

Monitoring & Evaluation Tools for Community and Stakeholder Engagement

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Critical Path to TB Drug Regimens 2016 Workshop
April 4, 2016
Washington, DC



TB ALLIANCE

GLOBAL ALLIANCE FOR TB DRUG DEVELOPMENT



Community and Stakeholder Engagement (CSE)

Community and Stakeholder Engagement (CSE) strengthens relationships between researchers and local communities, and helps to ensure that study participants, their families, key community stakeholders and others who may be affected by or at risk have an opportunity to partner in the development and implementation of research efforts.

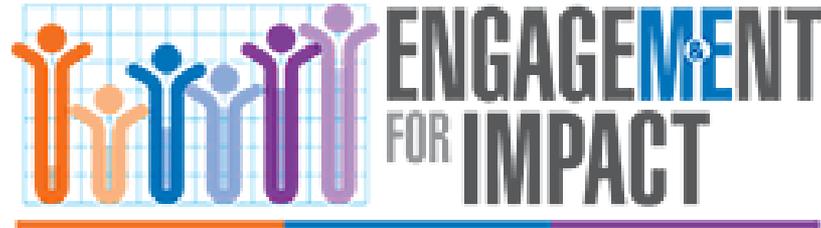
- Discuss community perceptions and concerns about research
- Increase community knowledge and understanding of clinical trials
- Incorporate input on protocol and informed consent documents
- Support recruitment and retention
- Ensure appropriate and respectful approach
- Build capacity to advocate for research
- Improve dissemination of the research findings
- Build acceptance & uptake of trial results if appropriate



Understanding the Impact of CSE

- CSE increasingly acknowledged as best practice in biomedical research
- Increased support for unified standards for CSE across all disease areas
- Adaptation and adoption of Good Participatory Practice (GPP) guidelines for TB drug Trials in 2012 (GPP-TB), as well as development of guidelines for other disease areas
- Evidence-base needed to understand impact of CSE on communities and on outcomes of clinical research
- Measuring the value and impact of CSE could influence researchers and donors to properly incorporate CSE practices into clinical research plans

Monitoring & Evaluation of CSE



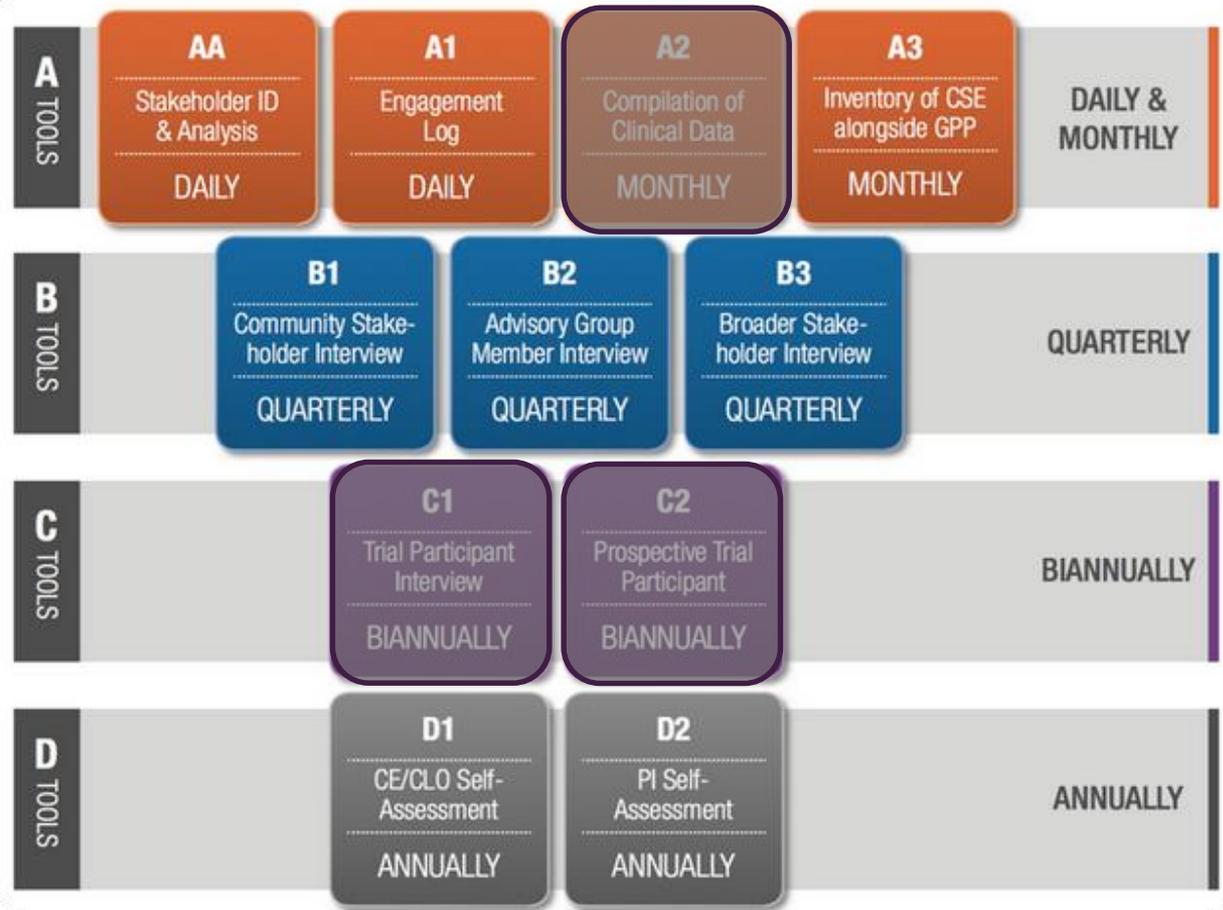
- M&E Toolkit development led by TB Alliance and AVAC with support and input from Working Group:
 - International AIDS Vaccine Initiative (IAVI), HIV/AIDS Network Coordination (HANC), International HIV/AIDS Alliance, NIAID and Wellcome Trust
- User friendly set of monitoring and evaluation tools designed to support CSE Implementers working on clinical trials to document activities on a daily, monthly, quarterly and biannual basis.
- Monitoring & Evaluation Manual, Database and User Guide
- Quantitative and qualitative methods to document and measure activities
- Web-based system to gather and analyze data

Monitoring & Evaluation Toolkit



ENGAGEMENT & FOR IMPACT

M&E Database for Community & Stakeholder Engagement in Clinical Trials



www.engagementforimpact.org

Introduction and Roll-out

- During development draft tools were piloted at TB and HIV clinical trial sites in South Africa in 2013 and 2014
- Toolkit first introduced to a group of TB and HIV CSE Implementers at a workshop in September 2014 in Johannesburg, South Africa.
- Broader use of toolkit helped with refinement and development of data analysis tools. Significant pool of data was needed.
- Toolkit widely launched at Combined Community Engagement Forum in September 2015 in Johannesburg, South Africa.
- CSE Implementers were introduced and trained on how to incorporate the toolkit into their ongoing programs.
- Launch garnered interest from multiple partners to use database both to understand CSE better and to document work.

Combined Community Engagement Forum 2015

- CCEF brought 80 CSE implementers together from over 25 clinical trial sites working on TB and HIV research in Southern and Eastern Africa.
- Coordinated by TB Alliance, AVAC and IAVI with participation of Aeras



Gathering Data & Challenge of Implementation

- Tools are widely available. Any group implementing CSE into clinical trials can create an account on the database and use the tools
- Achieving full incorporation of M&E plan into ongoing CSE activities has been a challenge thus far. Change of practice takes time, but has been slow
- Grantees of TB Alliance Community Engagement Program are required to incorporate use of tools to document engagements for reporting and quality assurance purposes. Program change still in process.
- Training is needed for new and current users to be able to fully utilize tools

Key Goals of M&E for CSE

- Help implementers improve planning of CSE activities around clinical trials for impact
- Better understand impact of CSE on different phases of clinical trial implementation (planning, initiation, recruitment and retention, follow up and dissemination of research findings)
- Ease documentation of CSE activities by providing easy tools to track and measure their work
- Improve reporting on progress and impact of CSE to trial sponsors and donors

Next Steps

- Conduct a series of training webinars in 2016 to improve skills to collect data and maintain momentum across partners
 - First webinar was held on Friday March 18th
- In-person workshop planned for July 2016 with attendees of CCEF
- Provide one-on-one support when needed to improve data quality
- Build new data analysis tools and improve current tools with more data in the system
- Initiate data analysis study in late 2016

Thank You!

For more information about M&E of CSE and the Toolkit please visit:

www.engagementforimpact.org