

Network Evaluation

Continuous Improvement of Our Network

Bob Salata

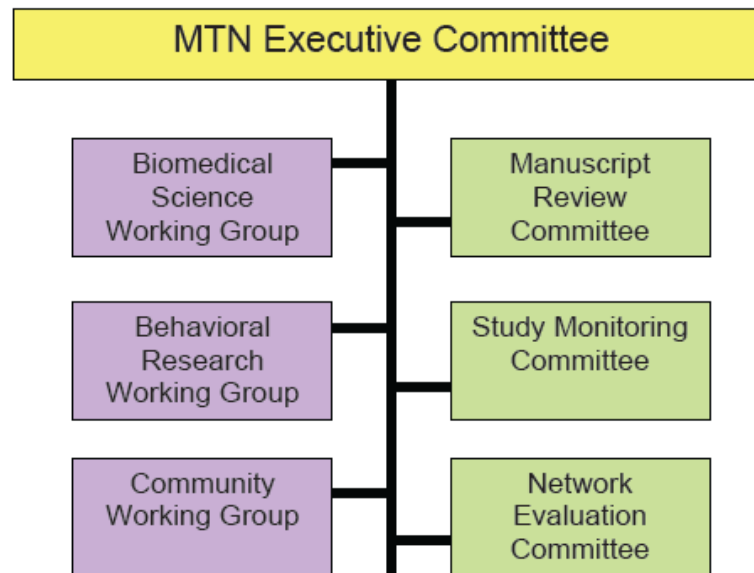
MTN Regional Meeting 2012



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



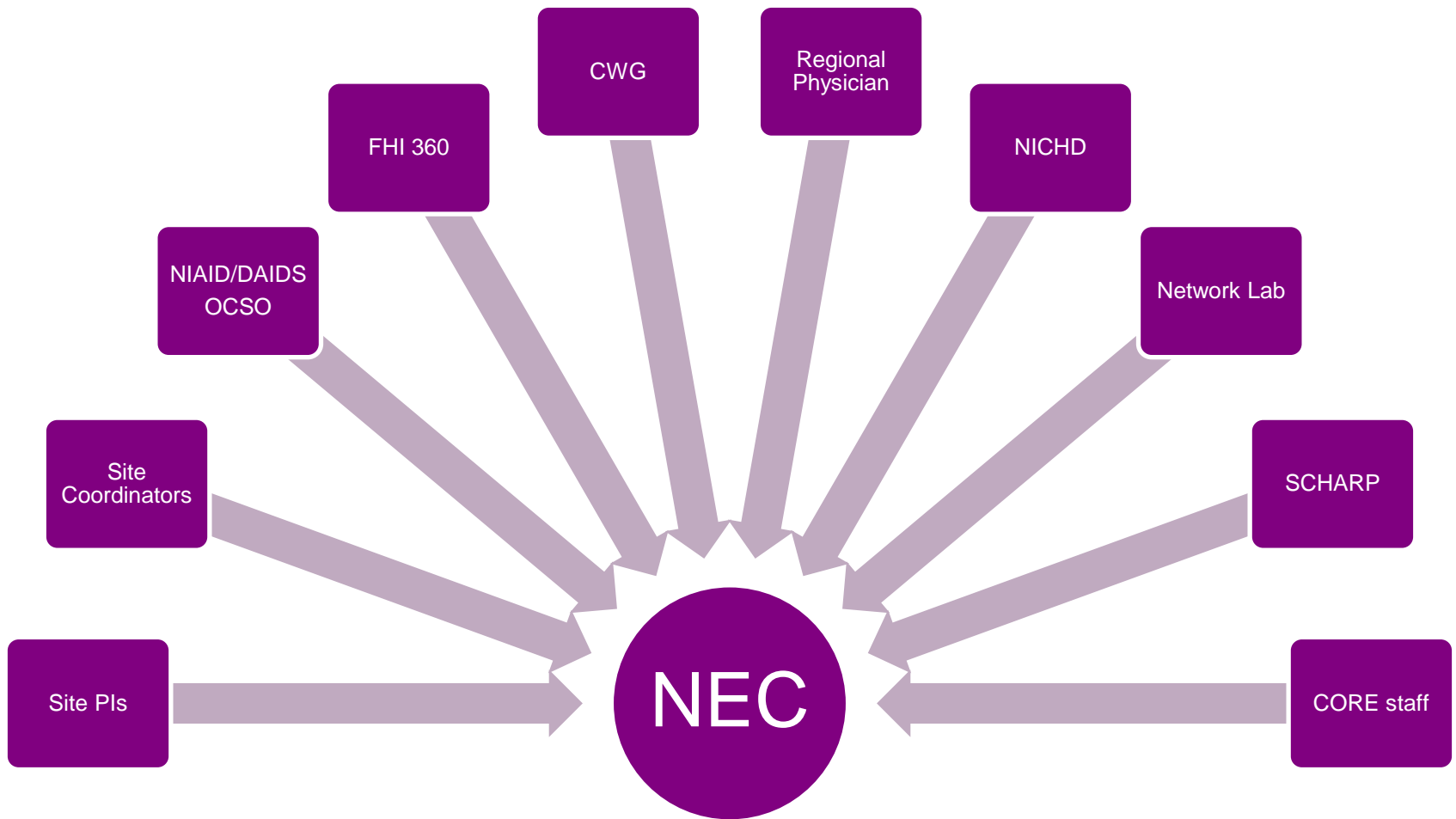


MTN's NEC: Who We Are

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

- Additional Members:
 - Site Investigator Kenneth Kintu
 - 2 Study Coordinators Margaret Mlingo, Carol Oriss
 - FHI 360 Kristine Torjesen
 - SCHARP Corey Miller
 - DAIDS (OCSO) Donna Germuga
 - NICHD TBN
 - Network Lab Ted Livant
 - CWG Rodger Beatty
 - CORE (Pitt) staff Judy Jones, Sarah Clayton

MTN's NEC





MTN's Commitment to Continuous Quality Improvement

- Evaluation program should include an evaluation of all components of the network
- Some areas may be evaluated by external experts, but most can be evaluated by the NEC
- Results must be useful, coordinated and able to be implemented



Evaluation of Components of MTN

- Clinical Research Sites
- CORE (Pitt)
- SCHARP
- FHI 360
- Network Laboratory



Process-Based Approach

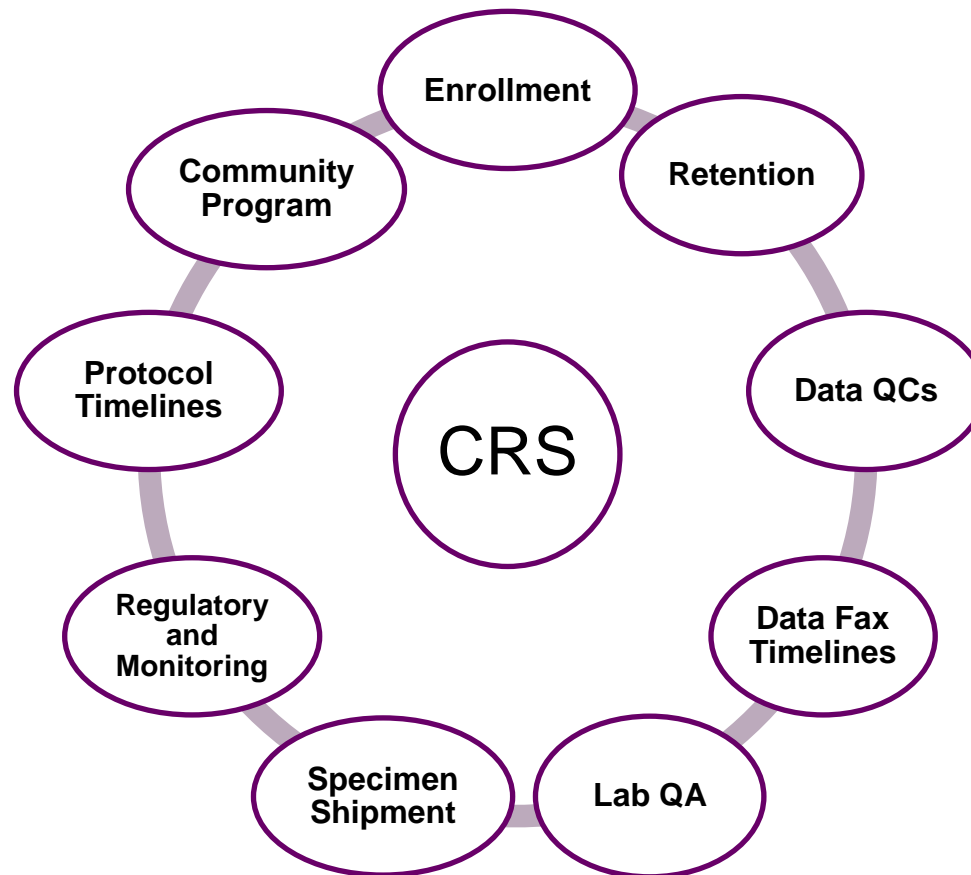
- Rather than attempt to evaluate everything that each component manages, the NEC and EC identified key processes to be reviewed within each component
- A detailed look at these key processes would be better able to pinpoint specific areas that work well and areas for improvement



CRS EVALUATION REPORTS

Annual CRS Evaluation

- The Annual CRS Evaluation Report includes assessment in 9 performance areas



Interim CRS Evaluation Reports

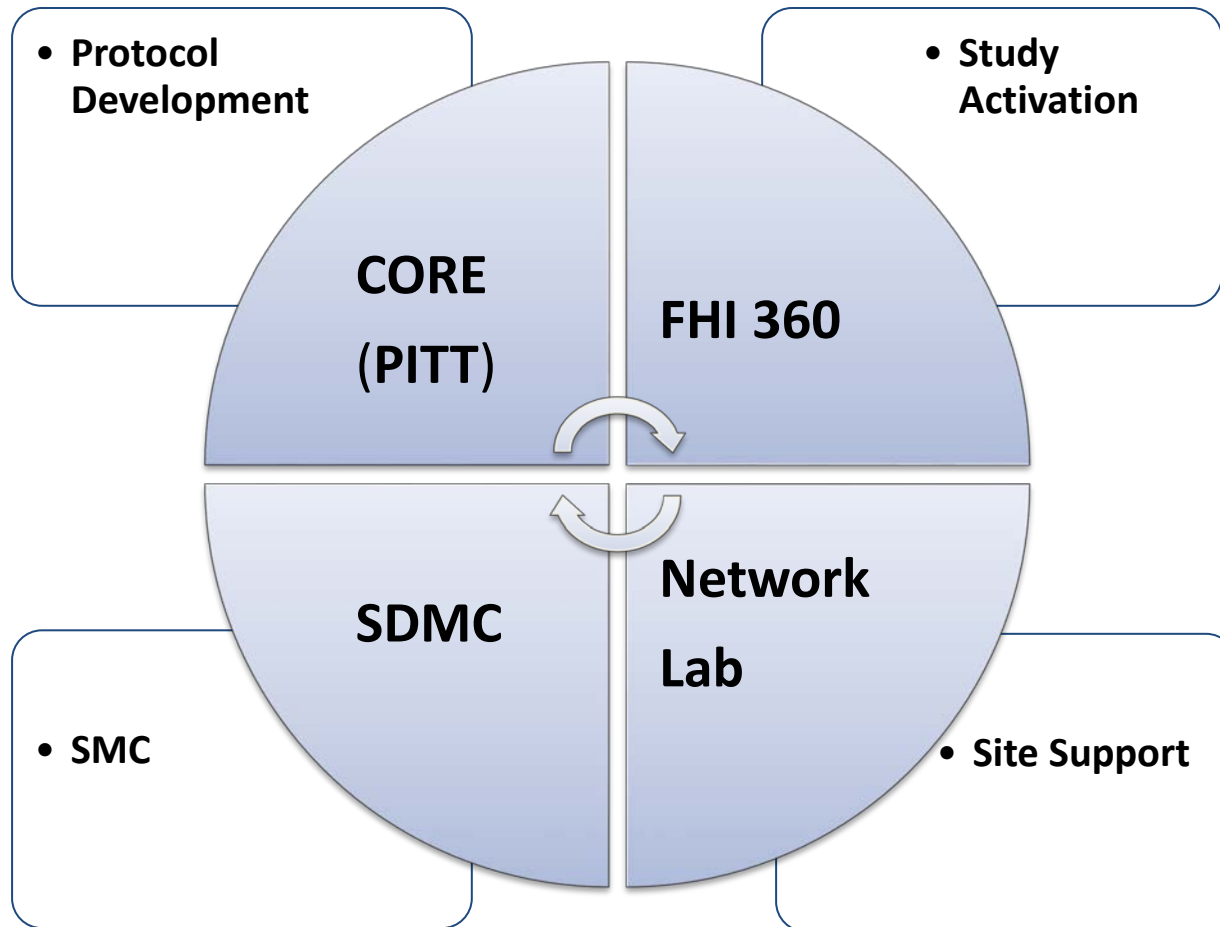
- Monthly: SCHARP Data Summaries are sent to sites from Network Evaluation Staff

- At the end of each calendar quarter, a Performance Report is sent with the data summaries
 - Quarterly reports provide a snapshot of how the site metrics compare with benchmarks or standards in the areas of enrollment, retention, procedure completion, QCs, and datafax timeliness
 - A Corrective and Preventive Action Plan (CAPA) is requested if there are any deficiencies and further discussion with NEC Chairs and OSCO as needed



EVALUATION OF OTHER NETWORK COMPONENTS

Other Network Components: Processes Identified for Evaluation





EVALUATION OF PROTOCOL DEVELOPMENT PROCESS

CORE(Pitt): Protocol Development

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

- Methods:
 - Quantitative assessment: time required to create approved protocol
 - Qualitative assessment: a survey to protocol team members for multiple protocols

STATUS: COMPLETED

Protocol Development: Evaluation of Efficiency

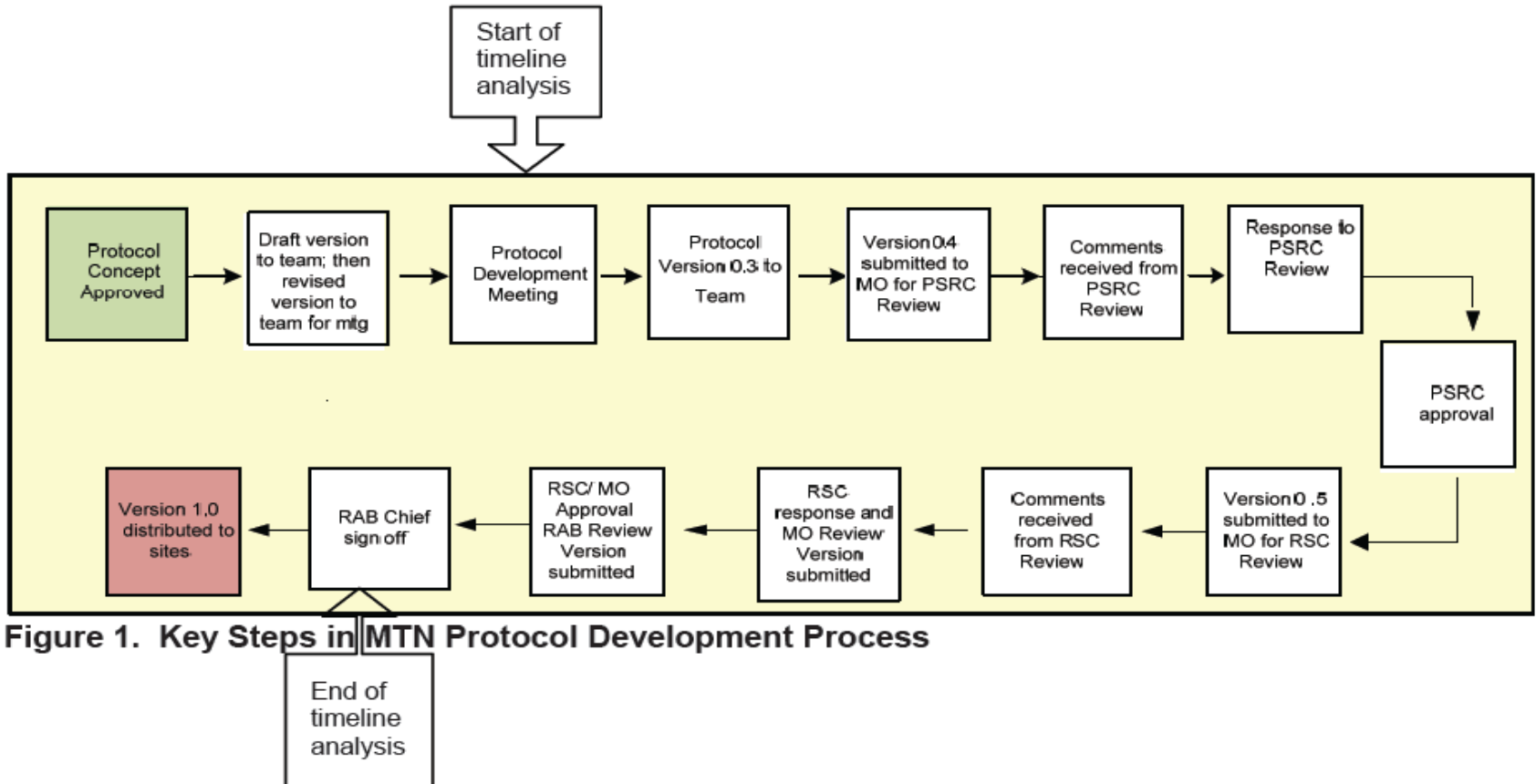


Figure 1. Key Steps in MTN Protocol Development Process

Protocol Development: Evaluation of Efficiency

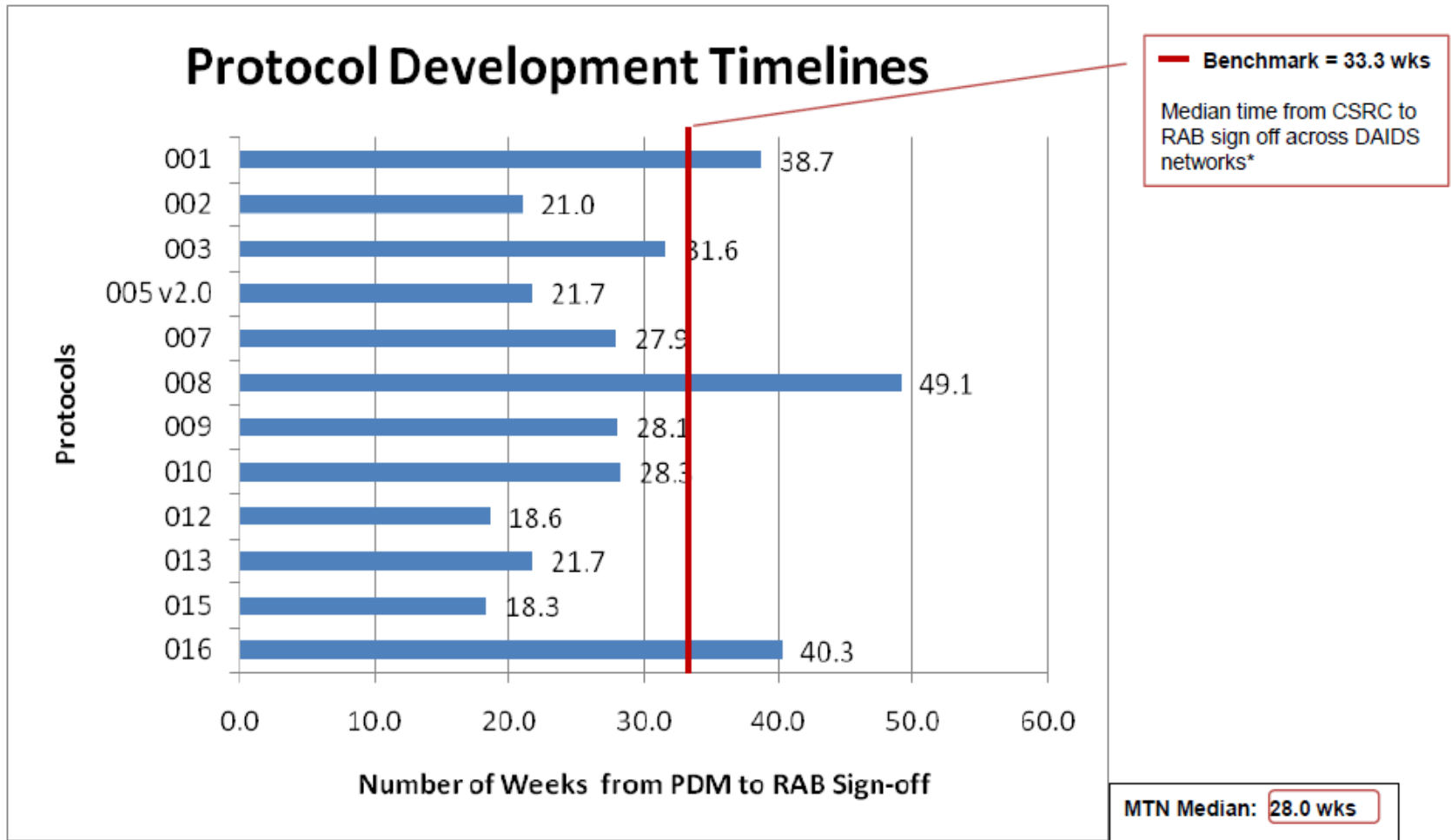


Figure 2. MTN Protocol Development Timelines



Protocol Development Process: Survey Results

- Summary of results
 - Protocols are of good quality
 - Team members are sent the revised protocols frequently enough
 - All responders felt that team members had adequate input into discussions and decisions regarding the protocol
 - Most thought that team members have enough time to review each revision (some thought more time is needed)
 - Most thought that the in-person Protocol Development Meetings are effective, well-run (some thought we should consider web-based and conference call meetings for some protocols)



Protocol Development: Summary of Suggestions from the Survey

- Include a BRWG representative earlier in the process
- Add a management team call after PSRC to review any protocol revisions
- Face-to-face meeting is very effective and efficient, but some people are open to trying a web-based meeting for some protocols
- Try to allow more time for review of protocol versions when possible



IMPACT: Your Feedback Caused These Changes

- BRWG Representative is now involved from the beginning of the development process
- A management team call has been instituted after PSRC as part of the routine protocol development process
- A web-based meeting was held during the development of ASPIRE and will continue to try this for some studies
- As possible, more time is allowed for each review of the protocol by the team



EVALUATION OF SMC PROCESS

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: Qualitative Survey

STATUS: COMPLETED



Evaluation of SMC: Impact

- SCHARP has streamlined SMC reports
- SMC not required for every trial (Observational studies such as MTN-003C, MTN-015, MTN-016 can now use a different process for review of the study)
- Web-based technology used for review of reports
- Prior to the meeting, members are reminded to review meeting agenda, protocol design and all reports so the meetings can be efficient and focused on key performance indicators



FHI 360: Study Activation

GOAL: To assess:

- Efficiency of the study activation processes: SOPs, training, SSPs
- Whether site research staff members receiving enough support?
- SOPs: need more SOPs? Fewer?

METHOD: Qualitative Survey



FHI 360: Study Activation


□ STATUS

- Low response rate to the survey (possibly too long after some protocols had completed activation)
- Although there was a small number of responders, themes from comments included:
 - Need to adjust training to site and study needs
 - Reduce requirement of study-specific SOPs where a site-specific or template SOP would be sufficient




Evaluation of Study Activation: Impact

- Training is now adapted to the level of experience of the site and the complexity of the study
- Some training components occur via web meeting or conference calls
- Site SOPs can be used for cross-study procedures rather than requiring every site to adapt SOPs for each study
- NEC will re-evaluate within the next year to assess the current study activation procedures



Network Lab Site Support

- Goal: assess the MTN Network Laboratory (NL) site laboratory support, specifically:
 - Laboratory section of the Study-Specific Procedures (SSP)
 - NL response to questions from sites
 - NL site visits
 - NL review of SOPs
 - NL protocol training



Network Lab Site Support

- Summary of Survey Responses
 - Ratings were good in all areas, with the exception that many responders thought they could benefit from more frequent NL site visits
 - Good suggestions in the comments for a few improvements
 - NL developed responses to comments which were sent back to the sites



Evaluation of NL Site Support: Impact

- A new per-visit type sample testing and storage chart will be added to the SSP for new protocols
- As requested, a clarification regarding requirements of the wet mount test has been added to SSPs:
- NL is working with FHI 360 to be part of the mock flow at protocol training to assess the site level flow, logs and documents and see if adequate or too long
- As many site visits will be scheduled as feasible given cost and staffing considerations



Some Network Components are Evaluated by External Experts

- Some scientific areas of the Network may be better served by an evaluation by external experts rather than by the NEC
- Biomedical Science Working Group (BSWG) and the Behavioral Research Working Group (BRWG) were reviewed by an external group of experts



Upcoming Plans

- Enhanced CRS evaluations to include additional metrics
- Further evaluation of the Network Laboratories
- Re-assessment of Study Activation
- Survey of sites' opinions as to the helpfulness of the communications planning and documents
- NEC has requested an evaluation of its work by the Network and possibly by external experts

Success of the evaluation program depends on you!

- An opportunity to shape this Network together

