

NIH StrokeNet Standard Operating Procedure

SOP Number: ADM 20
SOP NAME: Data Quality Assurance and Control
Effective Date: 25-February-2015 (rev 24-Mar-2023)

1. Purpose

ICH-GCP requires that quality assurance and control be applied to each stage of data handling to ensure that all data are reliable and have been processed correctly. The purpose of this SOP is to describe data quality assurance and control procedures for StrokeNet clinical trials managed by the NDMC. For this SOP, data quality assurance is defined as a set of activities for ensuring quality in the processes by which clinical trial data are collected. Data quality control is defined as a set of activities for ensuring quality in the clinical trial data. Quality control activities focus on identifying and correcting errors in the data produced.

2. Definitions and Acronyms

CRF	Case Report Form
DCU	Unit at the Medical University of South Carolina which houses the NDMC
ICH-GCP	International Conference on Harmonization's Good Clinical Practice Guidelines
NDMC	National Data Management Center at the 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 data quality control, including the NDMC investigators/staff, site investigators/staff, biostatisticians, and contract monitors, for StrokeNet studies in which NDMC is responsible for data management.

4. Procedures

A. Quality Assurance

1. NDMC will follow StrokeNet and internal DCU SOPs pertaining to quality assurance.
 - A. CRF creation. Please refer to DCU SOP 05-001 Case Report Form (CRF) Design.
 - B. Database set up. Please refer to DCU SOP 05-003 Database Set-up.
 - C. Database validation. Please refer to DCU SOP 04-007 Computerized System Validation and DCU SOP 05-007 Database Validation.
 - D. Randomization validation. Please refer to DCU SOP 02-008: Validation of Randomization.
 - E. Training. Please refer to DCU SOP 05-015 CRF Completion Guidelines and DCU SOP 05-026 WebDCU User Manuals.

B. Quality Control

1. NDMC will follow internal DCU SOPs pertaining to quality control.

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- A. Database change implementation. Please refer to DCU SOP 04-016 System Change Control and DCU SOP 05-006 Database Changes.
- B. On-site and Central Monitoring. Please refer to DCU SOP 03-016 Monitoring of Clinical Sites, DCU SOP 05-019 Data Clarification Request Procedures, and StrokeNet Data Monitoring SOP ADM 19.

5. Applicable Regulations and Guidelines

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

6. References to Other Applicable SOPs

- A. ADM 19 Network Data Monitoring

7. Attachments and References

8. Document History

Version	Description of Modification	Completion Date	Issue Date	Effective Date
1.0	Final	25-Feb-2015	25-Feb-2015	25-Feb-2015
1.1	Biannual review with minor administrative changes	13-Dec-2016		
2.0	Final	19-Dec-2106	19-Dec-2016	19-Dec-2106
3.0	Administrative review	24-Mar-2023	20-Apr-2023	20-Apr-2023



NIH StrokeNet Network

Standard Operating Procedure (SOP)

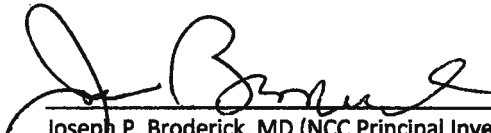
Data Quality Assurance and Control

Version 1

ADM #20

Originators: StrokeNet National Data Management Center Personnel

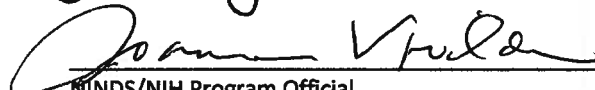
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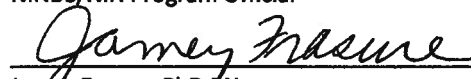
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