

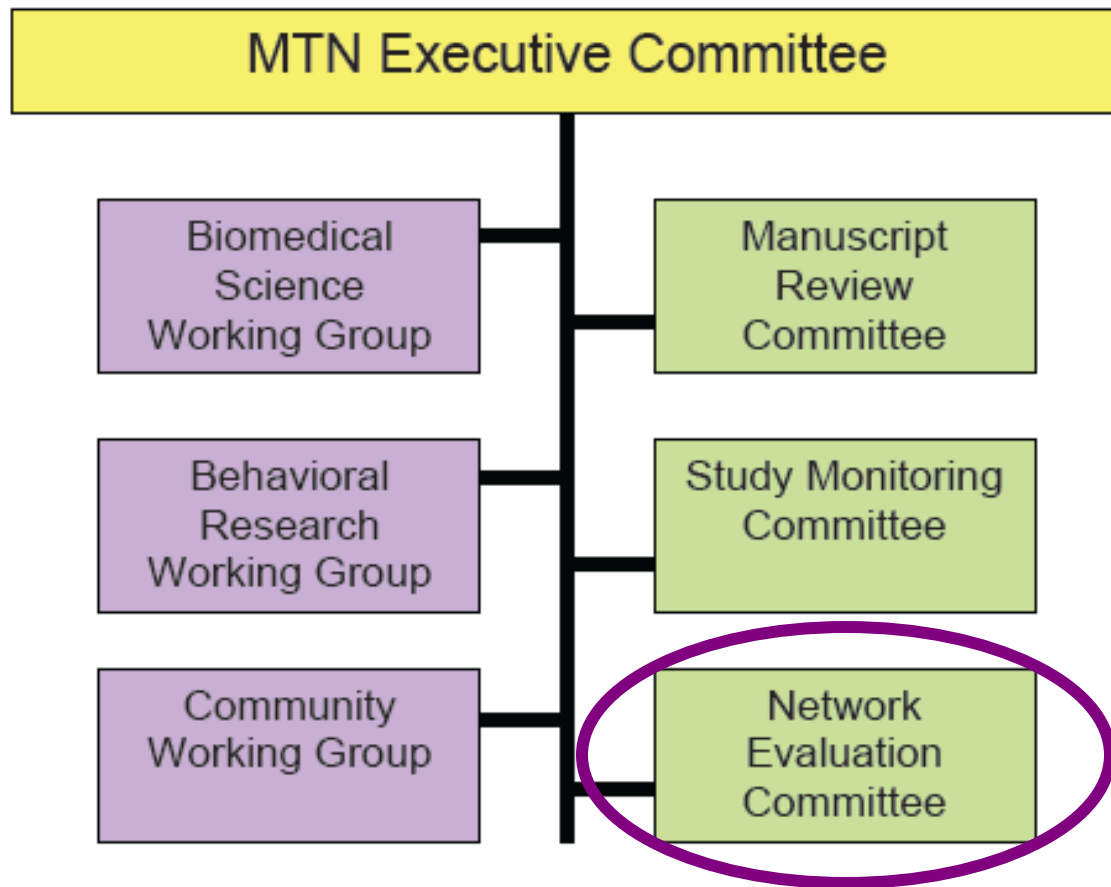


# **MTN's CRS Evaluation Program and Plans for ASPIRE**

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MTN Annual Meeting  
February 2013

# Where NEC Fits in the Network





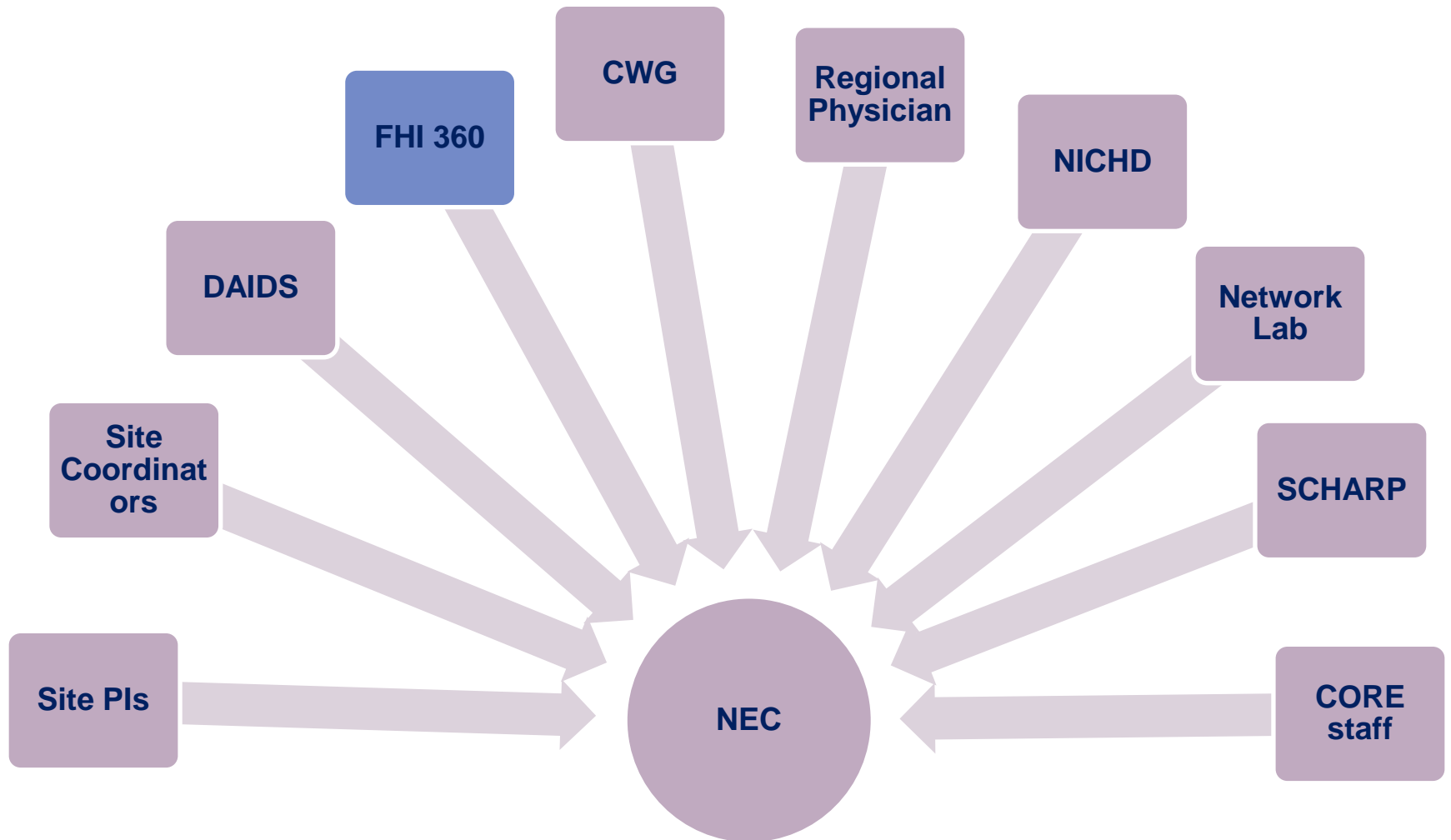
# **NEC's Mandate from the MTN Executive Committee**

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**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

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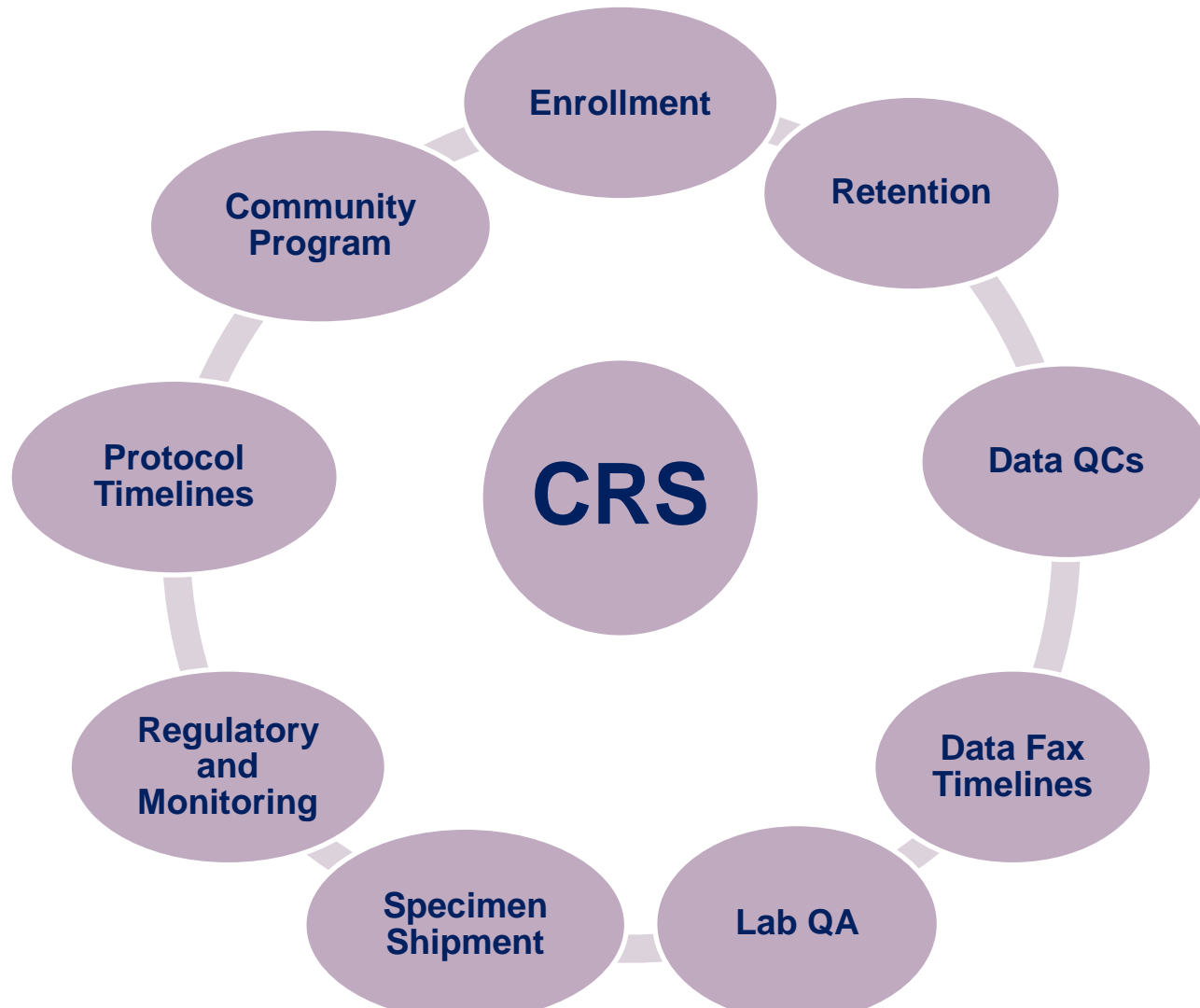
# MTN's NEC: Who We Are..

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- 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

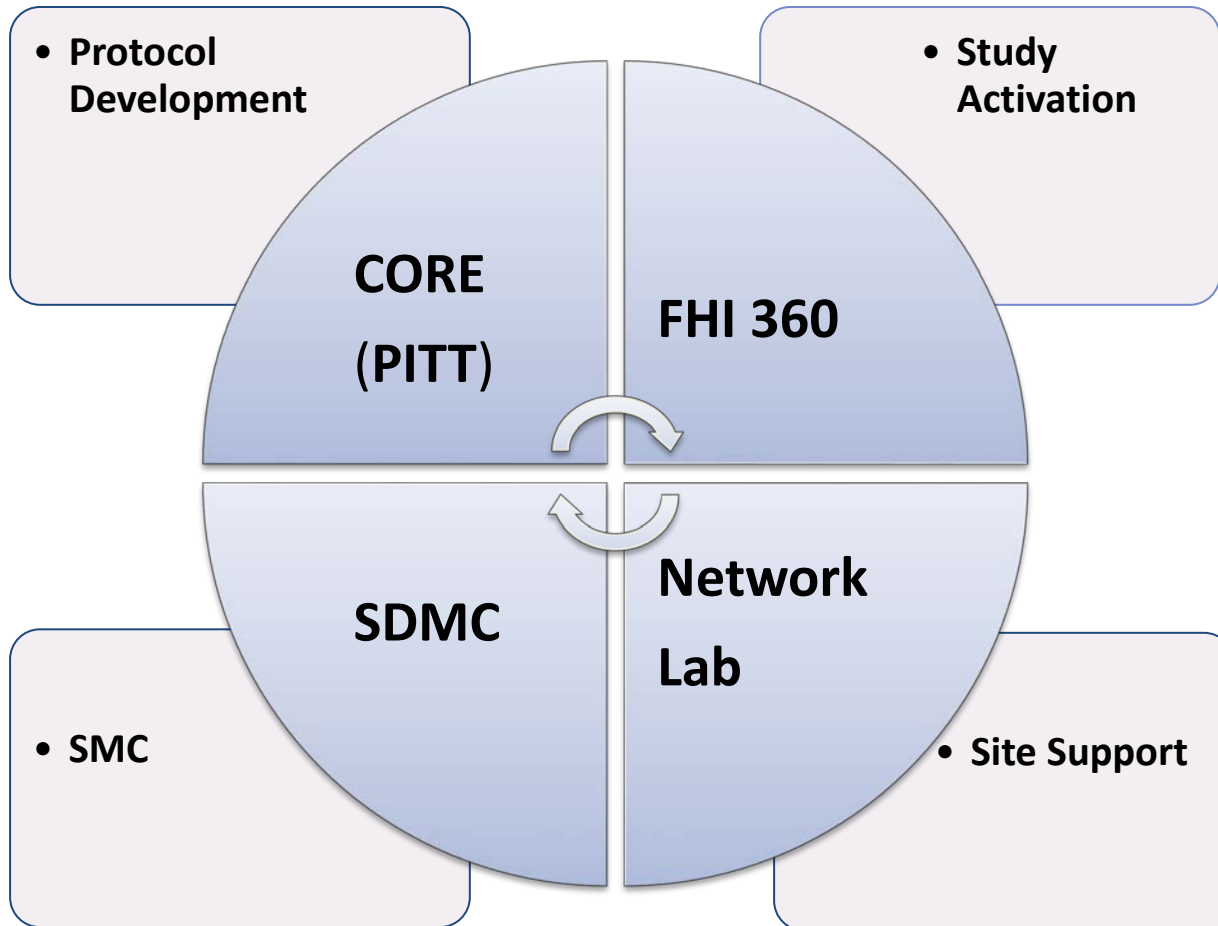
# Annual CRS Evaluation – 9 Performance Areas

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# Evaluation of Other Network Components

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# CRS Evaluation Reports

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- 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.



Performance Area	Performance Standard	Your Site's Performance and how it Compares with the Standard
Study Enrollment		MTN-020: Meets Standards
Participant Retention		MTN-020:
Procedure Completion		MTN-020:
Data Quality - Cumulative		MTN-020:
Monitoring and Regulatory Compliance		MTN-020:
External Lab Quality Assurance		
Specimen Shipment		
Protocol Deviations		
Community		



# How do you know your site's performance during the year?

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- 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

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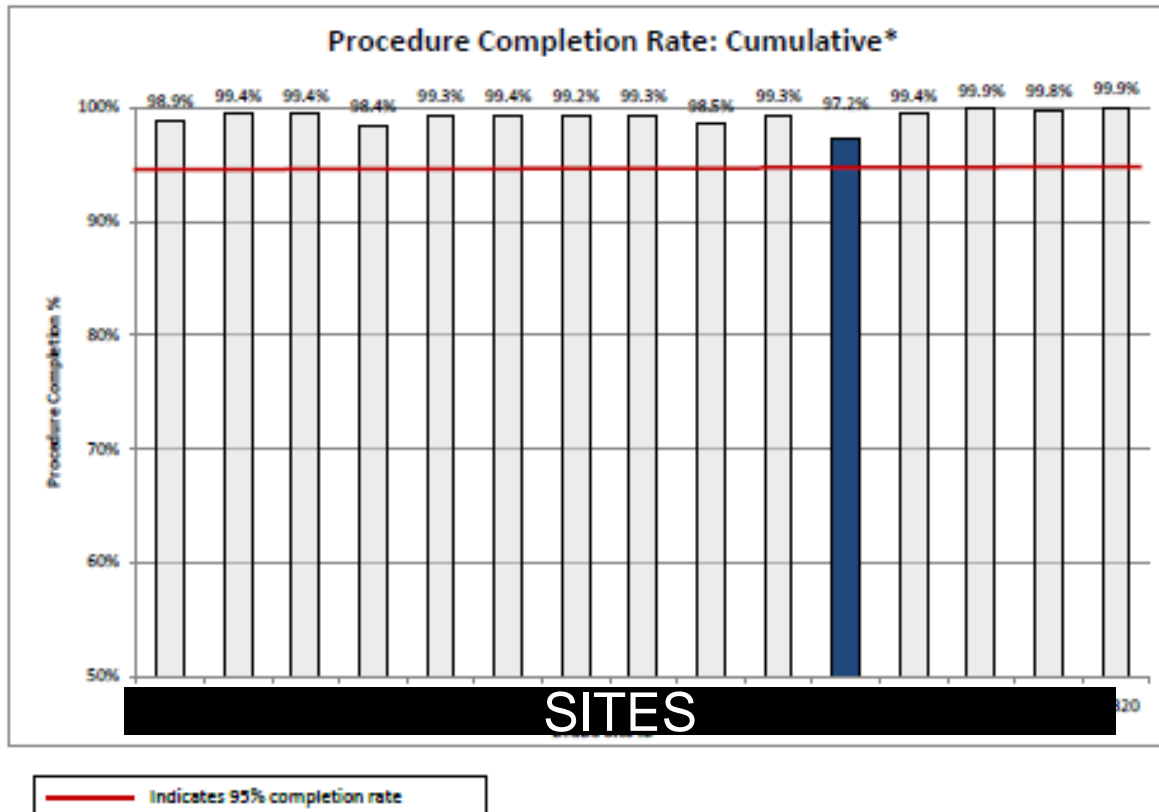
- Enrollment as of the report date and an assessment as to whether sites are generally on target to complete enrollment on time

# Retention

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- 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

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



# Trial Monitoring

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- From PPD monitoring reports
  - Consent violations
  - Entry criteria violations
  - EAE/SAE violations
  - Source documentation violations



# External Laboratory Quality Assurance

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





# Specimen Shipment

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- 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

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- FHI Coordinates the assessment of community stakeholder engagement.