

Type of Stakeholder	Number of SH's per type engaged this QTR	Reason for Engaging these Stakeholder Types – brief restricted narrative
ADVOCATE or ACTIVIST	9	Chairperson of the youth with TB network.
COMMUNITY BASED ORGANISATION STAFF	7	She's a leader in the community; familiar with TB work and the community
LOCAL LEADERSHIP – GOVERNMENT OR ELECTED	4	DOH is a partner in the project. they are supplying some of the drugs for the study as well as responsible in the planning and implementation of national policy, treatment, and prevention plans.
OTHER	4	The SH is part of the greater sex worker community. They would be valuable for recruitment and publicity of the trial in the community.
LOCAL HEALTH FACILITY STAFF	3	TAC advocates for a more proactive and vigorous Prevention and Treatment programs for HID & AIDS. They also advocate at national level for new and cutting edge findings on HIV and AIDS.
LOCAL FAITH BASED LEADER	3	
LEGAL EXPERT	1	The SH is a public interest law centre that seeks to influence, develop and use the law to protect, promote and advance human rights.
INTERNATIONAL ADVISORY BOARD	1	
DONOR	1	UNAIDS, the Joint United Nations Programme on HIV/AIDS, is an innovative partnership of ten United Nations Organizations that leads and inspires the world in achieving universal access to HIV prevention, treatment, care and support.



Logged - Actively engaged in this quarter



Form of Engagement by Engagement Type - Source A1

Q4/2014	
CAB Related	
Form of Engagment	**No. of CAB Related Engagements that used this form/approach**
ROUTINE/ SCHEDULED CAB MEETING	3

Q4/2014	
Consultations	
Form of Engagment	**No. of CONSULTATION Related Engagements that used this form/approach**
OTHER	5

Q4/2014	
Media	
Form of Engagment	**No. of MEDIA Related Engagements that used this form/approach**

No Form of Engagement specified for this quarter for MEDIA related activities.

Q4/2014	
Outreach	
Form of Engagment	**No. of OUTREACH Related Engagements that used this form/approach**

No Form of Engagement specified for this quarter for OUTREACH related activities.

Purpose of Engagement by Engagement Type - Source A1

	No. of Consultations that used this form/approach			
Form of Engagment	**CAB Related**	**Consultations**	**Media**	**Outreach**
Number of Engagements in this Quarter Per Consultation Type	*3*	*5*	*0*	*0*
CAB MANAGEMENT	2	0	0	0
COMMUNICATION PLAN	1	0	0	0
COMMUNITY ENTRY/INTRO	2	0	0	0
FORMATIVE WORK	0	5	0	0
RECRUITMENT CAB	1	0	0	0
ROLE CLARIFICATION	1	0	0	0
STUDY BRIEFING/TRAINING	2	0	0	0
OTHER	0	1	0	0

In addition to the pdf quarterly report that you can automatically generate on the database, you can also consider presenting your quarterly data, using some of the subheadings presented in the table below. You can export specific outputs, from the expaning outputs section of the database, and incorporate these into your report. With time, these outputs will be become more numerous. Alternatively, you can generate your outputs by working with your statistician, who can manipulate the data to meet your needs.

Table 16: M&E Quarterly Report Template

- **Title page** - Quarterly CSE M&E Report
- **Table of Contents**
- **Summary**
- **Summary of Work Plan for Quarter being reported upon**
  - Present Logical Framework for Quarter.
  - Narrative summary of progress (high point and low points) as compared to previous Quarterly Report.
  - Describe any adjustments to work plan and justifications.
- **Process Report and M&E Results**
  - This is the main body of the report where you will present an update on activities - successful and unsuccessful activities.
  - Present progress against the targets you set at the beginning of the quarter.

Target for this QTR	Achievement for the QTR	Explanation if any Variance

  - Present a summary of your M&E activities and present the key selected outputs.
  - Under each graph you note interpretation for implementation.

Pending specific sections of report

- **Conclusions for Planning**
  - Present conclusions drawn which led to the fulfilment of objectives.
  - Present real difficulties and challenges if any and how you overcame them.
- **Next Steps**
  - Explain how you have used the learnings to adapt your work plan for the next quarter.
  - Present your work plan for the next quarter.
  - Present your M&E targets.
- **Links**
  - Add links to photos.
  - Add links to documents.

The Database User Guide

This section of the manual is intended to serve as a working guide for the users of the CSEMES (Community and Stakeholder Engagement for Clinical Trials M&E Software). CSEMES is the web based data entry, data analysis and reporting tool, referred to as the 'database' in the manual. This section provides a detailed introduction to using the database.

SUPPORTED BROWSERS

CSEMES is designed to run on most browsers and it has been tested and validated using Internet Explorer, Firefox and Chrome. The application can be used on desktop, tablet and mobile devices; however, when entering data, it is better to use tablets and desktops.

To optimise your experience of the system, if you are using Internet Explorer, we recommend that you use IE 9 or above as Microsoft have included significant performance enhancements in these later versions. If your using Firefox or Chrome, ensure that the browser version is 32.0 and above.

GETTING STARTED

Users and Roles

The software is web-based; therefore, the only software required to access the system is a browser. Before you can use CSEMES, a user account should be created for you by the *Database Administrators*. Also a designated *Site Data Manager* with the "site data management" role can create user accounts for users at their site. Roles are defined within the database, and these determine which actions you are permitted to perform.

The roles available to site users are;

- **Site View Only** - can view toolkit forms (AA, A1, A2, A3, B1, B2, B3, C1, C2, D1, and D2) but cannot add or modify existing forms on the database. This role is for users who need to view the data but not make any changes.
- **Site Data Entry** - can view, add and modify toolkit forms (AA, A1, A2, A3, B1, B2, B3, C1, C2, D1 and D2). However, a user with this role cannot add new site users.
- **Site Data Management** - has all the permissions of the Site Data Entry role plus being able to manage site users, that is, adding new users and assigning/revoking permissions from the users.

Creating a new user

Each research site will have designated their own site data managers with the role of "Site Data Management" that will be responsible for creating new site users and granting them one of the application roles below (Site View Only, Site Data Entry or Site Data Management).

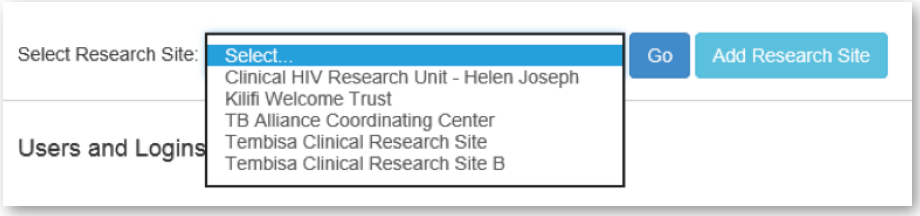
The user accounts for the site data manager(s) will be created by the database administrators as part of the process of setting up a new research site in the database. The site data manager should login into the database and follow the steps below to create a new user.

Step 1

From the home page, click on the site setup link. Note that you will only be able to see this link if you have been assigned a role with permissions to do this. View only roles don't have access to the site setup.

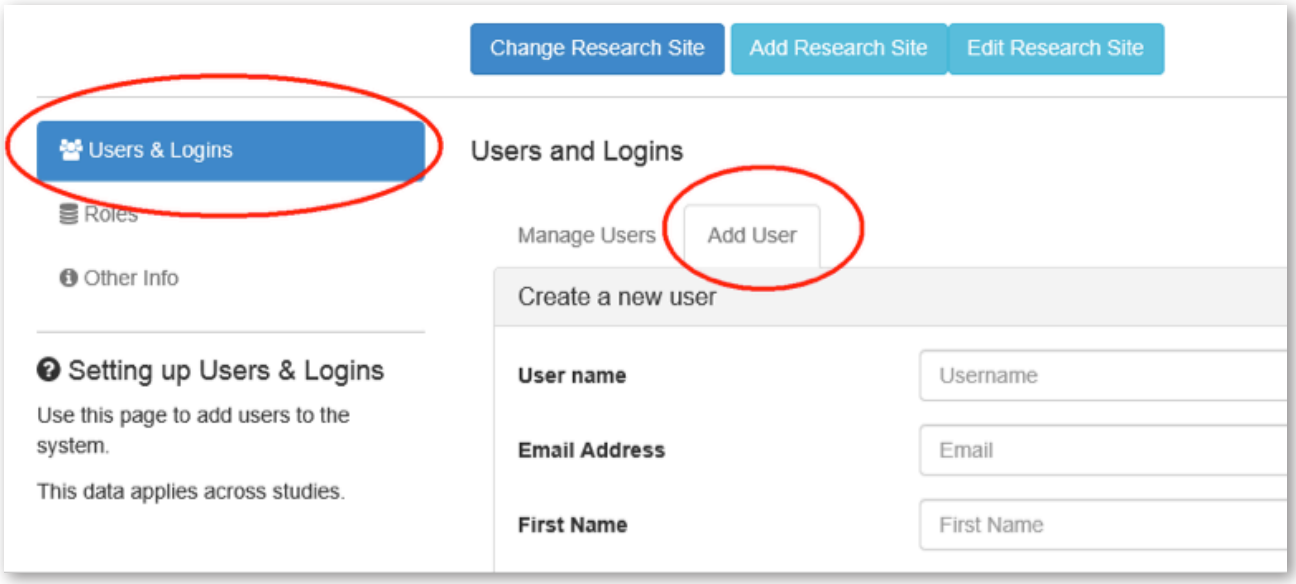
Step 2

Select a research site that the user will be added.



Step 3

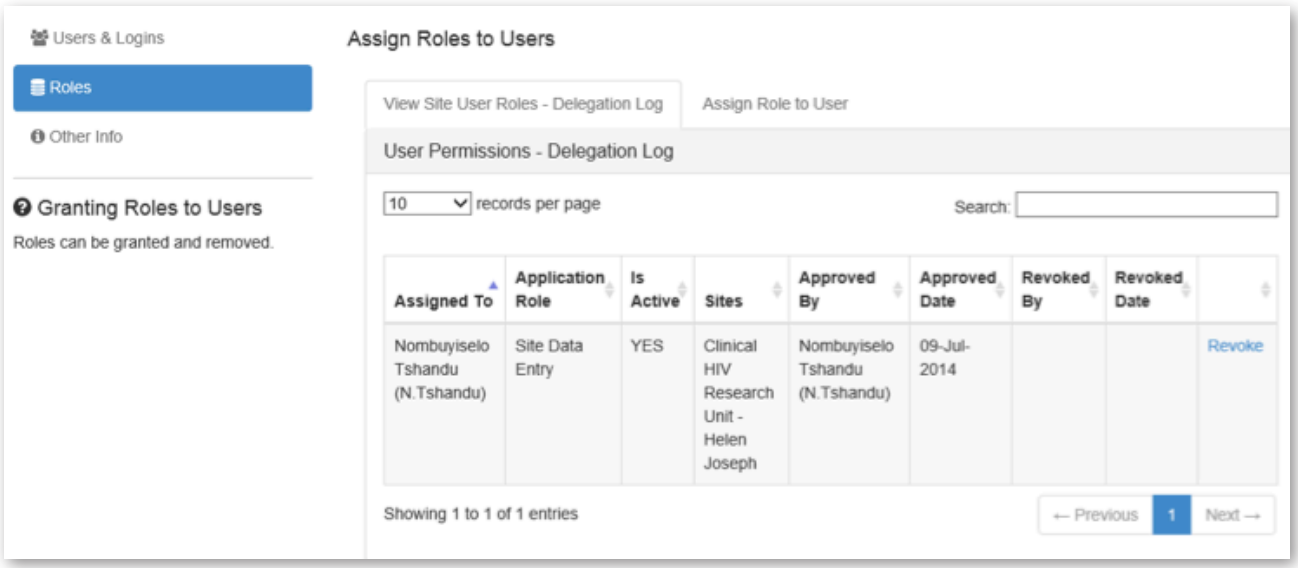
Now add the user (if user does not already exist).). Click on the first tab “Manager Users” to view the current list of users for your site; verify that a user account does not already exist for this user.



Step 4

Next, assign the user a role. If a user has been created but they have not been assigned a role, they will be able to login into the application but none of the menu options will be available to them.

View the list of user roles first to verify that the user does not already have an active role.

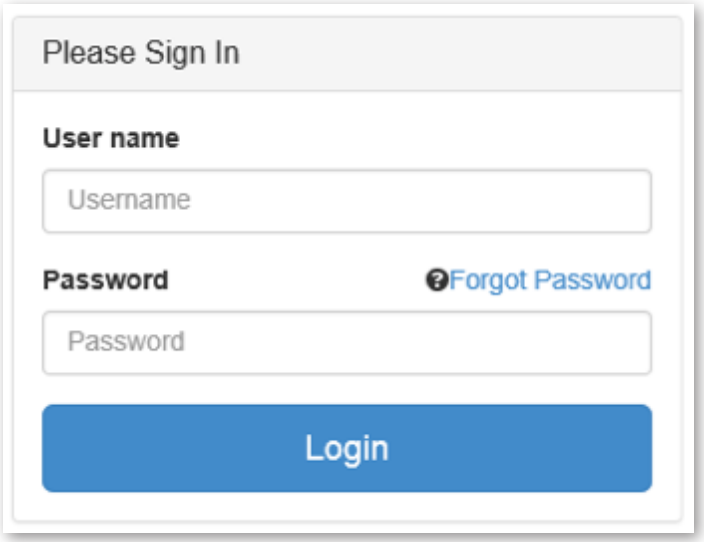


If the user does not have an active role, you can go ahead and assign them a role using the site setup screen. Note that you can select more than one site when assigning roles. Please ask the new user to log in using their new user account details to confirm that they can see the left menu and are able to add a new tool entry.

In summary, it is a two-step process of creating a user and then assigning one or more application roles to the user. In practice, you won’t need to assign more than one role to a user as the roles are cumulative, that is, a “site data entry” role does everything a “view only” plus being able to add and modify toolkit form entries. Creating a user account only grants them access to the database but they won’t be able to do anything after logging into the system.

Logging In

Access to the system is restricted. The Login page is presented to users when accessing the CESMES web interface prior to login, when their session has timed out or when their password has expired.



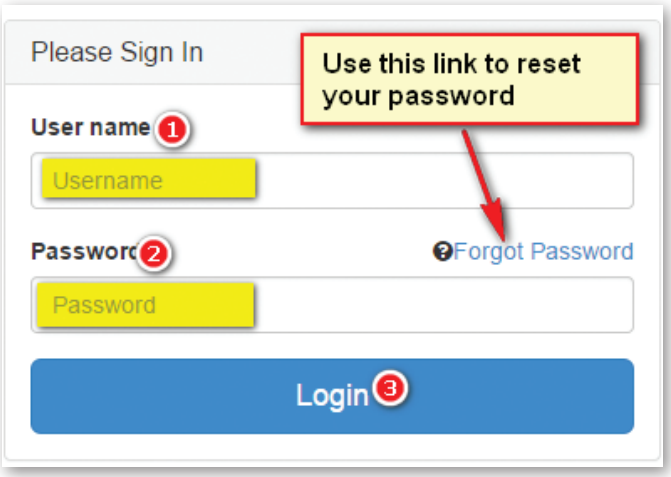
Below is the link to the application

Live Database: http://67.207.154.82/app/

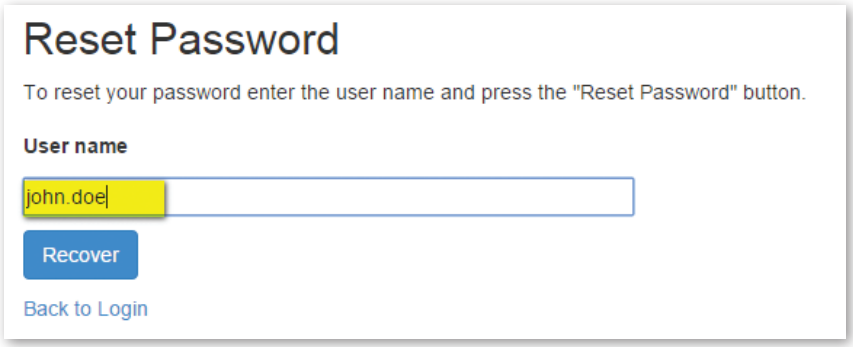
- The user logs into the system by entering a username/login name and password in the text input fields provided, and then selects the Login button. On successful login, users are presented with their Home Page.
- If incorrect or outdated data is entered, or the system is in a maintenance state, an appropriate error message will be displayed.
- In the case of new accounts, expired or forgotten passwords the Reset Password procedure should be initiated, for details see below.
- Users not registered with CSEMES can request a user account from either local site data manager or from TB-Alliance/AVAC as described in 3.2.

Resetting your Password

- Click on the reset password link



- You will be redirected to a page where you will be required to enter your username and click ‘Reset password’.

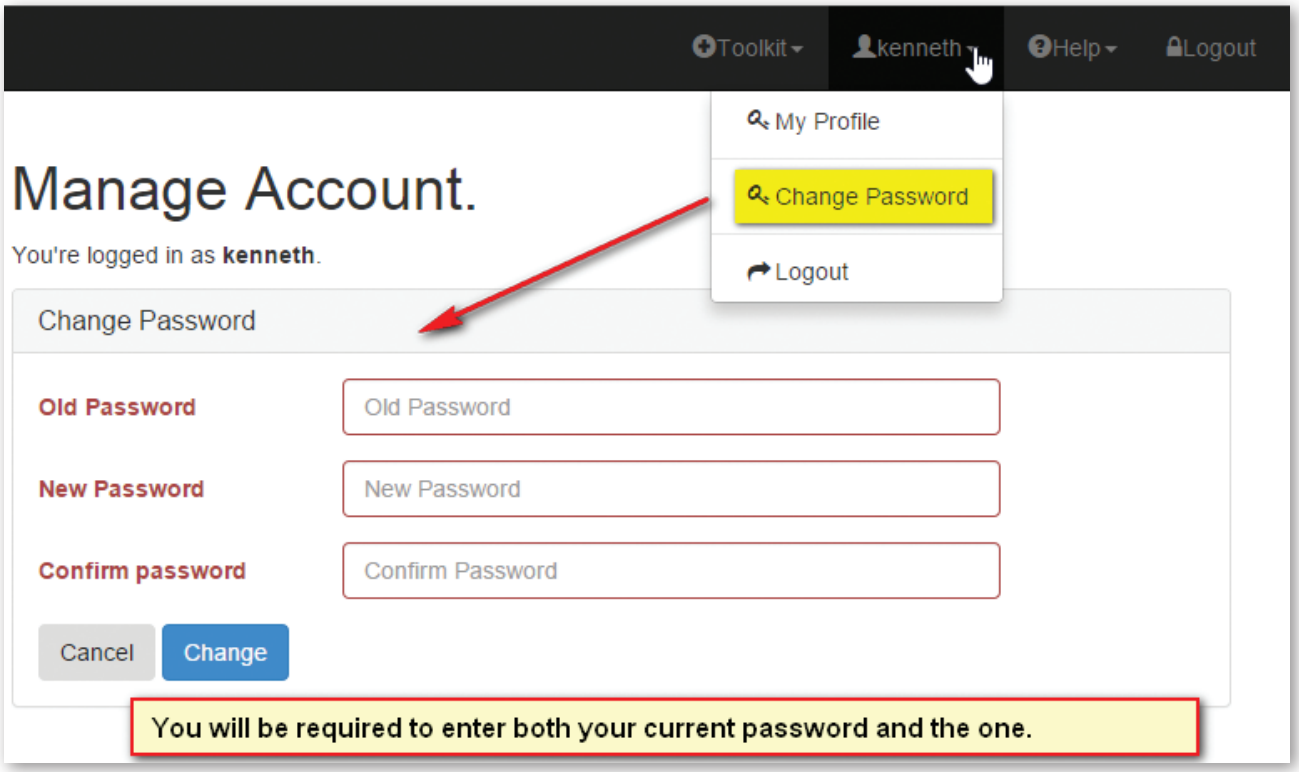


An email will be sent to your account with instructions on resetting your password. The link provided for resetting your password is active for 24 hours. Click the link, enter your new password and confirm it. Then click the green button labelled ‘Reset my password’.

After clicking ‘Reset my password’, you will get either a success message or an error if the details you provided are not valid. If successful, click on the link to go back to the login page and then log-in using new password you entered.

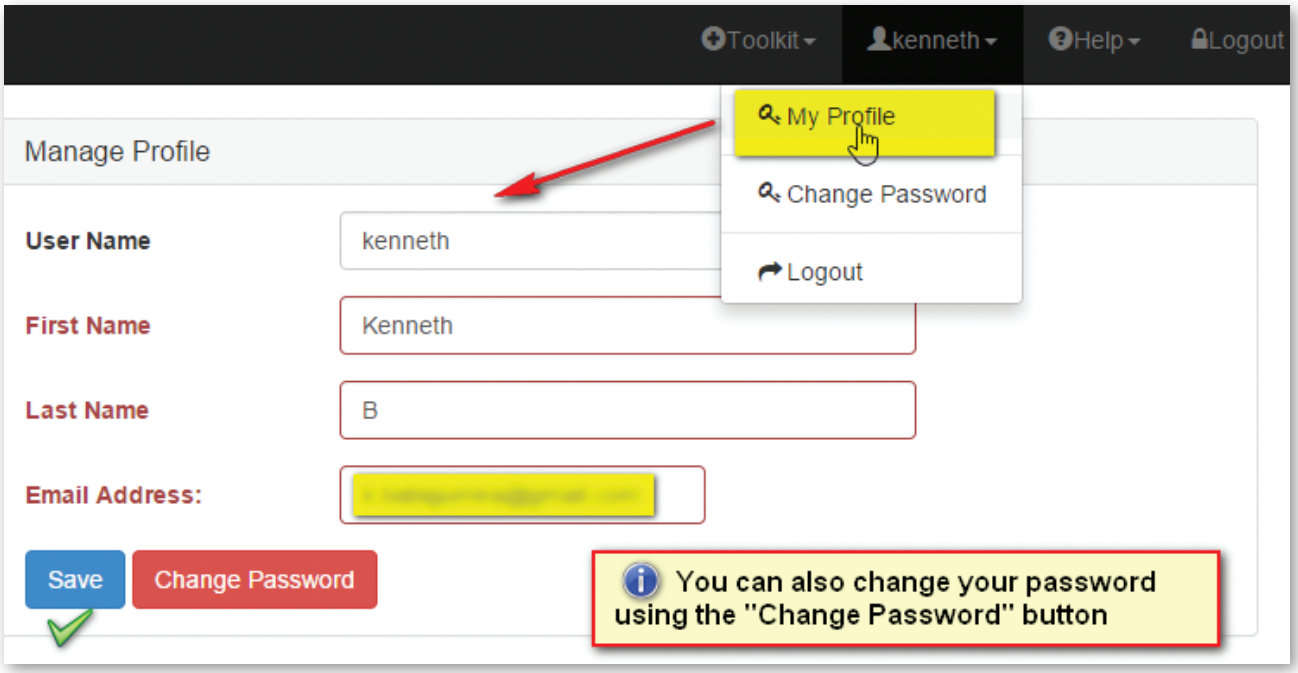
Changing your Password

You will also be able to change your password when logged in to the application.



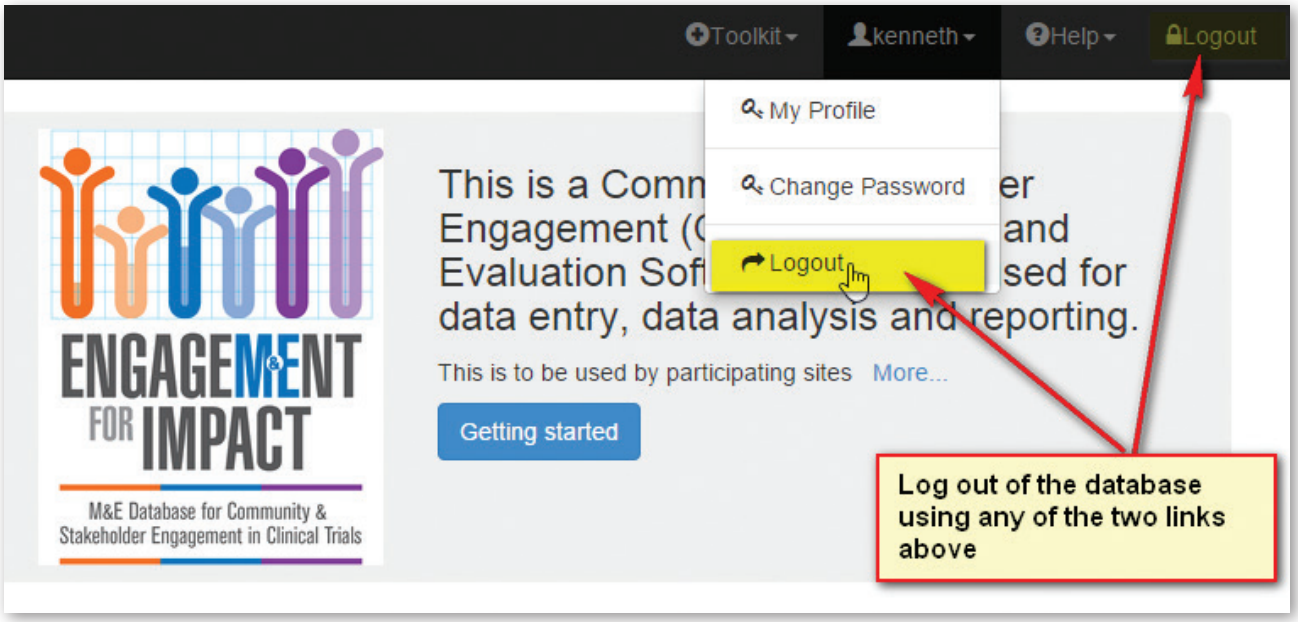
Updating your details (email address)

It is very important to keep your email address up-to-date in the database, as the instructions for resetting your email address are sent to that email address.



Logging Out

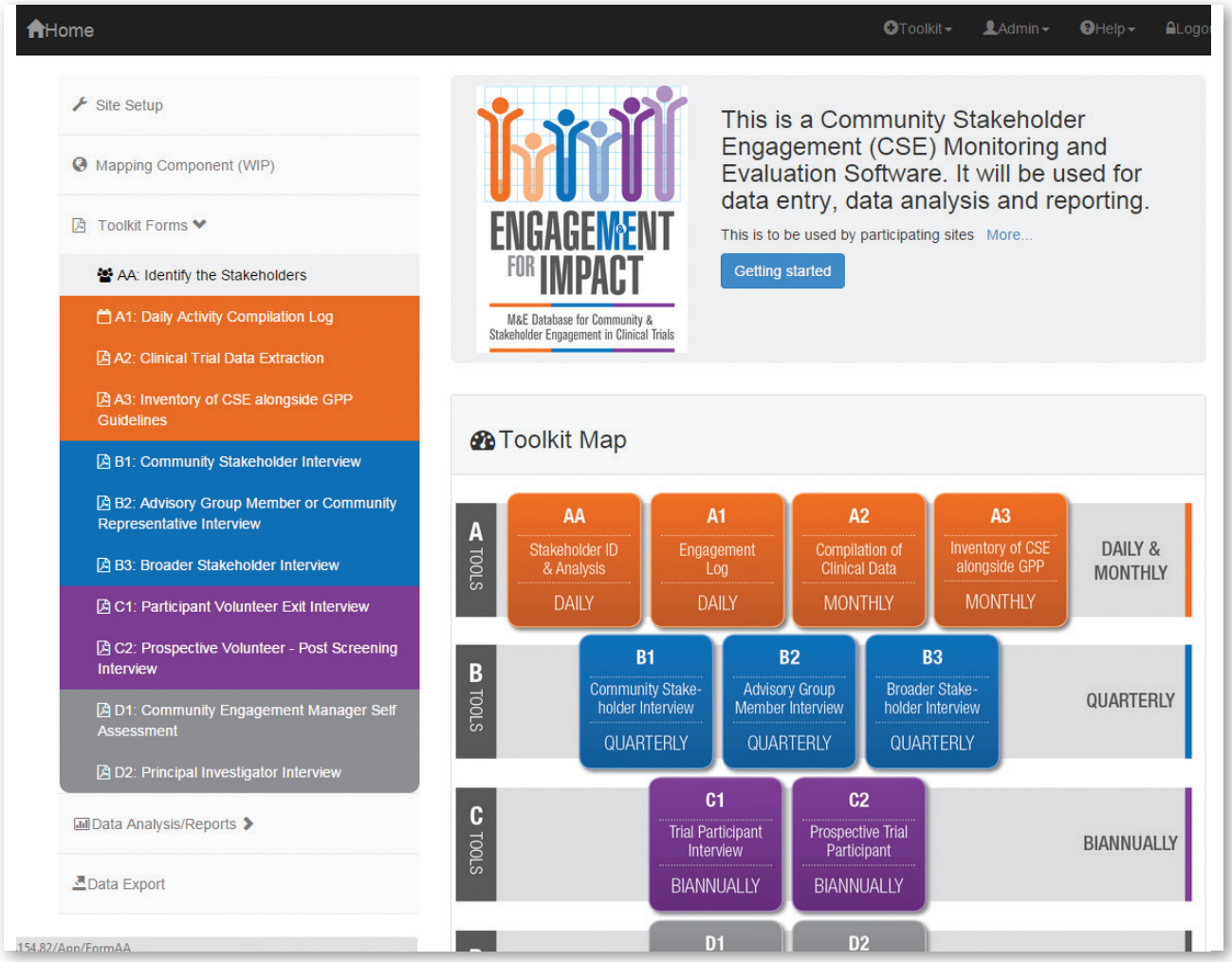
You should always log off when you are done. It is also recommended to close your browser after logging off.



HOME SCREEN

The home screen is the welcome screen you see when you login into the application.

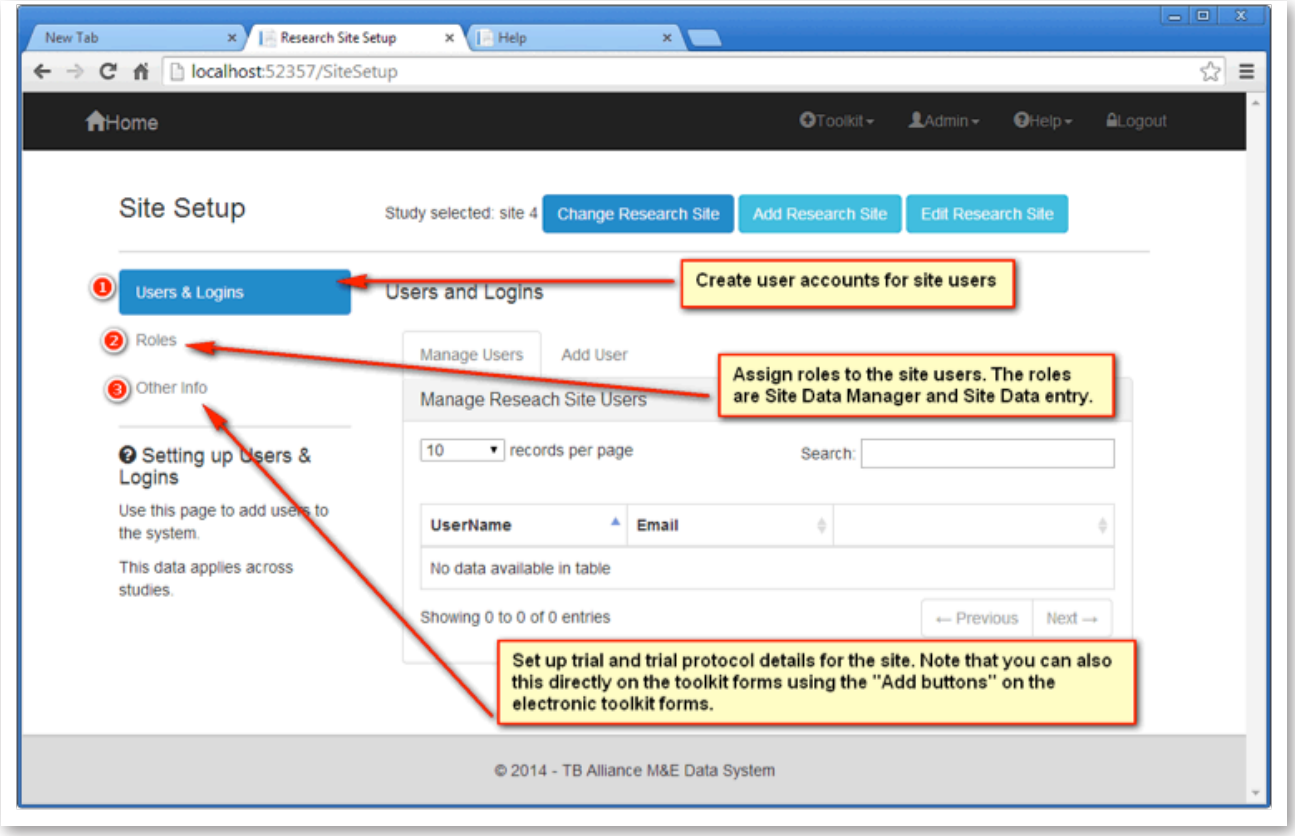
The home screen comprises of three main sections: the **top** menu, the **left** menu and the **toolkit map**.



The toolkit map shows the logical grouping of the forms with the A tools completed daily/monthly, the B forms completed quarterly, the C forms biannually or more often is possible and D forms every 6 months or at the least annually.

Site Setup

The Site Setup is used for managing users and other site details.



MANAGING SITE USERS

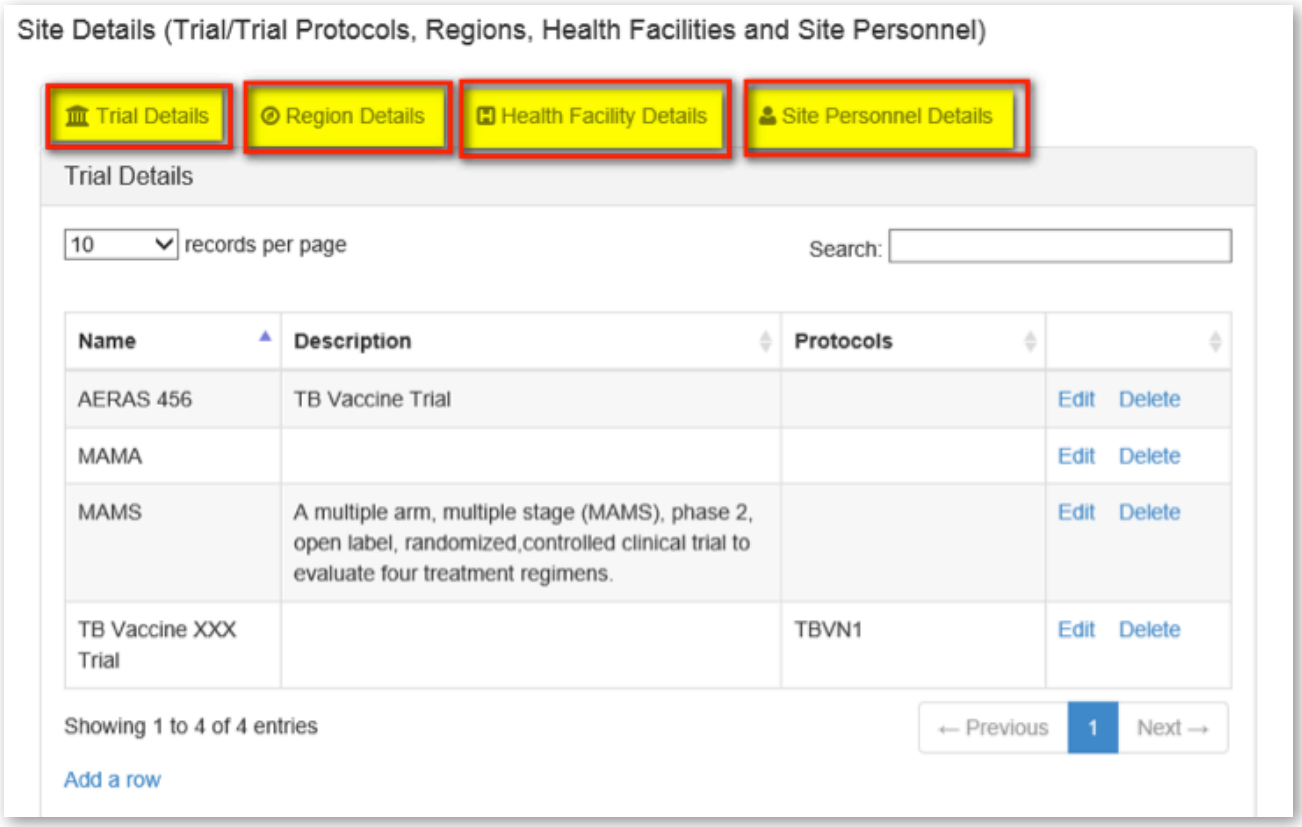
The process of creating new users and assigning roles has already been covered in great detail above; please refer to section 3.1 and 3.2.

MANAGING OTHER SITE DETAILS

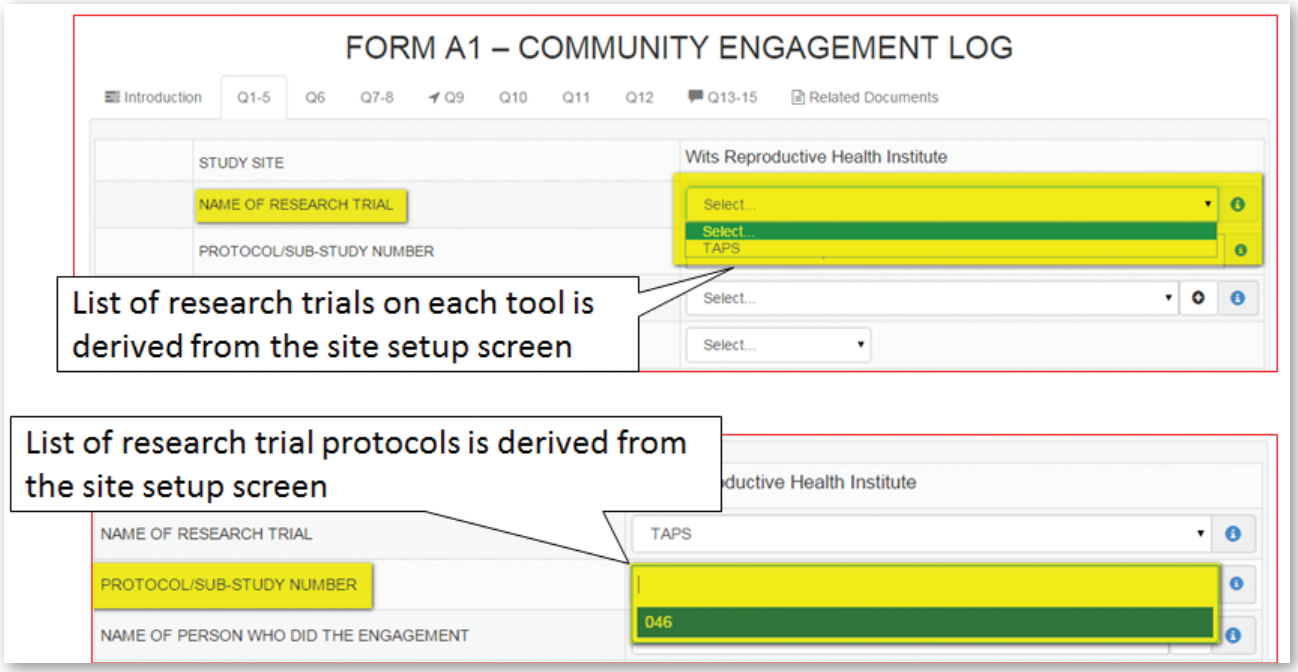
The section of the site setup is used for adding site information that is relevant for completing the forms.

- **Trial Details** - used on all the tools for populating list of research trials applicable to the site
- **Region 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 or interviewed

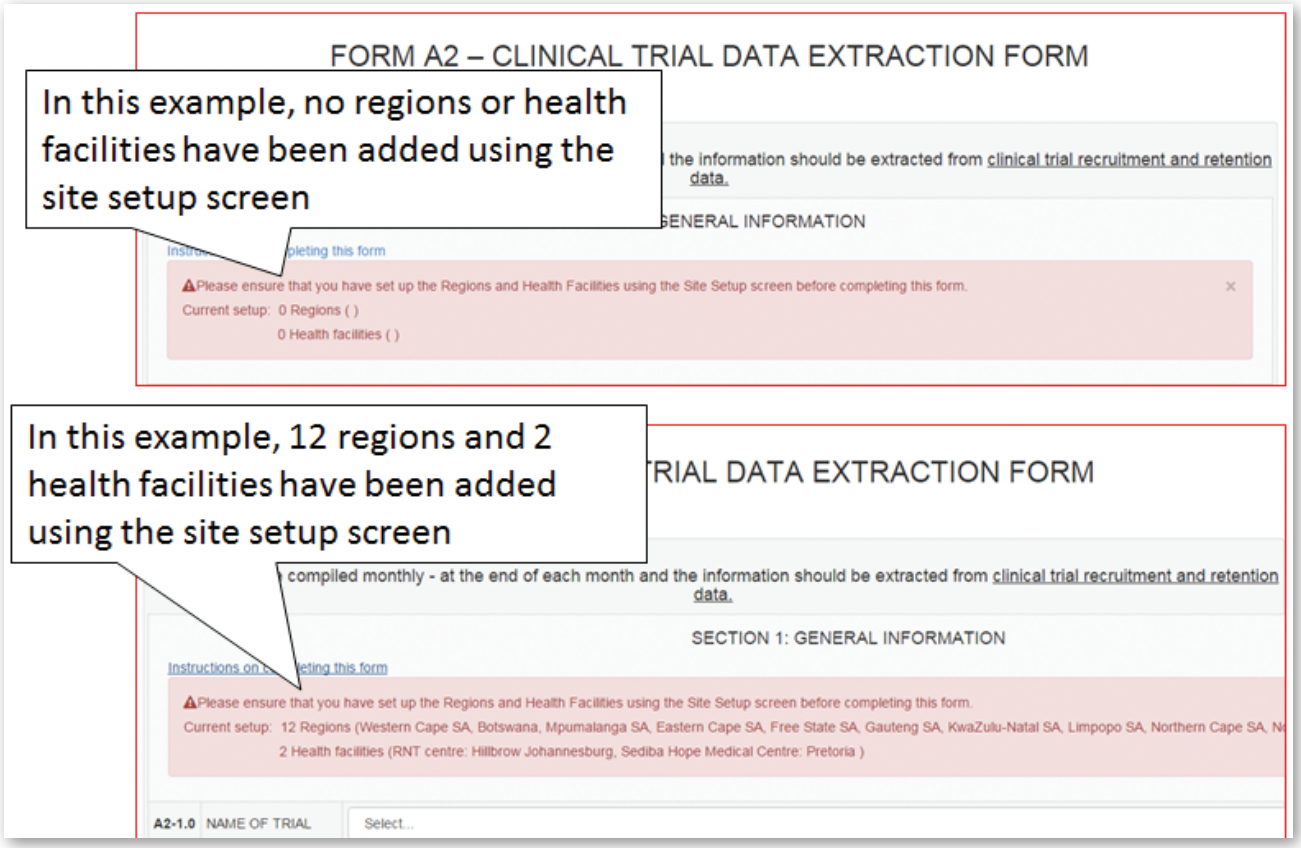
It is very important that sites enter all site details before they can start entering data using the tools.

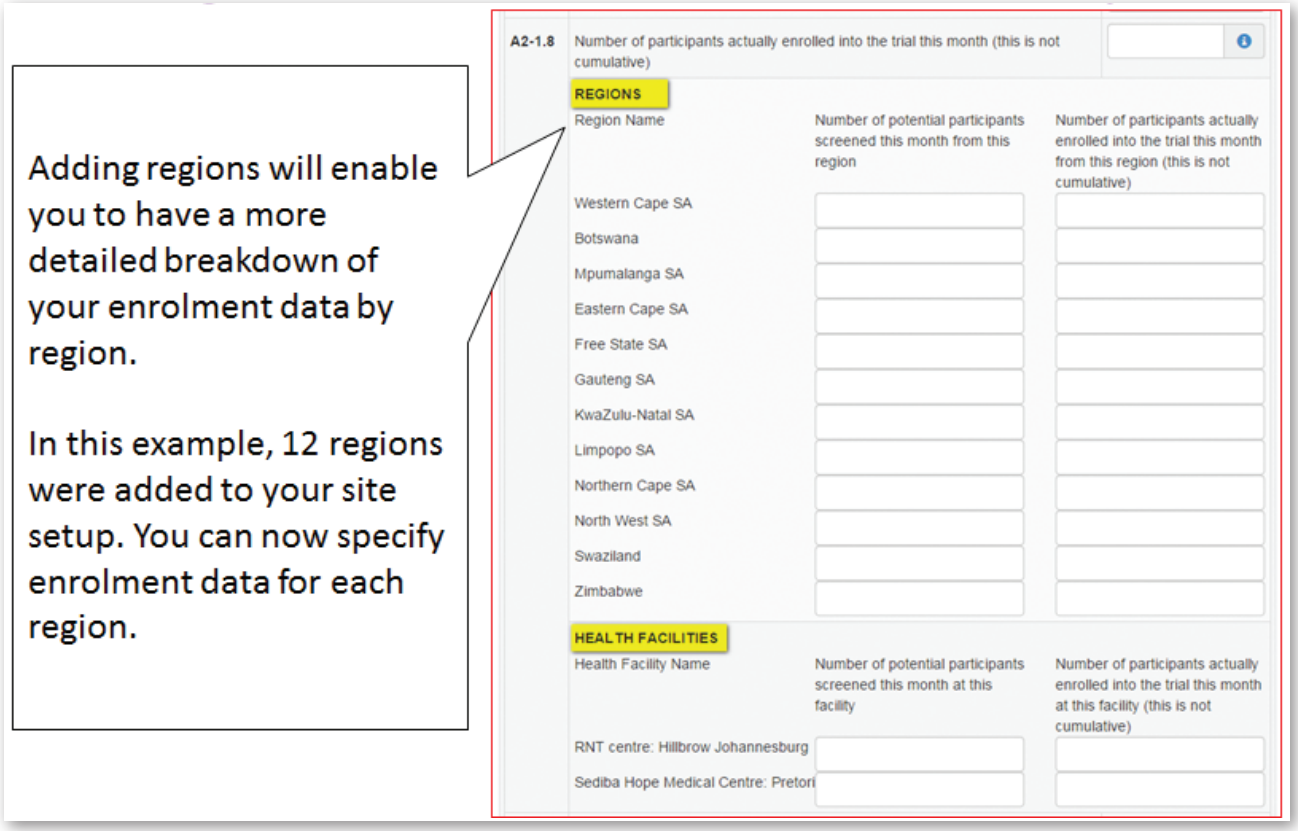


Trial Details – How are they used?

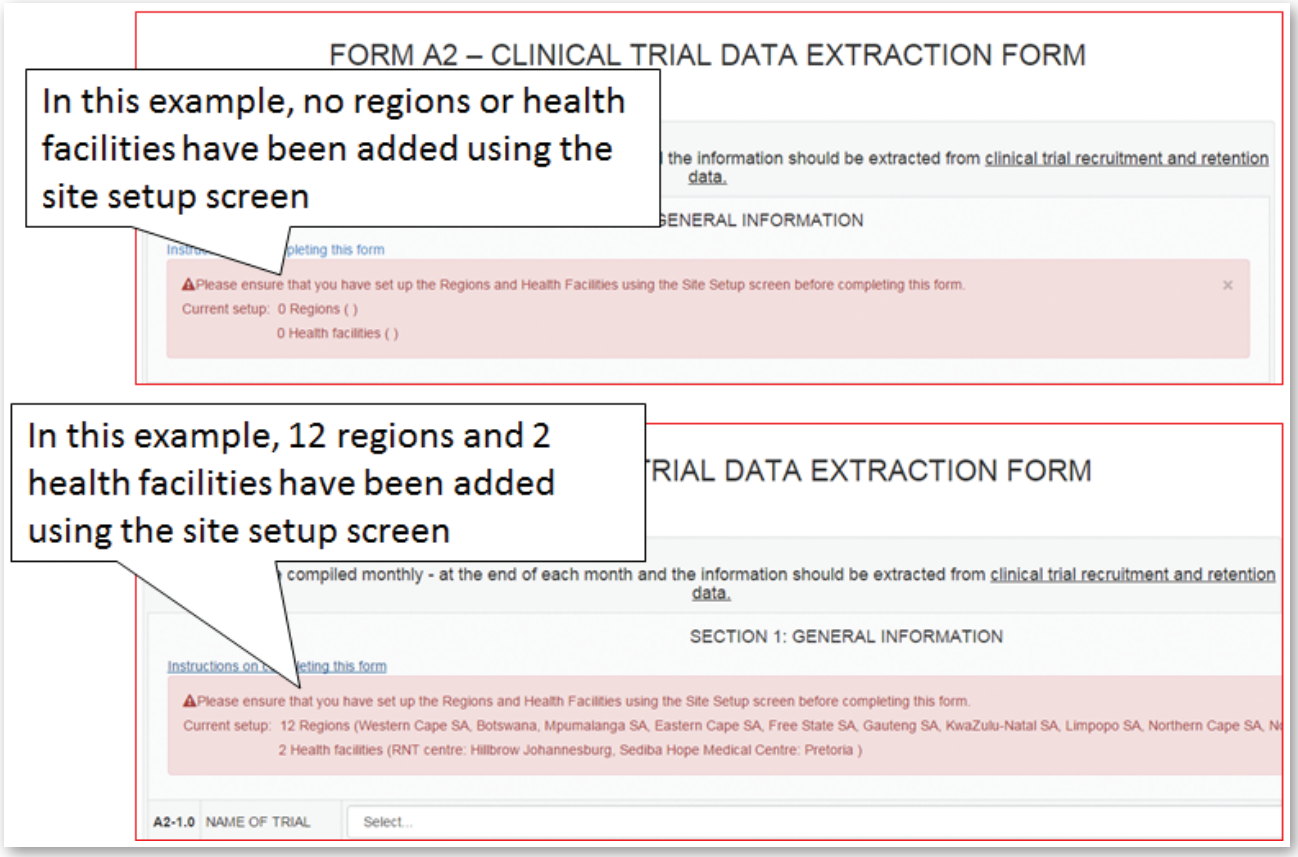


Region Details – How are they used?

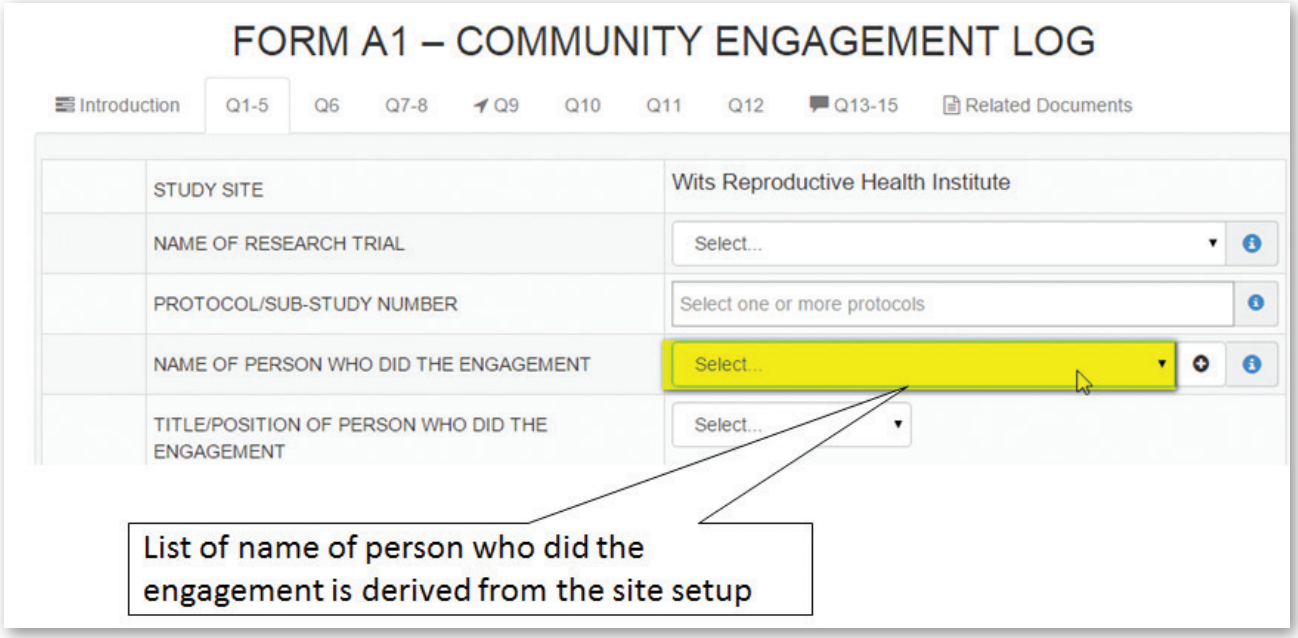




Health Facility Details – How are they used?



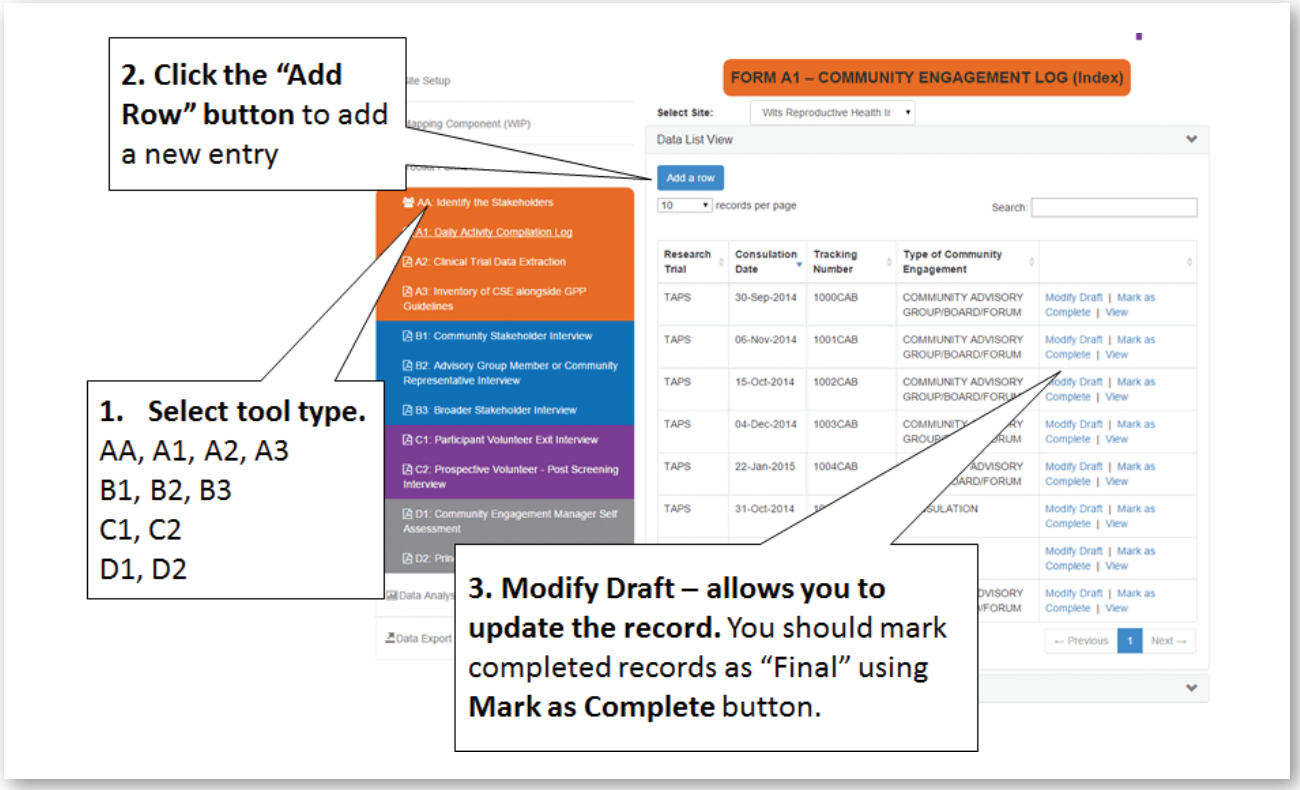
Site Personnel Details – How are they used?



ENTERING DATA AND UPLOADING DOCUMENTS

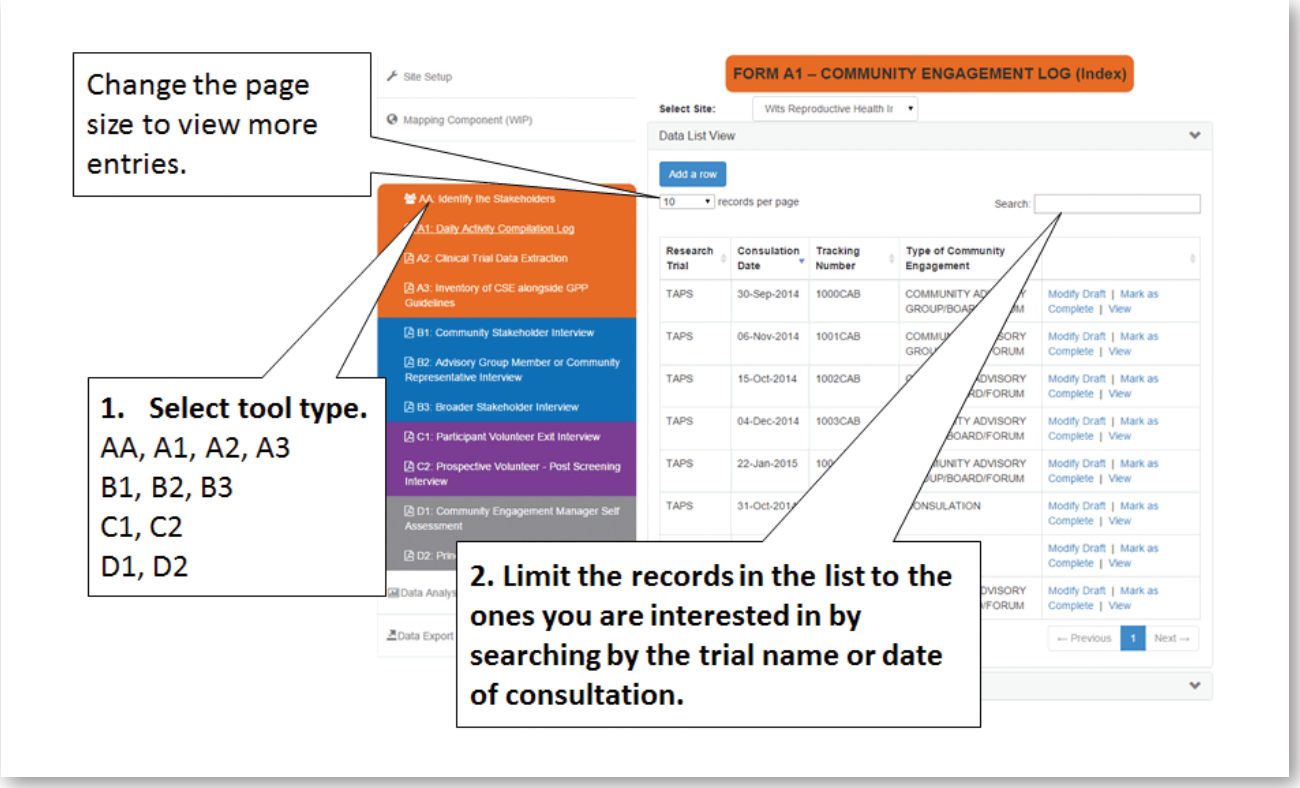
The application provides a number of tools (AA, A1, A2, A3, B1, B2, B3, C1, C2, D1 and D2) for capturing the Community and Stakeholder Engagement M&E data. To get started, click on the tool using the left hand menu, or click on the tool on the toolkit map (if on the welcome page).

Adding a new tool entry



Searching

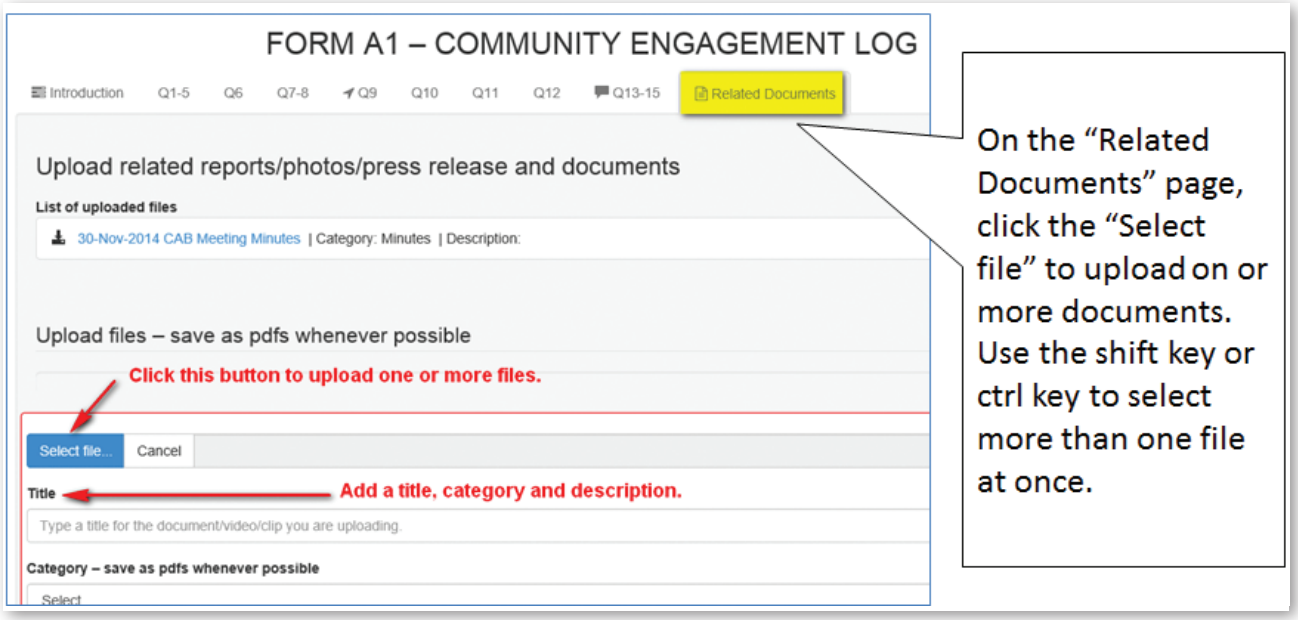
When modifying an existing record, you may find it useful to first search based on the tracking number or interview number. This will make it easier to find the entry that you would like to update.



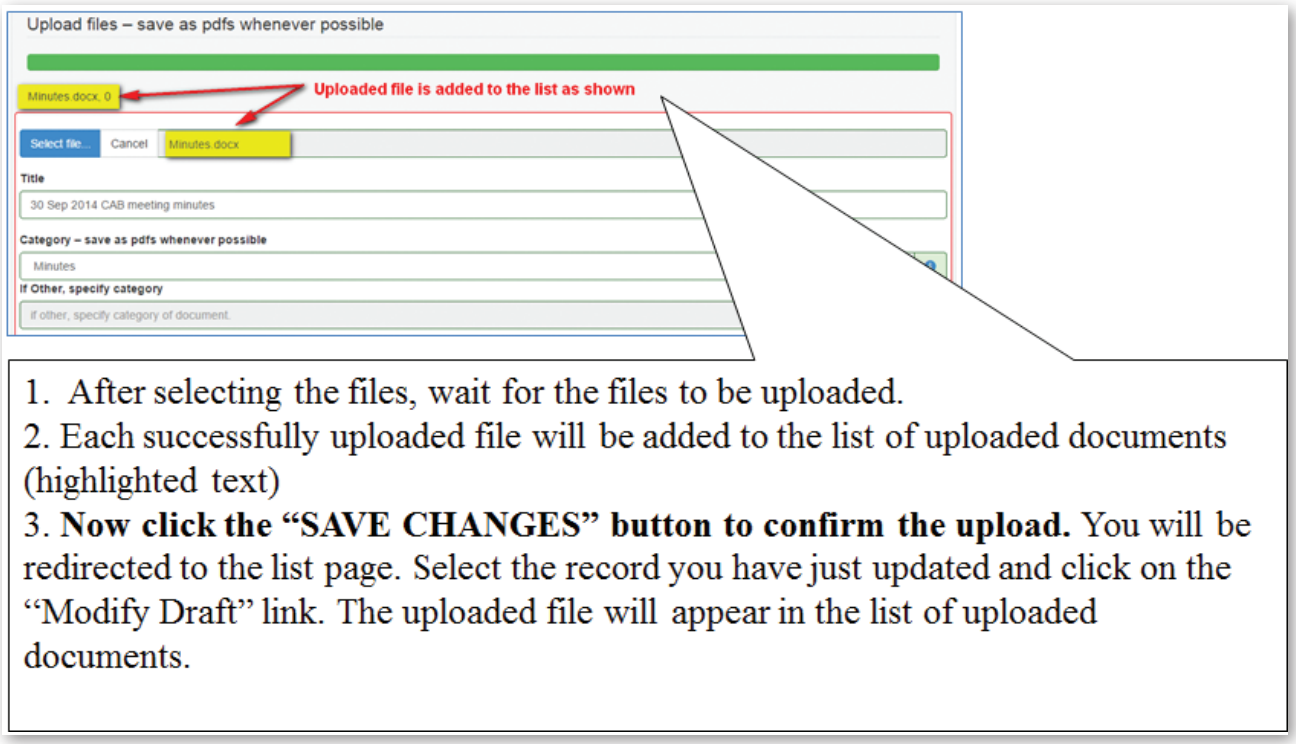
Uploading Documents

At the end of each tool, you will be able to upload related documents pertaining to the engagement, interview or stakeholder. The steps below describe the process of uploading documents.

Step 1

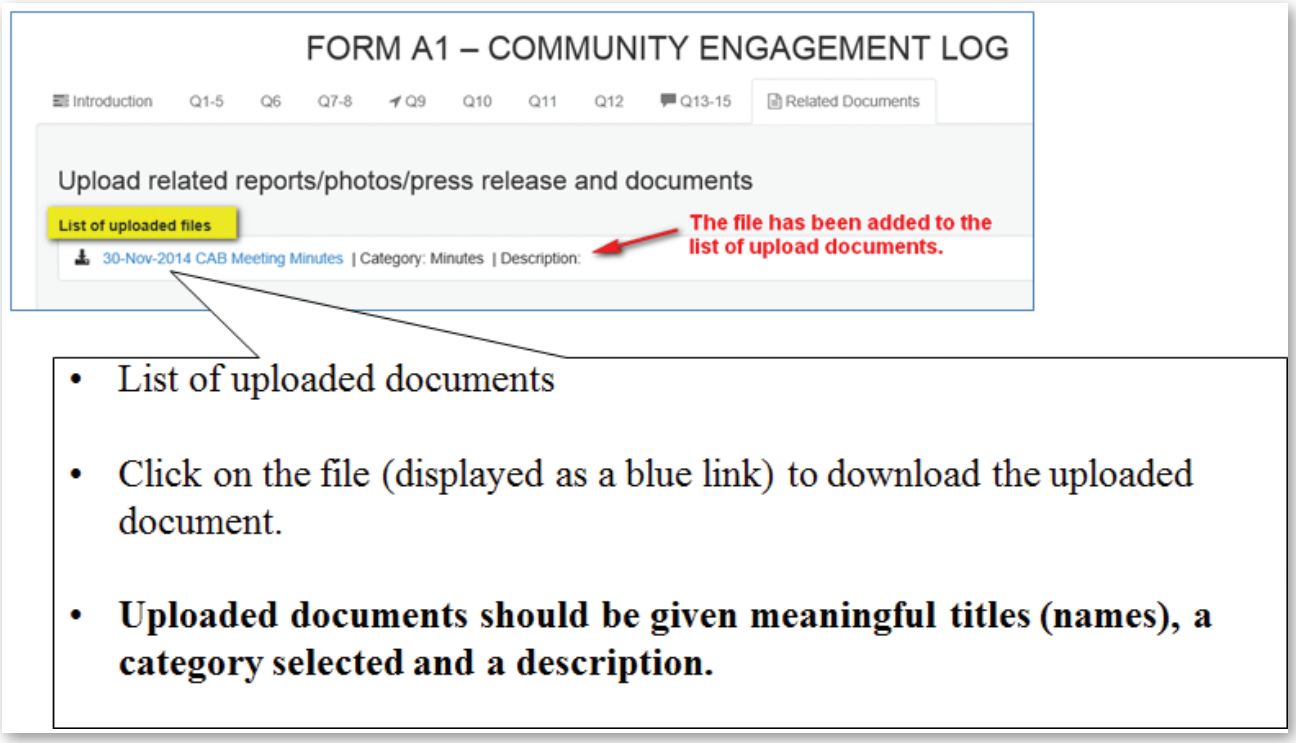


Step 2



1. After selecting the files, wait for the files to be uploaded.
2. Each successfully uploaded file will be added to the list of uploaded documents (highlighted text)
3. **Now click the "SAVE CHANGES" button to confirm the upload.** You will be redirected to the list page. Select the record you have just updated and click on the "Modify Draft" link. The uploaded file will appear in the list of uploaded documents.

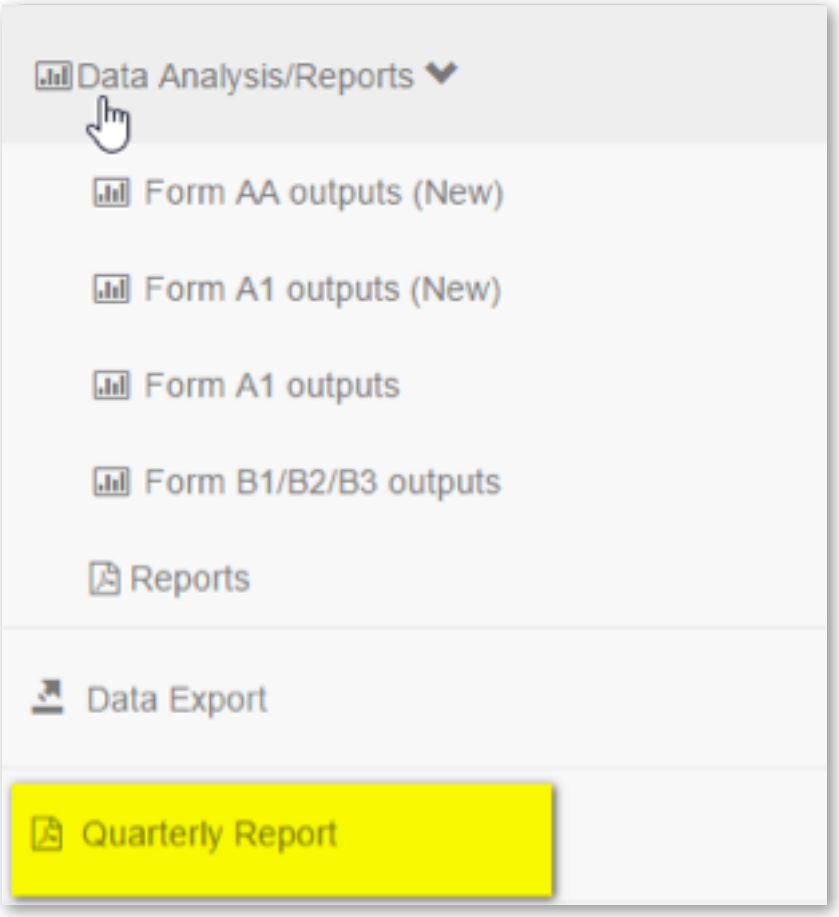
Step 3



- List of uploaded documents
- Click on the file (displayed as a blue link) to download the uploaded document.
- **Uploaded documents should be given meaningful titles (names), a category selected and a description.**

DATA ANALYSIS AND REPORTING

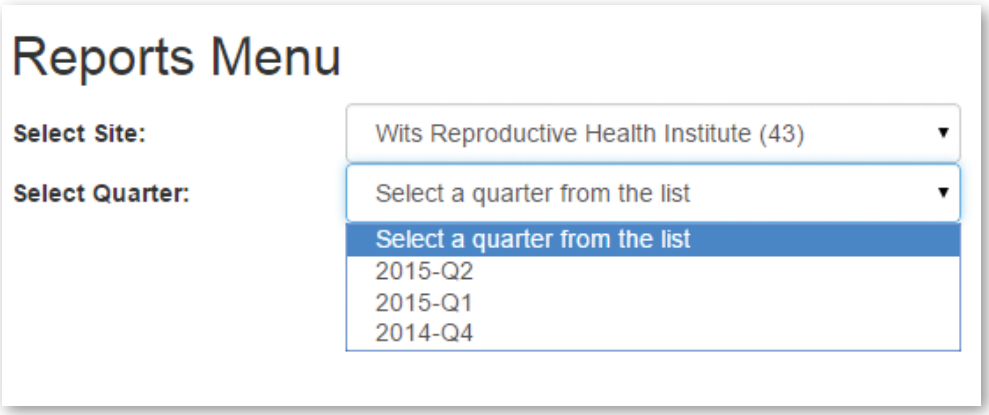
The data analysis and reporting tools can be clicking on the Data Analysis menu option).



Quarterly Report

As described elsewhere in the manual, the quarterly report provides a summary of the engagement activities for a given site for a given quarter. At this time, we are only providing reports for the A form outputs. This report can be accessed through the left hand menu; click on the Quarterly Report.

Step 1: Select the site and quarter for which you want to run the report for.



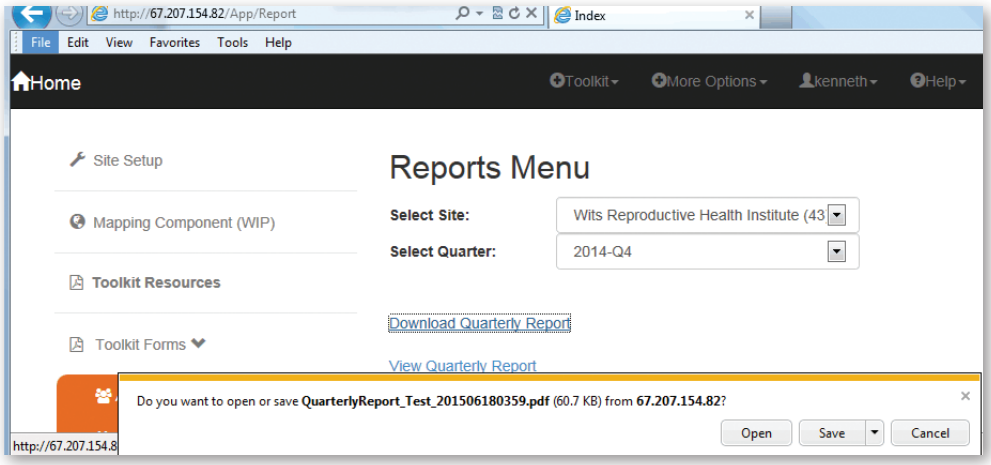
Step 2: Click on the Download Report link.

Step 3: The report (in PDF format) will be downloaded to your downloads folder. Open the report using acrobat reader.

It is worth mentioning that different browsers may behave differently when it comes to downloading files. Below are a few examples;

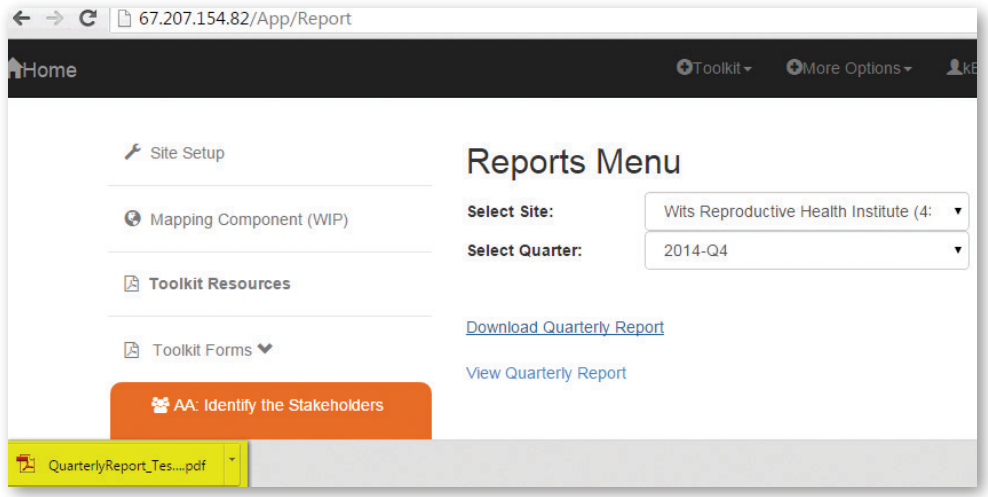
Internet Explorer

In Internet Explorer, you will be presented with a dialog or a prompt asking you if you want to save the file.



Chrome

Conversely, when using Chrome, the file is automatically downloaded without prompting you to confirm. Please check your "downloads" folder in case you cannot see the downloaded file.

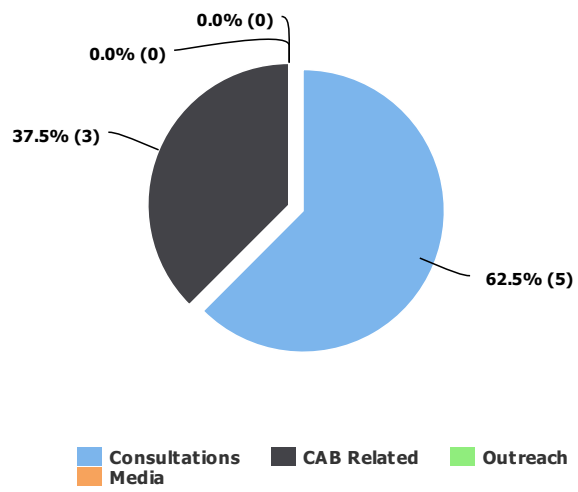


Step 4: Open the report using any PDF reader e.g. Adobe Acrobat Reader.

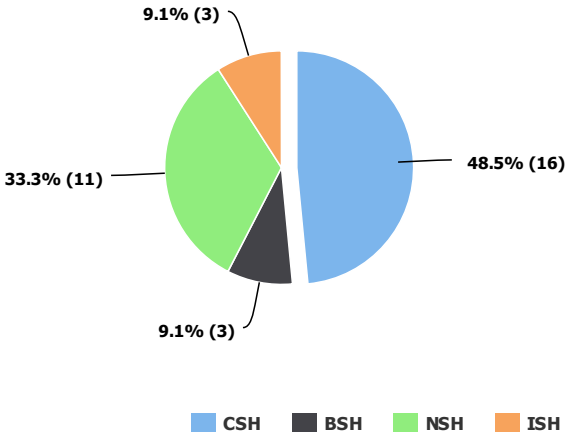
Site Quarterly Report: Q4/2014

Selected Site: <Site Name>

1. Type of Engagements - source A1



2. Category of Stakeholders Engaged/Updated - source AA



3. List of all Stakeholders - those engaged and not engaged

Specific Stakeholder Categories engaged	#
ADVOCATE or ACTIVIST	9
COMMUNITY BASED ORGANISATION STAFF	7
LOCAL LEADERSHIP – GOVERNMENT OR ELECTED	4
OTHER	4
LOCAL FAITH BASED LEADER	3
LOCAL HEALTH FACILITY STAFF	3
DONOR	1
INTERNATIONAL ADVISORY BOARD	1
LEGAL EXPERT	1
COMMUNITY HEALTH WORKER	0
INDIVIDUAL RESIDENT IN THE TARGET AREA	0
LOCAL BUSINESS	0
LOCAL BUSINESS OWNERS	0
LOCAL LEADERSHIP – TRADITIONAL	0
LOCAL POLICY MAKERS	0
MEDIA /JOURNALISTS	0
NGO STAFF	0
SCHOOL TEACHER	0
SPONSOR/COORDINATOR	0
TRADITIONAL HEALER	0
YOUTH WORKER	0
Total	33

Conclusions and Next Steps

This is the first attempt to capture CSE data in a formal way. The developers of this toolkit welcome your participation. The database will continue to be worked on and developed over time. As the system is populated with data, opportunities to strengthen the tools further and refine the analysis will arise. Without data in the system is it difficult to develop the toolkit further and to be able to draw any correlations between CSE work and indicators of success. TB Alliance and AVAC will be working on specific studies that look at the data in new and interesting ways, to shed light on CSE efforts in a variety of contexts. The developers of this toolkit welcome constructive feedback from users, using the formal feedback mechanisms on the database.

Appendix 1

Tools to Help you Plan

Develop a Programme Mind Map

Purpose: To document your overall Community and Stakeholder Engagement Programme as it currently exists.

Requirements: A piece of paper on which to draw a mind map.

Instructions:

1. Begin mapping the project system by writing down various words that relate to your programme.

For example;

- The target groups or constituencies, regions involved.
- Identify social characteristics that could affect the programme, for example social demographics.
- Identify the issues of the trial that could concern stakeholders and need to be addressed.
- The diversity of citizens or stakeholder groups or groupings.

2. Connect the related words or concepts with a line and use different colours to group your ideas.
3. Circulate your mind map for comment and enhance it until all the elements you and your team feel are important feature in the mind map.

Develop a Stakeholder List

Purpose: To develop an evolving list of all relevant stakeholders to your trial including those in all categories (see Figure 1 and 2).

Requirements: A team meeting dedicated to developing a list and updating it quarterly.

Instructions:

1. Begin by thinking about the obvious stakeholder who who influence your program.
   a) Are there any subsets of stakeholders that should be distinguished?
   b) Groups of stakeholders are not always homogenous.
   c) Who is often excluded from engagement processes? This could include young people, seniors, people with disabilities, people who don't speak the main language?
   d) Who within the various levels and departments of government/NGOs/industry need to be involved?
   e) Are there other people or groups that have been overlooked in the past?
2. Think about what the different stakeholders want to possibly get out of the engagement.
3. Then think about what you as a program needs from these stakeholders.
4. Note – that a lot of this will become clearer as you implement the tools in the toolkit, however, for form AA you need to begin listing your stakeholders and assessing different factors of their engagement.
5. Be inclusive and far reaching in your listing – remembering that it is the diversity of relevant stakeholders that will enable the CSE program to register the different or conflicting values or needs. Ultimately, the toolkit will enable you to monitor the range of opinions and experiences that will offer valuable insight into the design or adjustments to your engagement plan.

If your stakeholder list is weak and top or bottom heavy or the composition of your advisory mechanisms is random and not thought out, you will need to:

- Go on fact finding missions or activities.
- Build new coalitions.
- Strengthen local organisations so they can work with you.
- Partner with government departments and develop a common vision and shared goals.
- Ensure democratic and transparent representation on your committees.
- Create opportunities for leadership.
- Increase public awareness.

Review, Reflect, Report

One common trap in community and stakeholder engagement is to apply a method before having clearly defined the purpose of the engagement or having clearly justified the stakeholders who are engaged. This can be avoided by ensuring that your Review – Reflect – Report between Planning and Implementing and between Implementing and Evaluating. This means that you will be sufficiently prepared to embark on the next phase.

The self assessement tool D1 it is valuable for the PI and CSE staff and it should help you to review – reflect – report. In addition to the self assessment you can ask yourself these questions:

- What stands out to me now with regards to the stakeholders and your program in general?
- What concerns me about your program?
- What excites me about your program?
- What new insights have I gained through the process so far?
- Do our objectives and outputs need to be refined? If so how?

Appendix 2

Planning for a CSE Evaluation Checklist

The following checklist summarizes the major points to cover when developing a monitoring and evaluation plan for community and stakeholder engagement (CSE). For each question below, check all the items that apply.

1. You understand that you should have an M&E plan because:

- It guides you through each step of the M&E process
- It helps you decide what sort of information you and your stakeholders really need
- It keeps you from wasting time gathering information that isn't needed
- It helps you identify the best possible methods and strategies for getting the needed information
- It helps you come up with a reasonable and realistic timeline for each phase of your M&E
- It will help you improve your CSE initiative

2. You understand who your program's stakeholders are:

- Community groups
- Community advisory groups
- Sponsors, grantmakers and funders
- Researchers and research center management

3. You have taken into consideration:

- What your audience and various stakeholder types want to know from the M&E results
- What decisions stakeholders need to make
- How stakeholders would use the data to inform their decisions

4. When considering how to balance costs and benefits, you have asked yourself the following questions:

- What do you need to know?
- What is required of the community?
- What is required of funders and research trial management?

5. You understand these four main steps to developing an M&E plan:

- Step 1: Clarify the CSE program objectives and goals
- Step 2: Develop M&E questions
- Step 3: Develop M&E methods
- Step 4: Set up a timeline for each phase

Step 1 - Clarify the CSE program objectives and goals:

- Make a table of CSE program components and elements

Step 2 - Develop the M&E questions:

- You understand the four main categories of evaluation questions:
  - Planning and implementation issues
  - Assessing attainment of objectives
  - Impact on participants
  - Impact on the community
- You have considered the best possible methods to answer these evaluation questions

Step 3 - Develop methods to best address your M&E questions:

- You understand how to use the monitoring and feedback system's three main elements (process measures, outcome measures, and observational system).
- You understand how to use member surveys about the initiative (member survey of goals, member survey of process, and member survey of outcomes).
- You understand how to use the goal attainment report.
- You understand how to use behavioral surveys.
- You understand how to use interviews with key participants.
- You know how to use community-level indicators of impact.

Step 4 - Setting up a timeline for your M&E activities:

- You understand that you should begin right now, at the beginning of your program.
- You have outlined questions for each stage of development of your CSE program.
- You have completed a table listing: key M&E questions, type of M&E measures to be used to answer them, type of data collection, and experimental design.
- You have determined when you feel it is appropriate to provide feedback and reports.
- You will also provide periodic feedback and reports throughout the duration of the project or initiative.
- You will provide feedback and reports at the end of the evaluation.
- You have decided when the evaluation will end.
- You have mapped out a proposed evaluation timeline.

6. You know how you plan to present your findings:

- You will make a report that you can share with everyone involved, which includes effects expected by shareholders, differences in the behaviors of key individuals, and differences in conditions in the community.
- You have decided whether to also include specific tools (i.e. brief reports summarizing data), annual reports, quarterly or monthly reports from the monitoring system, and anything else that is mutually agreed upon between the organization and the evaluation team.

7. You know your Evaluation Standards:

- You have decided what standards you will use to ensure an accurate and useful evaluation.

Appendix 3

Developing a CSE Monitoring and Evaluation Plan

Example Template

The template below is intended to help structure your CSE monitoring and evaluation plan.

Key Questions	What do we want to know? (Monitoring Question)	How will we know it? (Indicator)	Where will the data come from? (Data Source/ Method)	Who will capture the data? (Responsibility)	When will data be captured? (Timeframe)	Estimated cost? (Budget)	Who will be involved? (Stakeholder, Participants	How will it be reported? (Output)	When will the evaluation occur? (Timeframe)
Ex. Impact of community advisory board	Levels of Participation on community advisory board	Number of members and attendance	List of members and attendance logs	CSE Team Member	Monthly	Minimal	Community advisory board members	Quarterly reports	At discretion of team
Ex. Value of the CAB as an engagement mechanism	Awareness of extent of role as CAB member	Key informant interviews/ questionnaire	Database – B2 Outputs	CSE Team Member	Over the course of a Quarter (2 per month for example)	Minimal	Community advisory board members	Quarterly reports	At discretion of team

Appendix 4

Key Informant Interviews Checklist

1. Scheduling

- Plan your key informant interviews into you M&E plan and your work plan.
- Make appointments personally.
- Choose the time and location carefully. Remember entering data online can save time.
- Give advance notice of the discussion topics.
- Confirm appointments shortly beforehand.
- Promptly notify an interviewee if the appointment must be postponed or cancelled.

2. Opening tips

- Be punctual.
- Explain the purpose of the interview and ask for the interviewee's consent to proceed.
- Explain what measures you will take to maintain the confidentiality of the data.
- Be prepared to respond to the interviewee's questions.

3. Asking questions

- Read the questions as they are written in the questionnaires and use probes to stimulate discussion and obtain more information, without giving weight to options
- Common probes include:
  - Please tell me more about that.
  - I'm not sure I understand, could you explain that again?
  - Can you tell me what you mean by that?
  - What would be an example of that?
  - Can you tell me something else about that?
  - Is there anything else?

4. Active listening

- Provide feedback, verbal and non-verbal, to the interviewee to ensure they know that the information is important.
- Overcome barriers to active listening.
  - Suppress disruptive habits (i.e. finger drumming, do not have any other work open on your computer while conducting the interview, email etc. Keep your phone off.)
  - Be aware of your biases and how they might be filtering the interviewee's message.
  - Don't jump to conclusions; hear out the interviewee.
  - Don't interrupt or debate.
  - Don't assume what the interviewee meant: request clarification, especially of key words or ideas.
  - Don't monopolize the conversation.
- Use verbal active listening techniques.
  - Make reassuring comments and sounds (i.e. "uh huh," I see," that's interesting").
  - Repeat back for the interviewee a statement they just finished making.
  - Probe the interviewee's initial responses in order to expand or clarify the information given.
  - On key points, restate in your own words what the interviewee has just said.
  - Summarize the main points of the discussion.

- Use non-verbal active listening techniques.
  - Maintain eye contact and keep your body in attention (i.e. not slumped, leaning forward).
  - Use occasional affirmative nods to show you understand and are interested (but don't do this too often or it will seem like you are approving, not just affirming the responses).
  - Take notes, as appropriate. You can also signal to the interviewee when they are getting off the subject by stopping taking notes, or even putting your pen down.
  - Use silence (i.e. an expectant pause) to indicate to the interviewee that more is expected. Sometimes this is referred to as a "silent probe".

5. Closing the interview

- Express appreciation for the interviewee's time.
- Describe the next steps in the inquiry and how the interviewee might be involved (if at all).
- You should not pay participants for attending your M&E interviews – a cup of tea should suffice.

Appendix 5

The following sheets act as a guideline for all things related to your data: collection, quality and subsequent use. This is also a communication tool so that a wider body of people understand some of the critical components of these sheets. Every indicator (information collected) should have some form of indicator information sheet.

Note: Not every indicator requires a complete set of information filled out in the indicator information sheets. You will find that for INPUT and OUTPUT data, the information and detail you will need to manage is far less.

Rational for Selected Indicators

Each of the indicators developed by the working group for this toolkit worked to satisfy the following conditions:

Simplicity	There is a general agreement that indicators do not describe the whole situation – they point to the direction of change rather than describe the change itself. Indicators simplify system processes so that they are easily accessible to a wider audience.
Proxy	Indicators are often proxies for changes taking place with complex systems. Proxy indicators are useful in two cases. When it is known that a specific indicator is a proxy for another one (e.g. published manuscripts are good proxies for scientific productivity), or when the issue to be monitored and evaluated through the use of indicators is too complex and abstract (e.g. changes in the development and achievement of research staff). In the latter case, the issue to be measured has to be broken down and indicators developed for each new category.
Measurement of change	Indicators are designed to measure changes. A number that conveys information but does not give information in relation to changes is a merely a statistic. Indicators are intended to provide information about change.
Direction	Indicators are useful for pointing the direction of change, whether this is positive or negative, whether the situation is improving or worsening.
Measurement of change over time	Indicators are designed to measure change over time.
Numerical or quantified qualitative data	Indicators are usually numerical. They can contain qualitative data, but it is usually quantified. When the numerical data is not based on numbers (e.g. when a number is assigned for each qualitative category), it is important to remember that these numbers cannot be treated as “normal” numbers. They can only be used with special statistical techniques.
Comparability to a baseline or norm	Indicators usually convey information that is compared to a baseline (i.e. the situation prior to the beginning of the program or the implementation of a policy, or to a norm).
Participation	Qualitative indicators can boost community stakeholders’ participation in the evaluation process given that their opinion would be required in order to produce the indicator. The extensive literature on participation has shown the benefits of using such an approach and it is therefore in the interest of program management to involve the different stakeholders from the very beginning of the program development cycle.

Appendix 6

Indicator Information Sheet Template

Indicator Protocol Reference Sheet Number: I
Name of Indicator: Simply put as possible, insert the name of this indicator.
Result to Which Indicator Responds: The specific result that this indicator corresponds to.
Level of Indicator: Does this indicator respond to an INPUT, OUTPUT, OUTCOME, or IMPACT level result?
Description
Definition: Unpack as much as possible the specific definition of this indicator. Spell out nearly every word so that all who come across use of this indicator have the same complete specific understanding of the intention of what this indicator is intended to measure.
Unit of Measurement and Desegregations: In what unit will this indicator be captured and are there any disaggregation (male / female, age, etc.)
Plan for Data Acquisition
Data Collection Method: When was this data collected?
Data Source: Where was the data collected? (Where was the data borne?)
Frequency and Timing of Data Acquisition: How often are the data collected?
Individual Responsible: Who is responsible (what position) is responsible for collected the data?
Location of Data Storage: Where, specifically (which office, which drawer) are the raw data stored?
Data Quality Issues
Known Data Limitations and Significance: Are there identified threats to the quality of this data? Consider: Validity / Reliability / Integrity / Precision / Timeliness
Actions Taken or Planned to Address this Limitation: What are some steps you have taken to manage the possible threats to data quality.
Internal Data Quality Assessments: Have you performed your own Data Quality Assessment?
Plan for Data Analysis, Review & Reporting
Data Analysis: Do the data from this indicator require a specific plan for analysis? If yes, please describe. If not, please delete this section for this indicator.
Review of Data: Do the data from this indicator require a specific plan for review (internal / external) before dissemination? If not, please delete this section.
Using Data: Where must the data from this indicator go? Funders? Internal / external decision makers. Who needs this information to make decisions?
This sheet was last updated on:
Other notes / comments:

Appendix 7

Target Setting Worksheet

Indicator:	Year One			Year Two			Year Three			Notes:
	Baseline	Target	Actual	Baseline	Target	Actual	Baseline	Target	Actual	

Appendix 8

Costing Template for M&E

Key M&E Activities (M&E Plan Development, Toolkit A Set, B St, C Set, D set, Reporting)	**Travel CSE team member**	**Travel Key Informant**	**Refreshments for respondents in case of key informant interviews**	**Internet Access Costs/ Phone Calls**	**Other Direct Costs**	**Activity Subtotal**
M&E Activity 1						
M&E Activity 2						
Totals						

Appendix 9

Evaluation of Indicator Value

The following table will support you in evaluating the value of your chosen list of indicators.

INDICATORS	Measurable	Measured within timeframe and resources	Clear and easily understood	Accurately and reliably measure what they are supposed to measure	Issues are raised as a result of collecting data on the indicator
Proportion and type of community members/ stakeholders consulted					
Number and frequency of community members/ stakeholders meetings held to review					
Proportion of contributing community members/ stakeholders who agree their input was informed and meaningful					
Number and type of community member/ stakeholder suggestions incorporated					
Perceived satisfaction of community members/stakeholders with input process					
Level of engagement of community members/stakeholders during periods of input					
Perceived value added of community member/stakeholder input on the part of research staff					
Percentage and reasons of drop out of stakeholders working in advisory capacity					
Proportion of dissatisfactions of community members/stakeholders during input					
Level of understanding demonstrated by consenting or dissenting trial participants					
Amount of time allocated for community member/stakeholder input					
Number and type of advisory mechanisms in place for research site					
Number of different sectors represented on research site's primary advisory mechanism (e.g. CAB)					
Number of stakeholders who report ability to operate independently from the research site					
Frequency of stakeholder meetings with research team					

INDICATORS	Measurable	Measured within timeframe and resources	Clear and easily understood	Accurately and reliably measure what they are supposed to measure	Issues are raised as a result of collecting data on the indicator
Proportion of resource devoted to type of advisory mechanisms in place for research site					
Appropriateness of mechanism chosen for range of community members/stakeholders					
Level of buy-in from community members/ stakeholders					
Number and type of community-driven engagement exercises					
Level of understanding of community members/stakeholders of the purpose and objectives of CSE mechanisms					
Perceived satisfaction of community members /stakeholders with the functioning of CSE mechanisms					
Perceived quality of plans developed					
Amount of time allocated for development of plans					
Reach and impact of communications plans					
Percent of expected participants enrolled on protocols during specified period					
Percent of expected participants retained on protocols during specified period					
Percent of trial participants that reflect demographics of the epidemic in respective communities					
Percent of patients lost to follow-up					
Percent of records reviewed without consent or enrollment violations					
Percent of records reviewed without missed SAEs					
Proportion and type of community members/ stakeholders consulted					
Number and type of community member/ stakeholder suggestions incorporated					

INDICATORS	Measurable	Measured within timeframe and resources	Clear and easily understood	Accurately and reliably measure what they are supposed to measure	Issues are raised as a result of collecting data on the indicator
Proportion of resource devoted to type of advisory mechanisms in place for research site					
Appropriateness of mechanism chosen for range of community members/stakeholders					
Level of buy-in from community members/ stakeholders					
Number and type of community-driven engagement exercises					
Level of understanding of community members/stakeholders of the purpose and objectives of CSE mechanisms					
Perceived satisfaction of community members /stakeholders with the functioning of CSE mechanisms					
Perceived quality of plans developed					
Amount of time allocated for development of plans					
Reach and impact of communications plans					
Percent of expected participants enrolled on protocols during specified period					
Percent of expected participants retained on protocols during specified period					
Percent of trial participants that reflect demographics of the epidemic in respective communities					
Percent of patients lost to follow-up					
Percent of records reviewed without consent or enrollment violations					
Percent of records reviewed without missed SAEs					
Proportion and type of community members/ stakeholders consulted					
Number and type of community member/ stakeholder suggestions incorporated					
Perceived value added of community member/stakeholder engagement efforts on the part of research staff					
Extent issues were addressed through community member and stakeholder engagement efforts					

INDICATORS	Measurable	Measured within timeframe and resources	Clear and easily understood	Accurately and reliably measure what they are supposed to measure	Issues are raised as a result of collecting data on the indicator
Number of participants reporting high levels of understanding of informed consent					
Perceived level on the part of researcher of participant understanding of informed consent					
Number and type of education mechanisms/ initiatives focused on relaying information to participants on informed consent					
Number of participants reporting positive experience at clinic visits					
Perceived satisfaction of participants with clinic visits					
Perceived quality of participant experience at clinic visits					
Extent participant experience at clinic visits is reviewed and used by research team					
Number of participants reporting access to quality package of products and services					
Perceived satisfaction of participants regarding access to quality package of products and services					
Number and type of high quality information resources distributed externally					
Number and type of education mechanisms/ initiatives to address misconception/rumors					
Number of stakeholders who report negative messages in community					

INDICATORS	Measurable	Measured within timeframe and resources	Clear and easily understood	Accurately and reliably measure what they are supposed to measure	Issues are raised as a result of collecting data on the indicator
Proportion and type of community members/ stakeholders consulted					
Number and type of community member/ stakeholder suggestions incorporated					
Perceived value added of community member/ stakeholder engagement efforts on the part of research staff					
Extent issues were addressed through community member and stakeholder engagement efforts					
Perceived satisfaction of community members/stakeholders with input					
Amount of time allocated for community member/stakeholder input					
Number of community member/stakeholder meetings held to review					
Level of engagement of community members/stakeholders during periods of input					
Number of community members and stakeholders who agree their input was informed and meaningful					
Number and types of distribution channels used for results dissemination					
Frequency that trial results are disseminated					
Awareness among community members and stakeholders of specific non-controversial trial results					
Number of participants reporting access to trial product, intervention, services post-trial					
Perceived satisfaction of participants regarding access to trial product, intervention, services post-trial					
Number of participants reporting access to quality package of products and services					
Perceived satisfaction of participants regarding access to quality package of products and services					

INDICATORS	Measurable	Measured within timeframe and resources	Clear and easily understood	Accurately and reliably measure what they are supposed to measure	Issues are raised as a result of collecting data on the indicator
Number and type of linkages with existing community-based structures					
Number and type of sustained community educational mechanisms/initiatives					
Extent of networking with diverse sectors					
Number and type of new opportunities for additional study/research					
Number and type of new opportunities for additional health services/care					
Number and type of new opportunities for additional community and stakeholder engagement					
Perceived level on the part of community members and stakeholders of utilization of knowledge in the community					
Perceived level on the part researchers of utilization of knowledge in the community					
Perceived level on the part researchers of healthcare and/or research capacity					
Areas of healthcare and/or research capacity identified for improvement					
Number of participants reporting high levels of trust for research process					
Perceived satisfaction of community members and stakeholders with research process					
Perceived level on the part of researchers of trust in community and among stakeholders for research process					
Number of trainings conducted					
Number of information resources distributed and engagement activities around research					
Number of post-test training scores higher than pre-test training scores					
Number of community members and stakeholders trained as trainers					

INDICATORS	Measurable	Measured within timeframe and resources	Clear and easily understood	Accurately and reliably measure what they are supposed to measure	Issues are raised as a result of collecting data on the indicator
Number of community members and stakeholders who report ability to independently speak on research agenda or trials					
Number of instances of community members and stakeholders making informed statements on research/trial					
Perceived level on the part of researchers of research literacy in community and among stakeholders					
Number and type of community members/ stakeholders consulted					
Perceived value added by researchers of community members/stakeholders input					
Perceived satisfaction of community members/stakeholders with input					
Level of engagement of community members/stakeholders during periods of input					
Amount of time allocated for community member/stakeholder input					
Number of community members and stakeholders who agree their input was informed and meaningful					

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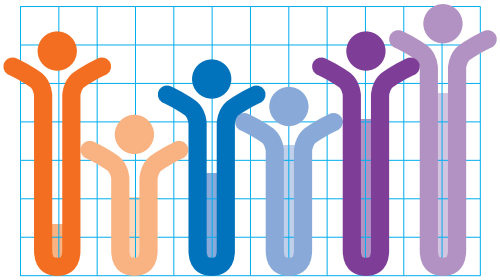

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