NeuroNEXT Network

Standard Operating Procedure (SOP)

Clinical Data Management
Version 3.0
SOP NN DM 1001

Originators: NeuroNEXT CCC and DCC Personnel

Reviewed and Approved by:

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1. POLICY

All data for NeuroNEXT protocols will be managed in compliance with NeuroNEXT policies, and applicable Sponsor and regulatory requirements. The NeuroNEXT Data Coordinating Center (DCC) will instruct site personnel to collect, transcribe, correct, and transmit the data onto source documents, CRFs, and other forms used to report, track and record clinical research data. The DCC monitors clinical sites to ensure compliance with data management requirements and Good Clinical Practices. The DCC is responsible for developing, testing, and managing clinical data management activities, as required, at the study sites, the clinical coordinating sites, and at the DCC.

2. SCOPE

This SOP has been developed to be in alignment with federal regulations and Good Clinical Practices (GCP) as set forth in the 2016 Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice E6(R2). The policies and procedures described in this SOP apply to the NeuroNEXT Clinical Coordinating Center (CCC) and DCC within the context of their oversight and advisory roles for the NeuroNEXT Network, and to all NeuroNEXT investigators, staff, subcontractors, or other entities associated with the NeuroNEXT Network who manage, oversee, and conduct research regulated by FDA and/or applicable review committees.

3. ROLES AND RESPONSIBILITIES

The DCC is responsible for all aspects of clinical data management, and for properly instructing key study personnel (including the CCC, the CSS, and DCC staff) on how to collect, transcribe, correct and transmit the data onto CRFs or other data collection forms and logs.

The DCC is responsible for establishing procedures to ensure that clinical data management activities occur as required at the CCC, the CSS, and at the DCC.

The responsibility to conduct any or all of these activities may be delegated at the discretion of the Sponsor to the DCC or to subcontractors of the DCC. Those individuals and entities also take on responsibility for meeting regulatory requirements on behalf of the Sponsor, but the Sponsor has the ultimate responsibility, and must therefore supervise those delegated activities effectively.

4. APPLICABLE REGULATIONS AND GUIDELINES

ICH E6, 2.10	The Principles of ICH GCP
ICH E6, 5.1	Quality Assurance and Quality Control
ICH E6, 5.5	Trial Management, Data Handling, Recordkeeping, and Independent Data Monitoring Committee

5. REFERENCES TO OTHER APPLICABLE SOPS

NN SS 401	Site Selection and Qualification
NN SS 402	Site Initiation Visits and Site Training
NN SS403	Routine Monitoring Visits
NN PM 503	Study Materials Development
NN PM 504	Investigational Site Staff Training
NN CS 702	Application Development and Validation

NN DM 1001

NN CS 704	System Security Measures and Website Access

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NN BIO 906	Report Writing
NN DM 1002	Data Management Plan Development
NN DM 1003	Case Report Form Development
NN DM 1004	Specifications Development, Testing Plans, and Validation Documentation
NN DM 1005	Data Collection and Data Handling
NN DM 1006	Adverse Event Coding
NN DM 1007	Standardization of Classification Systems

6. ATTACHMENTS AND REFERENCES

NN DM 1001 – A	Document History
NN DM 1005 – B	Data Change Request Form

7. TERMS AND ABBREVIATIONS

The following terms and abbreviations are used in this document:

CCC	Clinical Coordinating Center at Massachusetts General Hospital
Clinical Study Site (CSS)	Clinical site that conducts research for a NeuroNEXT protocol within or outside the Network
Clinical Study Site Principal Investigator	Investigator who is responsible for the implementation and conduct of a specific NeuroNEXT protocol at a Clinical Study Site
DCC	Data Coordinating Center at The University of Iowa
DM	Data Management Team at the DCC
Protocol Principal Investigator (PPI)	Principal Investigator of a NeuroNEXT protocol
PWG	Protocol Working Group

8. SPECIFIC PROCEDURES

A. Data Management Overview

#	*Who*	*Task*	*Attachment/ Reference*	*Related SOP*
1.	DCC DM	Develop and maintain the protocol Data Management Plan.		NN DM 1002 NN DM 1003 NN DM 1004 NN DM 1005 NN DM 1006 NN DM 1007
2.	PPI and DCC DM	Develop case report form (paper forms), protocol website specifications, and eCRF templates and specifications.		NN DM 1003

3.	DCC DM	After the website and data entry systems have been developed, test software applications and provide validation documentation.		NN CS 702 NN DM1004
4.	DCC DM	Create User Manuals that describe data management activities and processes.		
5.	DCC DM	Train and certify CSS, CCC, and DCC personnel in the proper procedures for entering and/or changing data, navigating the protocol website, and utilizing all applicable modules related to data entry.		NN DM 1005
6.	DCC DM	Create procedures and train CSS, DCC, and CCC personnel (if applicable) regarding the transfer of electronic data and/or paper CRF data.		
7.	DCC DM	Assist with the creation and management of data reports.		NN BIO 906

B. Data Collection and Transcription

#	***Who***	***Task***	***Attachment/ Reference***	***Related SOP***
1.	DCC	Ensure that the clinical protocol, the Data Management Plan, User Manuals and guides, and/or Manuals of Operation describe in detail all methods for collecting, evaluating, changing and transmitting subject data to the DCC.		NN PM 503 NN DM 1002
2.	PPI and DCC DM	Develop protocol-specific CRFs, other appropriate data collection forms, and log sheets to capture all required study information.		NN DM 1003
3.	DCC	During the Qualification and/or Site Initiation Visit, confirm that sites satisfy requirements for data collection, storage, transmission, and retention.		NN SS 401 NN SS 402
4.	DCC	During the Site Initiation Visit, or when appropriate, train site staff on proper completion of all CRFs, data collection forms, and log sheets.[1]		NN SS 402
5.	DCC	If using remote data entry or other electronic systems, train CSS personnel on the use of those systems.		NN CS 704
6.	DCC	Train site staff on proper correction of incorrect entries.1	NN DM 1005-B	NN DM 1005

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#	Who	Task	Attachment/ Reference	Related SOP
Note: [1]Include the following CRF completion guidelines: Transcribe data to the paper CRF (or enter data into the eCRF) in a timely manner from the source documentation; record all subject data and information in black ballpoint pen on paper CRF; complete all fields according to protocol specifications and site initiation training; correct errors on paper CRF by striking through the error with a single straight line, making the correction and then dating and initialing the correction; ensure the original entry is not obliterated by the correction and if necessary, note an explanation or clarification in the CRF margin. “White-Out” or similar products that obscure original data or information may not be used to correct errors on source documents or paper CRFs under any circumstances.				

C. Data Management and Retention

#	Who	Task	Attachment/ Reference	Related SOP
1.	DCC DM	Specify a method for site staff to review (and/or audit) and correct data prior to transmission to the DCC.[1]		NN SS 402 NN SS 403 NN DM 1005
2.	DCC	If sites do not comply with data management procedures, work with the PPI/CCC to document noncompliance and (if necessary) institute training or termination procedures.		
Note: [1] Monitors must not make any changes to original subject documentation or CRF.				

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Attachment NN DM 1001 – A Document History

NeuroNEXT Network Standard Operating Procedure (SOP) Clinical Data Management SOP NN DM 1001					
Version	**Description of Modification**	**Reason or Justification for Modification**	**Issue Date**	**Effective Date**	**Reviewer(s)**
1.0	New	N/A	30MAR2012	29APR2012	N/A
2.0	Updated “1996 ICH E6 Consolidated Guidance” to “2016 Integrated Addendum to ICH E6(R1): Guideline for Good Clinical Practice E6(R2)”. Updated signature block to accommodate for electronic signatures.	Updates for version 2.0	22Feb2023	08Apr2023	Catherine Gladden
3.0	Minor edits for clarity	Periodic review	01Mar2024	15Apr2024	Preeti Paul

NN DM 1001 Clinical Data Management v3.0 clean

Final Audit Report 2024-03-11

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Document page count:	7
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