Hub Performance Assessment

Hub complex performance assessment will be assessed with a standardized report card mechanism. The report card draws on data quality reports, enrollment reports, and monitoring activity. The report card shows individual Hubs what specific areas or procedures may need to be improved, it allows hubs to see how they compare to other hubs across the network, and it provides an excellent 'early warning system' that allows the CCC to identify areas where additional monitoring, training, or other interventions are needed. This tool is based on a 'balanced scorecard' instrument shown below that provides feedback around both the internal processes and external outcomes in order to continuously improve strategic performance and results. Each active clinical trial will be scored individually. The individual scores will be compiled to provide the total Hub score. The time period covered by the report card will be the calendar year (January-December) of each year of the active network.

In addition to the report card, the CCC will review and address any substantial data quality, regulatory violations or human subject protection on a case-by-case basis. Due to the serious and urgent nature of these last two items, they will be dealt with immediately rather than through a biannual report card. The primary intention of all performance assessment in the network is to improve quality and process outcomes, but deficiencies that cannot be remedied may result in termination of participation in the network.

Category	Weight	Points	Criteria	Reporting Responsibility
1. IRB proposals, renewals & amendments submitted / approved on time & sent to CCC	10 %	10 5 0	On time 0-120 day "late" > 120 delay	CCC Site Manager will track and report
2. "Essential Documents Binder" completeness	10 %	10 5 0	Complete Minor deficiencies Major deficiencies	CCC monitor will track and report
3. Enrollment success (% eligible)	50 %	(50/ highest number of subjects enrolled at top enrolling Hub) *number of subjects enrolled with the Hub		Information provided by SDMC
4. Data entry is timely (within pre-specified form specific time lines) and accurate (<10% Data Monitor query rate)	10 %	10 5 0	Completed in timeframe Completed but not in timeframe Not completed	Information provided by SDMC and CCC project monitors
5. Meets site monitoring recommendation on time (within 6 weeks)	10 %	10 5 0	Completed in timeframe Completed but not in timeframe Not completed	CCC monitor will track and report
6. Team contributions of site PI leadership, participation in network activities, attendance at meetings, etc.	10 %	10 5 0	Excellent Adequate Insufficient	CCC monitor will track and report

[#] Studies deemed inappropriate for site or where there is conflict with other research are exempted from the denominator.

SCORING CRITERIA

1. IRB approvals, renewal, and amendment outcome letters submitted and approved within required time lines and forwarded to CCC.
    a. PDF file copies of all final versions of protocols and amendments will be made available to each participating site on the network WebDCU site.
    b. The CCC will notify each Hub and participating site that the protocol is available for submission and confirm receipt of the email notification.
    c. Scores will be determined by measuring the time between the availability of the submission document and the date the document was submitted to the participating IRB.
    d. Participating sites will be responsible for providing documentation of the IRB submission date.
    e. Scoring Guidelines (0,5,10)
        i. 0 = submitted >28 days after protocol was available
        ii. 5 =submitted 14-28 days after protocol was available
        iii. 10 = submitted in <14 days after protocol was available

2. Essential Document Binder completeness
    a. The criteria will be based on findings reported during monitoring visits to the site.
    b. Scores will be assessed for each protocol conducted at each site monitored during visits. The scores will be averaged for the final score in this category.
    c. Scores will be based on the following criteria:
        i. “No Tolerance” Deficiencies: Any deficiency which affects research subject protection/safety or irrevocably contaminates data quality including:
            1. enrolling participants during an IRB approval lapse
            2. practices which seriously jeopardize participant privacy
            3. failure to consent a participant
            4. failure to disclose risks to participant
            5. enrollment of participants who do not meet inclusion/exclusion criteria and in whom patient safety is impacted
            6. fabrication of data, source documents, or regulatory documents
            7. access to medical records, key regulatory documents, or drug inventory is not provided on the day of visit
            8. inappropriate administration of drug to a study participant
            9. inappropriate delegation of authority by site PI
        ii. Major Deficiencies: Any deficiency which could affect research subject protection/safety or contaminates data quality including:

1. failure to report Serious Adverse Events within protocol specified timeframes
2. access to over 50% of medical records, key regulatory documents, or drug inventory is not provided on the day of a site monitoring visit
3. investigational drug inventory discrepancy
4. enrollment of participant(s) who do not meet inclusion/exclusion criteria and in whom patient safety is not impacted

iii. Moderate Deficiencies: Access/data quality issues resolved the day of visit or in specified follow up period. Also included are deficiencies which do not affect participant safety and protection including:

1. significant number of data reporting errors, corrected on the day of visit
2. key regulatory documents (e.g. IRB submissions) are not readily accessible, but provided on the day of visit
3. Investigator Commitment Form signed at the beginning of the study was not located, but provided in follow up.
4. incorrect consent form used to consent patient (no safety risks involved)
5. current, printed Manual of Operations is not present at the site

iv. Minor Deficiencies: Issues that do not affect participant safety or data quality but are required as part of Good Clinical Practices (GCP), including:

1. training certificates/medical license/CV not located in regulatory binder, but provided by the end of visit or in specified follow up period
2. few data reporting errors, all corrected at the time of visit
3. location of previous versions of study documents not specified

d. Scoring guidelines

i. 0= one “no tolerance” deficiency, or > 3 major, or >10 moderate deficiencies
ii. 2.5 = 3 major deficiencies, or > 7 moderate, or > 9 minor deficiencies
iii. 5 = 2 major deficiencies, or 3-7 moderate, or 6-9 minor deficiencies
iv. 7.5 = 1 major deficiency, or up to 2 moderate, or up to 5 minor deficiencies
v. 10 = meets all key components (0major, <2 moderate, < 5 minor deficiencies)

3. Enrollment success (% eligible)
    a. Enrollment goals at each Hub complex will be predicted and agreed upon by the Hub PI and NETT leadership before the start of each study.
    b. Errors in completion of the screening log will impact the score in the Essential Documents Binder completeness criteria noted above.
    c. The percentage of enrollment assigned to each Hub is determined via the following calculation: (50/ highest number of subjects enrolled at a Hub)*number of subjects enrolled.

4. Data entry is timely
    a. The CCC and SDMC will evaluate and make a determination if the data entry was timely and accurate. Data entry goals will be set for each protocol at the beginning of the trial. If more than one study is reviewed the scores are averaged.
    b. Scoring Guidelines:
        i. 0 = ≥ 79% of the data entries are timely and accurate
        ii. 5 = ≥ 80% of the data entries are timely and accurate
        iii. 10 = ≥ 90% of the data entries are timely and accurate

5. Meets site monitoring recommendation on time (within 6 weeks)
    a. The CCC study monitor will compile a report for each site and each study. Averages are calculated when there is more than one study with site monitoring, unless Hub PIs determine otherwise in advance.
    b. Scoring Guidelines:
        i. 0 = recommendations are not completed within 90 days of the timeframe specified in the site monitoring report
        ii. 5 = recommendations are completed after the specified timeframes but within 90 days of the timeframe specified in the site monitoring report
        iii. 10 = recommendations are completed within the specified timeframe.

6. Team contributions of site PI leadership, participation in network activities, attendance at meetings, etc.
    a. The Network Administrator will compile a report for each site on attendance at meetings, activities, and study-related training. The NETT PI, with input from the trial-specific PIs and NETT-EC, will provide input on scoring for leadership criteria. Final scores will reflect an average of the scores for participation and attendance.
    b. Scoring Guidelines:
        i. 0 = Hub PI or designee does not attend 2 or more meeting and/or training sessions. Provides high level of leadership with the hub complex for network activities

ii. 5 = Hub PI or designee attends all but 1 meeting and/or training sessions. Provides high level of leadership with the hub complex for network activities
iii. 10 = Hub PI or designee attends all meetings and/or training sessions. Provides high level of leadership with the hub complex for network activities

CORRECTIVE ACTION

Hubs found to have major and/or ongoing deficiencies will be required to comply with the following at the discretion of the NETT PIs and/or NETT Executive Committee:

1. Meeting with the NETT leadership and project staff either in person or via teleconference.
2. Additional and/or refreshing protocol training
    a. Training will be required as deemed appropriate based on the nature of the deficiency.
    b. Trial-specific refresher training will be mandated for Hub Complexes that do not enroll a subject in the specified trial for six (6) consecutive months.
3. Interruption in study related activities including suspension of enrollment in all trials.
4. Other actions deemed appropriate and necessary by the NETT PIs and/or NETT Executive Committee: