MTN’s CRS Evaluation Program and Plans for ASPIRE

MTN Annual Meeting
February 2013
Where NEC Fits in the Network

MTN Executive Committee

- Biomedical Science Working Group
- Behavioral Research Working Group
- Community Working Group
- Manuscript Review Committee
- Study Monitoring Committee
- Network Evaluation Committee
NEC’s Mandate from the MTN Executive Committee

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.
Representativeness of NEC

Diagram:
- NEC
- Site PIs
- Site Coordinators
- DAIDS
- CWG
- Regional Physician
- NICHD
- Network Lab
- SCHARP
- CORE staff
- FHI 360
MTN’s NEC: Who We Are..

- Chairs: Bob Salata, US Site Investigator
  Patrick Ndase, Regional Physician

- Additional Members:
  - Kenneth Kintu
  - Margaret Mlingo, Carol Oriss
  - Kristine Torjesen
  - Anne Davis
  - Corey Miller
  - Donna Germuga
  - Denise Russo
  - Ted Livant
  - Judy Jones, Sarah Clayton
Annual CRS Evaluation – 9 Performance Areas

- Enrollment
- Retention
- CRS
- Protocol Timelines
- Regulatory and Monitoring
- Specimen Shipment
- Lab QA
- Data QCs
- Data Fax Timelines
Evaluation of Other Network Components

- Protocol Development
- Study Activation
- SMC
- Site Support
CRS Evaluation Reports

- An ANNUAL CRS EVALUATION REPORT reviews site performance during the previous year - 9 performance areas
  - A report that displays data for all sites and all studies active during the previous year
  - Also included is a Performance Summary that assesses the specific site’s performance as compared to benchmarks established by the network
  - A Corrective and Preventive Action Plan (CAPA) is required to be submitted back to the NEC from the site if standards are not met for any of the performance areas
Example of Performance Summary

Performance Summary
Site Name (DAIDS-ES 99999)

The table below summarizes your site’s performance in each of the nine performance areas that were assessed from 01 Jan 12 to 31 Dec 12 as part of the 2012 Annual CRS Report. Your site’s performance is compared to the MTN standard in the table below. Detailed information regarding each performance area is also included in the table.

<table>
<thead>
<tr>
<th>Performance Area</th>
<th>Performance Standard</th>
<th>Your Site’s Performance and how it Compares with the Standard</th>
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<tr>
<td>Study Enrollment</td>
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<td>MTN-020: Meets Standards</td>
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<td>Participant Retention</td>
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<td>MTN-020:</td>
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<td>Procedure Completion</td>
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<td>MTN-020:</td>
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<td>Data Quality - Cumulative</td>
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<td>Monitoring and Regulatory Compliance</td>
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<td>Specimen Shipment</td>
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<td>Protocol Deviations</td>
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<tr>
<td>Community</td>
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How do you know your site’s performance during the year?

- **Monthly**: SCHARP Data Summaries are emailed to sites from Network Evaluation Staff:
  - Performance areas: enrollment, retention, procedure completion, QCs, and datafax timeliness

- At the end of each calendar **quarter**, a Performance Report is sent with the data summaries and a CAPA is required to be submitted back to the NEC if performance does not meet standards in any of the areas assessed
Enrollment

- Enrollment as of the report date and an assessment as to whether sites are generally on target to complete enrollment on time
Retention

- 95% retention at each visit
- Will also look at “Product Coverage”
  - Includes all retained visits plus any visits for which a ring had been dispensed in anticipation of the missed visit
Procedure Completion
Data Management Quality Measures

- Within the previous month and cumulative overall:
  - QC rate per 100 records
  - % QCs resolved
  - Mean days to fax
Trial Monitoring

- From PPD monitoring reports
  - Consent violations
  - Entry criteria violations
  - EAE/SAE violations
  - Source documentation violations
External Laboratory Quality Assurance

- From EQA reports
- Sites are ranked by percentage of CAP and Acutest EQA panels scoring 100%
Specimen Shipment

- Major and minor errors in shipments of specimens to Network Labs
  - % shipments with no errors
  - % shipments with minor errors only or no more than 1 major error
  - % shipments with 2 or more major errors
Community

- FHI coordinates the assessment of community stakeholder engagement.