SOP Number: ADM 19
SOP NAME: **Data Monitoring**
Effective Date: 10-Dec-2014 (rev 24-Mar-2023)

1. Purpose

The purpose of this SOP is to describe monitoring procedures for StrokeNet clinical trials monitored by the NDMC. Monitoring is defined as the act of overseeing the progress of a clinical trial, and of ensuring that it is conducted, recorded, and reported in accordance with the protocol, SOPs, GCP, and the applicable regulatory requirement(s). It has an integral role in the quality control of a clinical trial and is designed to verify the ongoing quality of the study. The purpose of monitoring is to ensure that:

- The rights and well-being of the human subjects are protected
- The reported trial data are accurate, complete and verifiable from source documents
- The conduct of the trial is in compliance with the currently approved protocol/amendment(s), GCP and the applicable regulatory requirements.

2. Definitions and Acronyms

GCP	Good Clinical Practice
FDA	Food and Drug Administration
NDMC	National Data Management Center, Medical University of South Carolina
SOP	Standard Operating Procedure
WebDCU™	Web-based central trial management system developed by NDMC

3. Scope

This SOP applies to all personnel involved with monitoring, including the NDMC investigators/staff, site investigators/staff, biostatisticians, and site monitors, for StrokeNet studies in which NDMC is responsible for trial monitoring.

4. Procedures

A. Monitoring Plan

1. A monitoring plan will be developed for each study to facilitate compliance with good clinical practice (GCP) guidelines, applicable FDA regulations (21 CFR 812 and 813), and the FDA's "Guidance for Industry. Oversight of Clinical Investigations- A Risk-Based Approach to Monitoring". Monitoring plans will be updated as appropriate.

2. The level, detail, frequency, and method of monitoring will be described in each study's Monitoring Plan.

3. Oversight of all monitoring activities specified in the plan is the responsibility of the NDMC.

B. Site Monitoring

1. The number of anticipated site monitoring visits for a particular clinical study will be based on critical risks, the complexity of the study design, its phase of development,

previous site experience and compliance with study requirements, rate of subject enrollment, and other pertinent attributes of the study or site.

2. Site monitoring will be conducted by the NDMC and/or Clinical Research Associates, and may include site initiation visits, routine monitoring visits, and site close-out visits.

3. Site monitoring may be performed remotely and/or on site.

4. Sites will provide site monitors access to subject source documentation. If site has their own policy regarding on-site or remote monitoring, site will provide this policy to the site monitor in advance of the site visit.

5. Following any site monitoring visit:
   a. The monitor will complete the Monitoring Visit Report in WebDCU™ .
   b. The NDMC will review and approve the report in WebDCU™.
   c. The site Principal Investigator will review and approve the report in WebDCU™.

C. Central Monitoring

1. Central monitoring will be conducted by NDMC using web-based data validation rules, data manager review of entered data, statistical analysis, and on-going review of site metrics.

2. Documentation of central monitoring activities will be housed on NDMC servers.

5. Applicable Regulations and Guidelines

International Conference on Harmonisation. (2001). ICH harmonised tripartite guideline: Guideline for good clinical practice. *Journal of Postgraduate Medicine, 47*(3), 199-203.

US Food and Drug Administration. (2013). Food & Drugs, 21 C.F.R. § 312. Retrieved from http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRsearch.cfm?CFRPart=312

US Food and Drug Administration. (2013). Food & Drugs, 21 C.F.R. § 812. Retrieved from http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=812

US Food and Drug Administration. (2013). Guidance for industry. Oversight of clinical investigations: a risk-based approach to monitoring. Retrieved from http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM269919.pdf.

6. References to Other Applicable SOPs

7. Attachments and References

8. Document History

Version	Description of Modification	Completion Date	Issue Date	Effective Date
1.0	Final	10-Dec-2014	10-Dec-2014	10-Dec-2014
1.2	Biannual review with minor administrative changes	13-Dec-2016		
2.0	Final	19-Dec-2016	19-Dec-2016	19-Dec-2016
3.0	Administrative review	24-Mar-2023	28-Jun-2023	28-Jun-2023

NIH StrokeNet Network

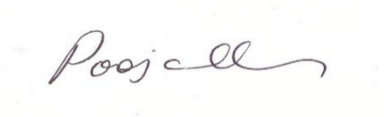
Standard Operating Procedure (SOP)

Data Monitoring

Version 3.0

ADM #19

Reviewed and Approved by:



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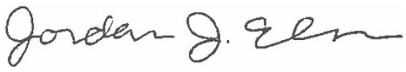

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