Hub Performance

Purpose and Scope

To describe processes for the assessment and improvement of overall citizenship and performance of Award Hubs, Hubs, and Spokes in SIREN. Performance assessments are generally intended to include recruitment rates, data quality, retention rates, and fidelity of protocol implementation. Hub performance also includes administration of spokes. Award Hub performance may also include community building and training efforts. Methods of improvement include overall and specific feedback, training and tools targeted to systematically address common deficits, and analysis of root causes and corrective or preventative actions for specific problems.

Responsible Individuals

Performance assessment and improvement is a shared responsibility of the SIREN Award Hubs, Hubs, Spokes, the SIREN CCC and DCC, and the NIH partners in SIREN.

Definitions

Award Hub	An institution or group of institutions awarded a grant by the NIH to organize and support Hubs and Spokes that serve as enrollment sites in SIREN.
Hub	An institution that contracts directly with the CCC to enroll at their own site and at one or more Spokes with whom they subcontract
Site	Any institution or entity that enrolls in SIREN trials inclusive of Hubs and Spokes
Spoke	An institution that contracts with a Hub to enroll at their own site

Abbreviations

CCC	Clinical Coordinating Center at the University of Michigan (UM)
CRF	Case Report Forms
DCC	Data Coordinating Center at the Medical University of South Carolina (MUSC)
DCR	Data Clarification Request
GCP	Good Clinical Practice
NIH	National Institutes of Health
SIREN	The Strategies to Innovate Emergency Care Clinical Trials Network
WebDCU	The Clinical Trial Management System used by SIREN, created and managed by the DCC

Procedures

1. Assessments and metrics

Performance of Award Hubs, Hubs, Spokes, and other sites is assessed in SIREN through a variety of metrics and data sources. These tools describe different domains of performance. Some tools aggregate data across trials and sites, while others are specific to the needs of particular trials. Some metrics are live and updated continuously in WebDCU and are available to sites and network leadership on demand. Other metrics are produced and distributed in periodic reports. Some reports are explicitly designed to be site-facing, while others are primarily for trial or network leadership groups. Assessment metrics and reports can evolve and change over time, and vary somewhat between trials, but the following overview describes examples and the scope of assessments.

WebDCU Network Dashboard
- Enrollment metrics by Award Hub and Trial (graphically and numerically)
- Operations and data quality by Award Hub (retention, regulatory document collection, CRF collection)

WebDCU Network CRF Data Entry Summary Table, by Award Hub, Hub, Spoke or Site, and by Trial
- # CRFs posted, CRFs data entered, CRFs submitted
- % Site CRFs first submitted by due date, Site CRF data entry over due
- # DCRs, Average DCR response days, DCRs closed, Average DCR closing days
- # DCRs not responded, DCRs responded not closed
- # Open rule violation, Confirmed warning rule violation, Confirmed protocol violation
- % Site data error rate

Trial-specific reports by Trial and Site
- Enrollment reports, “black box” graphic showing screening and enrollment across sites, with ranking
- Clinical standardization reports, adherence and transgressions from trial-specific treatment parameters
- Site performance reports (“report cards”), combinations of enrollment and data quality metrics.

Site and data monitoring by Trial and Site
- Risk-based monitoring report, evaluates statistical outliers and other variances predicting error or fraud risk.
- Site monitor visit report. See the Site Monitoring SOP for descriptions of this feedback tool.

2. Improvement strategies

The network leadership selects metrics for monitoring trial execution across sites. Network leadership watches for threats and common problems in data collection and advises site investigators about opportunities to improve trial conduct and quality. Award Hub and Hub leaders also independently watch for and use provided metrics to identify opportunities for improvement within their communities and spokes. At all levels the network encourages the academic study of performance assessment and improvement processes and tools.

Exploration and sharing of tools and processes from a scientific and academic perspective is encouraged. The following categories of processes are used to improve site performance.

Quality by design

Sites performance is optimized when study processes are designed to facilitate adherence and data fidelity. We support site investigators to maintain high trial quality. We provide clear manuals of operations and definitions of procedures. Data integrity is enhanced using CRFs with real-time form-based restrictions on data entry based on logic or range checks that flag non-physiological or improbable data at the moment of data entry. Quality by design also involves avoiding excessive unnecessary data collection or eligibility criteria, simplifying CRF design, and ensuring study processes are implemented in clinical practices as seamlessly as possible. Quality by design is intended to reduce systematic and logistic barriers, to discourage errors and improve feasibility, thereby facilitating better site performance.

Site-directed improvement processes

Hubs and spokes, individually or collectively within their Award Hub community, are primarily expected to work internally to continuously improve their performance. Many assessment tools, described above, are provided to sites to describe different domains of screening and enrollment, adherence to clinical standardization plans, and data collection and fidelity. Sites use these tools to maintain or improve over time and to identify problem areas that need to be addressed. Sites can also use these tools to benchmark against others in the network to motivate improvements through a sense of competition. Award Hubs are also motivated to perform well on performance assessment through awareness that some performance metrics will be assessed at the time of Award Hub grant renewals and potentially in annual progress reports to NIH.

Data and site monitoring

Data variances identified by central data monitoring or data inconsistent with source documentation identified by site monitoring trigger data clarification requests (DCRs). Monitoring of trial data includes visits to sites by experienced site monitors for direct inspection of primary source data and comparison with CRFs. A report that includes action items for performance improvement is produced for each monitoring site visit and is reviewed with the Site PI and a trial leadership PI. See the SIREN Site Monitoring SOP for details. SIREN feedback is always phrased as a dialogue about how to improve performance, sometimes requiring a written corrective action plan.

Remediation and suspension

The SIREN leadership, inclusive of the CCC, DCC, trial leaders, and network and trial Executive Committees, also centrally follow site performance metrics. Although performance improvement is primarily a local activity, there are several central roles in performance improvement processes. The network and trial leaderships are responsible for developing, adapting, evolving, and providing the assessment metrics provided above that sites need to direct internal improvement efforts. Leadership is also responsible for identifying issues impairing performance across sites that may need mediation by central process improvement or clarification, or by additional or enhanced training across the network or a trial. The network is also dedicated to the ongoing professional development of site research staff which can help drive site performance improvements. The

network and trial leaderships can also provide feedback beyond the provision of performance metrics when sites appear to be unaware of, or are struggling to improve performance through local efforts. When needed, feedback directly to sites will be a dialogue about how to improve performance, sometimes including a written corrective action plan. Corrective action plans should be written in order to preserve a trail of accountability for protocol adherence and quality monitoring. Leadership may also help remediate low performing sites by facilitating peer-to-peer consultation with high performing sites. Ultimately, as a last resort, SIREN and trial leadership may suspend a site from trial participation after continued non-compliance or failure to remediate.

3. Research on research

SIREN's goal of promoting "research on research methods" includes the study of trial quality control processes from a scientific and academic perspective. Describing the ability of each aspect of performance improvement and feedback to increase enrollment performance, clinical adherence, protocol compliance, and data quality has the potential to inform future trial processes.

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NIH Administrative PO Sign-off: _____ JEREMY BROWN -S Digitally signed by JEREMY BROWN -S Date: 2025.12.16 11:31:48 -05'00'