Network Evaluation – What is it? Why are we doing it?

Bob Salata

MTN Annual Meeting 2012

What is Evaluation?

"The systematic assessment of the operation and/or outcomes of a program or policy compared to a set of explicit or implicit standards **as a means of contributing to the improvement of the program or policy**."
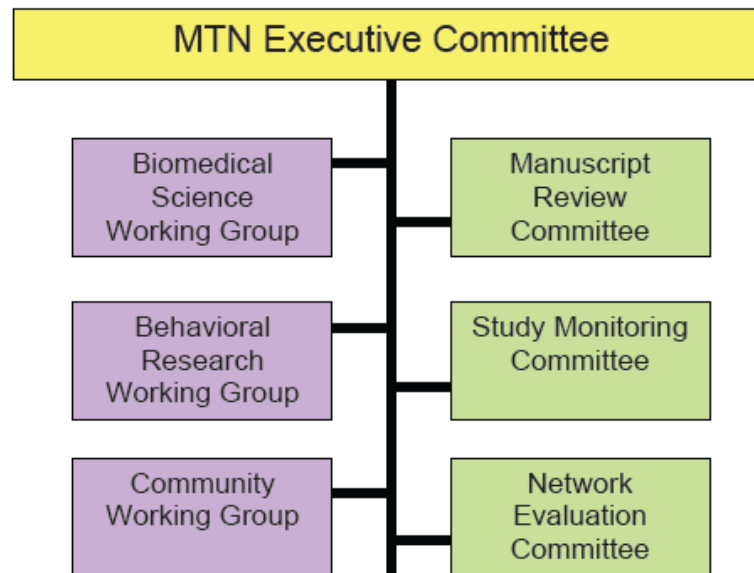
Weiss, 1998

Why is MTN Conducting Evaluations?

1. A requirement of our funding through NIAID/DAIDS

2. Because we want to assess the efficiency and quality of our work, and continue to improve

Network Evaluation Committee (NEC)

NEC was formed and given the mandate:

Use quantitative and qualitative methods to evaluate key components of the network to identify strengths and weaknesses at all levels of network processes in order to improve the quality and efficiency of our work
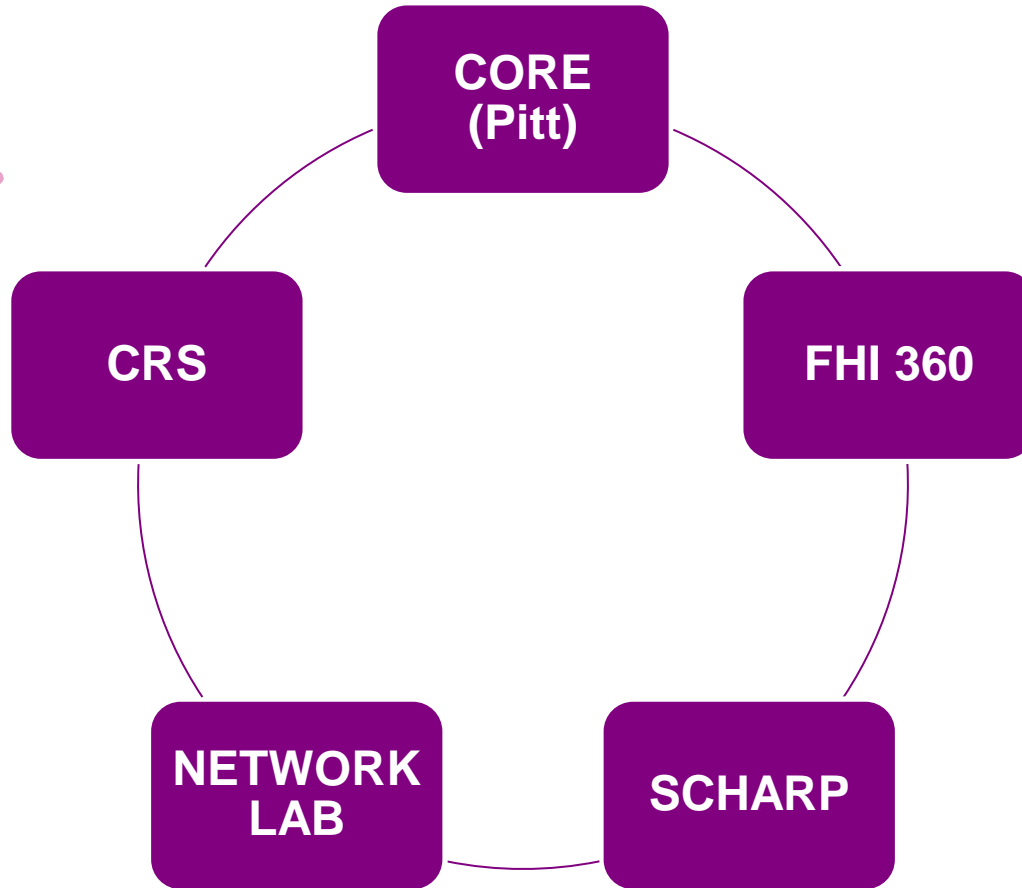
MTN's NEC: Who are we?

- Chairs: Bob Salata, Site Investigator, Cleveland, Ohio

  Patrick Ndase, Regional Physician, Uganda

- Additional Members:
  - Site Investigator
  - 2 Study Coordinators
  - FHI 360 rep
  - SCHARP rep
  - DAIDS (OCSO) rep
  - NICHD rep
  - Network Lab rep
  - CWG rep
  - CORE (Pitt) staff

Kenneth Kintu

Margaret Mlingo, Carol Oriss

Kristine Torjesen

Corey Miller

Donna Germuga

TBN

Ted Livant

Rodger Beatty

Nathan Angeloff, Judy Jones

Network Areas to Evaluate – CRS Evaluation and More

EVALUATION OF NETWORK AREAS: SUMMARY OF PROGRESS

CRS EVALUATION

- ❑ Quarterly reports assess enrollment, retention, procedure completion, QCs, datafax timeliness

- ❑ The Annual Report includes additional performance areas

- ❑ Reports are created, sent to sites with a summary and a request for Corrective Action Plans in areas of deficiency

> **Reports completed: 2009 Annual**
> **2010 Q1, Q2, Q3, and Annual**
> **2011 Q1, Q2, Q3 (Annual in progress)**

MTN
microbicide trials network

CORE(Pitt): Protocol Development

- GOAL: To assess:
  - Efficiency of the process
  - Inclusiveness of the process
  - Coordination, Communication

- Used quantitative assessment (time required to create approved protocol) and qualitative assessment (survey to protocol team members)

STATUS: COMPLETED in 2011

Evaluation of Protocol Development Process: Results

- Overall positive comments and timelines
- 4 suggestions were provided and have already been implemented
  - Include a BRWG representative earlier in the process
  - Add a phone call with the team or management group after PSRC
  - May want to try web-based technology for protocol meetings as appropriate
  - Provide more time for review of protocol drafts by the team whenever possible

SCHARP: Study Monitoring Committee (SMC) and Review Process

GOAL: To assess whether:

- ☐ Meetings have been focused on study conduct as outlined in MOP?

- ☐ Meetings are efficient

- ☐ Reports/feedback clear and helpful to protocol teams?

Method of assessment: Qualitative Survey

STATUS: COMPLETED and SCHARP has modified the SMC process

FHI 360: Study Activation

GOAL: To assess:

- ❑ Efficiency of the process: SOPs, Training, et al?

- ❑ Are site research staff members receiving enough support?

- ❑ Need more SOPs? Fewer?

Method of assessment: Qualitative Survey

FHI 360: Study Activation

- STATUS
  - Low response rate to the survey (possibly too long after some Protocols had completed activation)
  - Can't make conclusions based on small number of responders, but themes include:
    - Need to adjust training to site needs
    - Reduce requirement of study-specific SOPs where a site-specific or template SOP would be sufficient

- Will reevaluate in the coming year

Success of the evaluation program depends on you!

- ☐ An opportunity to help to shape this Network together

Plans

- Evaluation of Network Lab, DAIDS (related to MTN interactions), and NEC

- Add new quantitative metrics to CRS reports: timeliness of AEs (especially SAEs), # protocol deviations