NeuroNEXT Network

Standard Operating Procedure (SOP)
Concomitant Medications Coding
Version 2.0
SOP NN DM 1007

Originators: NeuroNEXT CCC and DCC Personnel

Reviewed and Approved by:

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NN DM 1007

NEURONEXT NETWORK STANDARD OPERATING PROCEDURE FOR CONCOMITANT MEDICATIONS CODING

1. POLICY

This SOP provides guidance for the coding of concomitant medications and therapeutic products administered to or used by subjects who are participating in clinical trials supported by the NeuroNEXT Network. The NeuroNEXT Data Coordinating Center (DCC) uses a standardized classification system to ensure that clinical trial reports that summarize and categorize medicinal and therapeutic products are concise, easily analyzed, and accurately interpreted.

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

Depending on the nature and requirements of the study protocol, DCC personnel may be responsible for coding concomitant medications for NeuroNEXT clinical trials.

4. APPLICABLE REGULATIONS AND GUIDELINES

ICH E6	Good Clinical Practice: Consolidated Guidance

5. REFERENCES TO OTHER APPLICABLE SOPS

NN BIO 904	Generation and Validation of Analysis Datasets
NN BIO 906	Report Writing

6. ATTACHMENTS AND REFERENCES

NN DM 1007 - A	Document History
WHO Drug Dictionary Enhanced Guide	*the* Uppsala Monitoring Centre (UMC), August 15, 2005. http://www.umc-products.com/graphics/2489.pdf
S. Eric Ceh	Documenting Concomitant Medications in Clinical Trials. *Journal of Clinical Research Best Practices,* Vol. 3, No. 7, July 2007. www.firstclinical.com

7. TERMS AND ABBREVIATIONS

The following terms and abbreviations are used in this document:

ATC Code	Anatomical-Therapeutic-Chemical classification used for the coding of therapeutic drugs. One drug may code to several ATC codes, depending on its therapeutic applications.
eCRF	Electronic Case Report Forms

CCC	Clinical Coordinating Center at Massachusetts General Hospital
CSS	Clinical Study Site(s)
DCC	Data Coordinating Center at The University of Iowa
DCC Coders	Trained personnel at the DCC who perform coding and classification of concomitant medications or other therapeutic products.
EDC	Electronic Data Capture system at the DCC
PPI	Protocol Principal Investigator
WHO	World Health Organization
WHO-DDE	World Health Organization Drug Dictionary – Enhanced; maintained by the Uppsala Monitoring Centre (UMC), Uppsala, Sweden

8. SPECIFIC PROCEDURES

A. Concomitant Medications Coding

The term 'concomitant medication' refers to any medicinal product that is not a study drug or part of the study protocol, and is taken by or administered to a subject during the course of her/his participation in a clinical trial. These products most often refer to medications, although the concomitant use of other therapeutic products, such as herbal remedies, biologics, dietary supplements, diagnostic substances, or contrast media, may also be of interest in the analysis of clinical trial data. For the purposes of this SOP, the term 'concomitant medications' refers to any medicinal or therapeutic product that is used by the subject during the course of a NeuroNEXT clinical trial.

According to the requirements of the protocol, concomitant medication information is recorded on source documents at the clinical site, and is then entered into the electronic data capture (EDC) system through the appropriate electronic Case Report Form (eCRF). Because concomitant medications may be referred to in multiple ways (e.g. a drug may be referred to by its trade name, generic name, or chemical substance name), it is important for quality assurance and data analysis purposes that the names and classifications of these products are standardized. The coding process described below may be employed by the DCC to verify that concomitant medications are accurately represented in the study database and to minimize confusion and ambiguity that may result from the application of multiple naming conventions that may be used by different NeuroNEXT Clinical Study Sites (CSS).

As required by a NeuroNEXT protocol, DCC Biostatisticians may prepare reports containing listings of concomitant medications with coding conventions applied from data that are stored in the study database. The listings are then reviewed by trained DCC personnel to standardize the information. During the coding process, a unique drug code is assigned, along with associated Anatomical/Therapeutic/Chemical (ATC) classification codes. Each drug is coded with an "Official" ATC Code, but a drug also may be referenced to several "Alternative" ATC Codes. The DCC coder will evaluate drugs that are referenced to multiple alternative codes, and will select a common code based on medical review so that identical concomitant medication products are listed under a single name or classification.

The reviewed coding results are used by DCC Biostatisticians to group the concomitant medications data in an analytically meaningful way, and to create final reports that are readily interpreted.

The current version of the World Health Organization Drug Dictionary-Enhanced (WHO-DDE) will be used as a reference during coding for appropriate NeuroNEXT studies. If it is established that the WHO-DDE will not be used for a study, the DCC will collaborate with the PPI and the CCC to develop a standardized system for coding and classification for a study based on WHO or other appropriate coding conventions. The standardized system may be used to standardize drug names, assign drug codes, identify active ingredients, and classify drugs according to their ATC classification.

#	*Who*	*Task*	*Attachment/ Reference*	*Related SOP*
1.	CCC and DCC	Collaborate to develop a plan for standardizing and tabulating concomitant medications for the NeuroNEXT Network.		
2.	CSS	Submit a list of all concomitant medications for a study subject on the appropriate electronic Case Report Form (eCRF), using the standardized format.		
3.	DCC	In consultation with the PPI and CCC, create a standardized format for tabulating concomitant medications for the study.		
4.	DCC Biostatisticians	For each applicable NeuroNEXT study, create a listing of all concomitant medications that have been submitted to the DCC database through the EDC system.		NN BIO 904
5.	DCC Coder	Code and classify concomitant medications according to the plan for standardizing and tabulating medicinal and therapeutic products for the study.		
6.	DCC Coder	Categorize concomitant medications by Organ or System and Therapeutic Indication using WHO drug coding guidelines, the WHO-DDE (if applicable), or another agreed-upon coding system.		
7.	DCC Biostatisticians	Generate reports that summarize concomitant medications data for the study.		NN BIO 906

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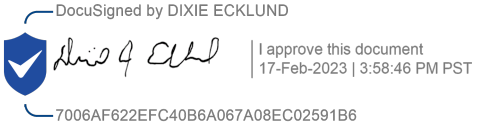
DIXIE ECKLUND dixie-ecklund@uiowa.edu Security Level: Email, Account Authentication (Required)	 Signature Adoption: Drawn on Device Signature ID: 7006AF62-2EFC-40B6-A067-A08EC02591B6 Using IP Address: 128.255.112.230 With Signing Authentication via DocuSign password With Signing Reasons (on each tab): I approve this document	Sent: 2/17/2023 8:42:08 AM Viewed: 2/17/2023 6:57:53 PM Signed: 2/17/2023 6:58:50 PM
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Marianne Chase MCHASE@mgh.harvard.edu Sr Director, Clinical Trial Operations Insight OBO The Massachusetts General Hospital Security Level: Email, Account Authentication (Required), Logged in	 Signature Adoption: Pre-selected Style Signature ID: 58FE690F-6BCA-4F23-90E3-DA15BCE3F578 Using IP Address: 73.114.253.109 With Signing Authentication via DocuSign password With Signing Reasons (on each tab): I approve this document	Sent: 2/17/2023 8:42:08 AM Viewed: 2/17/2023 1:20:25 PM Signed: 2/17/2023 1:20:51 PM
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