

# NeuroNEXT Network

## Standard Operating Procedure (SOP)




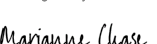
### Data Management Plan Development

#### Version 3.0

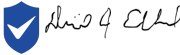
#### SOP NN DM 1002

Originators: NeuroNEXT CCC and DCC Personnel

Reviewed and Approved by:

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## NEURONEXT NETWORK STANDARD OPERATING PROCEDURE FOR DATA MANAGEMENT PLAN DEVELOPMENT

### 1. POLICY

A comprehensive Data Management Plan will be created for the NeuroNEXT Network that describes areas of Data Management (DM) oversight and activities that will be conducted for the Network. The NeuroNEXT Network comprehensive Data Management Plan may include, but is not limited to, the following components:

- Overview
- Website development
- Database model
- Database and website environments
- Electronic CRF (eCRF) development and testing
- Save-audit testing
- Subject identification system
- Clinical data entry procedures
- Reports
- Data backup and archiving
- Data sharing
- Electronic data transfer
- Adverse event tracking and management
- MedDRA coding system
- Data quality assurance
- Glossary
- Appendices, including all study-specific Data Management Plans

The NeuroNEXT Data Coordinating Center (DCC) DM Team will collaborate with the NeuroNEXT Clinical Coordinating Center (CCC) to develop the comprehensive Data Management Plan. The Plan will be maintained by the DCC DM Team, and may be updated (as needed) in collaboration with the CCC.

#### ***Study-specific Data Management Plans***

A study-specific Data Management Plan will be developed by the DCC DM team for each study protocol, in collaboration with the CCC, the Protocol Principal Investigator (PPI) and study team, and others as needed. The study-specific Plan will be included as an appendix to the NeuroNEXT comprehensive Data Management Plan. The study-specific Plan is established at the beginning of the study, and will be maintained as a living document.

The primary purpose of the study-specific Data Management Plan is to convey website details, protocol information, and data entry application details to the IT application developers at the DCC. While the Plan may contain informational materials related to the project, certain information provided in the Plan may be considered to be written specifications. Components that may be included in the study-specific Data Management Plan are described in section 8.C.

### 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 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 DM Team is responsible for creating a comprehensive Data Management Plan for the NeuroNEXT Network with an appendix for each study protocol, in consultation with the CCC and NeuroNEXT Leadership (CCC PI and DCC PI).

The DCC DM Team will maintain the comprehensive Data Management Plan, and will update the Plan as needed in collaboration with the NeuroNEXT CCC.

Individual Study-Specific Data Management Plans will be created and maintained by the DCC Data Management Team as appendices to the main Data Management Plan in collaboration with, but not limited to, the NeuroNEXT CCC, the Protocol Principal Investigator (PPI) and study team, and others as needed.

The responsibility to conduct any or all of these activities may be delegated at the discretion of the Sponsor to 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, 6.0 Clinical Trial Protocol and Protocol Amendment(s)

ICH E8 General Considerations for Clinical Trials (December 1997)

#### **5. REFERENCES TO OTHER APPLICABLE SOPS**

NN GA 103	Document Development and Change Control
NN GA 107	Data Sharing
NN CS 702	Application Development and Validation
NN CS 703	IT Environments
NN CS 704	System Security Measures and Website Access
NN CS 705	Data Backup, Recovery, and Contingency Plans
NN QA 801	Quality Assurance Audits
NN QA 802	Quality Management
NN BIO 904	Generation and Validation of Analysis Data Sets
NN BIO 905	Validating Statistical Programs and Deliverables
NN BIO 906	Presenting Statistical Results for a Final Study Report
NN DM 1001	Clinical Data Management
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

#### **6. ATTACHMENTS AND REFERENCES**

NN DM 1002 - A Document History

#### **7. TERMS AND ABBREVIATIONS**

The following terms and abbreviations are used in this document:

AE Adverse Events

CCC	Clinical Coordinating Center at Massachusetts General Hospital
CFR	Code of Federal Regulations
DCC	Data Coordinating Center at The University of Iowa
DM	Data Management
FDA	Food and Drug Administration
GCP	Good Clinical Practices
ICH	International Conference on Harmonisation
PPI	Protocol Principal Investigator
QA	Quality Assurance
SAE	Serious Adverse Events

## 8. SPECIFIC PROCEDURES

### A. Maintaining the NeuroNEXT Network Comprehensive Data Management Plan

The DCC DM Team will create the NeuroNEXT Network comprehensive Data Management Plan as described in the Policy section, and will maintain the Plan as described below:

#	Who	Task	Attachment/ Reference	Related SOP
1.	DCC DM Team Lead	Determine who is responsible for reviewing and modifying the comprehensive Data Management Plan.		NN DM 1001
2.	DCC DM Team	As needed, update the Data Management Plan to reflect changes in DM procedures.		
3.	DCC DM Team	After all revisions are complete, update the version date and increment the version number to the next whole number (1.x to 2.0).		NN GA 103

### B. Creating and Maintaining a Study-Specific Data Management Plan

#	Who	Task	Attachment/ Reference	Related SOP
1.	DCC DM Lead	Assign a Data Management Team member to create and maintain the study-specific Data Management Plan.		
2.	Assigned DCC Team Member	Create the study-specific Data Management Plan, and include applicable components described in section 8.C.		
3.	DCC DM Lead	Review the study-specific Data Management Plan and offer feedback, if necessary.		
4.	DCC DM Team Lead	Include the final study-specific Data Management Plan as an appendix in the NeuroNEXT Network comprehensive Data Management Plan.		
5.	DCC DM Team Leader	Periodically review the study-specific Data Management Plan, and track any major changes on a document change log.		

### C. Components of a NeuroNEXT Study-Specific Data Management Plan

Each Study-Specific Data Management Plan may include, but is not limited to, the components described in this section.

#	Who	Task	Attachment/ Reference	Related SOP
1.	DCC DM Team	<b>Study Overview</b> Describe the rationale, intervention, and study design.		
2.	Study Team	<b>CRF Development</b> Describe all CRFs that are developed for the study, and the process for developing, finalizing, and approving paper CRF templates for the study.		NN DM 1003
3.	DCC DM Team	<b>Electronic CRF Availability</b> Describe the availability of eCRFs including, but not limited to, the order of events and CRF visits.		
4.	DCC DM Team	<b>Subject Identification</b> Describe the subject ID system, if different than the NeuroNEXT customary system.		NN CS 704
5.	DCC DM Team	<b>Access to Subject Enrollment and Data Entry</b> Describe these processes in detail.		NN CS 704
6.	DCC DM Team	<b>Website</b> Describe any additional necessary information about the website that is not included in the comprehensive Data Management Plan.		NN CS 704
7.	DCC DM Team	<b>Reports</b> Describe basic reports that the Data Management team may produce that are not already mentioned in the comprehensive Data Management Plan.		NN BIO 904 NN BIO 905 NN BIO 906
8.	DCC DM Team and DCC QM Team	<b>Data Quality Assurance</b> Describe any QA processes and QC metrics that are specific to the NeuroNEXT study.		NN QA 801 NN QA 802
9.	DCC DM Team	<b>Glossary</b> Define any study-specific terms		
10.	DCC DM Team	Incorporate additional sections, as appropriate.		

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