Summary of Core Recommendations: Myasthenia Gravis CDEs

Start-up Resource – NINDS Myasthenia Gravis CDE Recommendations

The National Institute of Neurological Disorders and Stroke (NINDS) and other Federal agencies and international organizations have the common mission of developing data standards for clinical research. Through the efforts of subject-specific working groups, topic-driven data elements have been created. The first set of Common Data Elements (CDEs) for Myasthenia Gravis was developed in 2011. The Core data elements to be used by an investigator when beginning a research study in this disease/disorder are listed in this resource document. All other recommendations are listed on the website and should be considered based on study type.

Each CDE or instrument could be classified per the definitions below:

General Core: A data element that is required for all NINDS funded studies.

Disease Core: A data element that collects essential information applicable to any disease-specific study, including all therapeutic areas. The NINDS and its appointed working groups assign the disease "Core" classification based on the current clinical research best practices. In each case, the disease Core CDEs are a small subset of the available CDEs, where it is anticipated that investigators will need to collect the disease Core CDEs on any type of study. These are required for all disease-specific studies.

Disease Supplemental - Highly Recommended: A data element which is essential based on certain conditions or study types in clinical research studies. In most cases, these have been used and validated in the disease area. These data elements are strongly recommended for the specified disease condition, study type or design.

Disease Supplemental: A data element which is commonly collected in clinical research studies. Use depends upon the study design, protocol or type of research involved. These are recommended, but not required, for studies.

Disease Exploratory: A data element that requires further validation but may fill current gaps in the CDEs and/or substitute for an existing CDE once validation is complete. Such data elements show great promise but require further validation before they are ready for prime-time use in clinical research studies. They are reasonable to use with the understanding that it has limited validation in the target group.

Summary of Core Recommendations: Myasthenia Gravis CDEs

National Institute of Health (NIH) Resources: *The NINDS also strongly encourages researchers to use these NIH developed materials for NINDS-sponsored research, when appropriate. Utilization of these resources will enable greater consistency for NINDS-sponsored research studies. These tools are free of charge.*	• **NIH Toolbox** • **Quality of Life in Neurological Disorders (Neuro-QOL)** • **Patient-Reported Outcomes Measurement Information System (PROMIS)**

Core CDEs for all NINDS Studies[1]:

Domain/Sub-Domain	CDE Name	CDE ID	Study Type
Participant Characteristics; Demographics	Birth date	C00007	All studies
Participant Characteristics; Demographics	Ethnicity USA category	C00020	All studies
Participant Characteristics; Demographics	Race USA category	C00030	All studies
Participant Characteristics; Demographics	Birth sex assigned type	C58676	All studies
Participant Characteristics; Demographics	Gender identity type	C58677	All studies
Participant History and Family History; General Health History	Medical history condition text	C00322	All studies
Participant History and Family History; General Health History	Medical history condition SNOMED CT code	C00313	All studies

[1] Note: Education year count C00015 is no longer a general Core CDE

Summary of Core Recommendations: Myasthenia Gravis CDEs

Core CDEs for Myasthenia Gravis Studies:

Domain; Sub-Domain	Data element	CDE ID
Participant/Subject Characteristics; Demographics	Ethnicity USA paternal category	C00021
Participant/Subject Characteristics; Demographics	Ethnicity USA maternal category	C00022
Participant/Subject Characteristics; Demographics	Race USA paternal category	C00032
Participant/Subject Characteristics; Demographics	Race USA maternal category	C00033
Participant/Subject Characteristics; Demographics	Birth location state name	C12611
Participant/Subject Characteristics; Demographics	Ethnic race relation indicator	C17973
Participant/Subject Characteristics; Social Status	Education level USA type	C00012
Participant/Subject Characteristics; Social Status	Marital or partner status	C00207
Participant/Subject History and Family History; General Health History	Medical history taken date and time	C00314
Participant/Subject History and Family History; General Health History	Medical history global assessment indicator	C00315
Participant/Subject History and Family History; General Health History	Medical history condition end date and time	C00316
Participant/Subject History and Family History; General Health History	Medical history condition start date and time	C00317

Summary of Core Recommendations: Myasthenia Gravis CDEs

Domain; Sub-Domain	Data element	CDE ID
Participant/Subject History and Family History; General Health History	Medical history condition ongoing indicator	C00319
Participant/Subject History and Family History; General Health History	Family history medical condition indicator	C00721
Participant/Subject History and Family History; General Health History	Family history medical condition relative type	C00722
Treatment/Intervention Data; Drugs	Medication prior or concomitant dose	C02006
Treatment/Intervention Data; Drugs	Medication prior or concomitant dose frequency	C02011
Treatment/Intervention Data; Drugs	Medication prior or concomitant start date and time	C02016
Treatment/Intervention Data; Drugs	Medication prior concomitant dose unit of measure	C02022
Treatment/Intervention Data; Drugs	Medication side effect or complication indicator	C12641
Treatment/Intervention Data; Drugs	Myasthenia gravis treatment type	C12689
Treatment/Intervention Data; Drugs	Medication prior or concomitant response text	C12691
Disease/Injury Related Events; Classification	Confirmatory diagnostic test assay type	C12777
Disease/Injury Related Events; Classification	Test assay perform indicator	C12778
Disease/Injury Related Events; Classification	Test assay perform date	C12779
Disease/Injury Related Events; Classification	Test assay abnormality indicator	C12780
Disease/Injury Related Events; Classification	Test assay result	C12781

Summary of Core Recommendations: Myasthenia Gravis CDEs

Domain; Sub-Domain	Data element	CDE ID
Disease/Injury Related Events; History of Disease/Injury Event	Medical history taken date and time	C00314
Disease/Injury Related Events; History of Disease/Injury Event	Symptoms first appeared date and time	C08006
Disease/Injury Related Events; History of Disease/Injury Event	Diagnosis first given date and time	C08007
Disease/Injury Related Events; History of Disease/Injury Event	Symptom first experienced type	C10502
Disease/Injury Related Events; History of Disease/Injury Event	Symptom first experienced distribution category	C12642
Disease/Injury Related Events; History of Disease/Injury Event	Myasthenia Gravis Foundation of America (MGFA) classification type	C12643
Assessments and Examinations; Imaging Diagnostics	Imaging modality type	C02437
Assessments and Examinations; Imaging Diagnostics	Imaging study date and time	C02494
Assessments and Examinations; Imaging Diagnostics	Imaging chest result	C12809
Assessments and Examinations; Imaging Diagnostics	Diagnosis thymoma type	C12810
Assessments and Examinations; Laboratory Tests and Biospecimens/Biomarkers	Lab specimen collection date and time	C01701
Assessments and Examinations; Laboratory Tests and Biospecimens/Biomarkers	Lab test name	C01705
Assessments and Examinations; Laboratory Tests and Biospecimens/Biomarkers	Lab test result value	C01706

Summary of Core Recommendations: Myasthenia Gravis CDEs

Domain; Sub-Domain	Data element	CDE ID
Assessments and Examinations; Laboratory Tests and Biospecimens/Biomarkers	Lab test abnormality significance type	C01707
Assessments and Examinations; Laboratory Tests and Biospecimens/Biomarkers	Lab test result status	C01709
Assessments and Examinations; Laboratory Tests and Biospecimens/Biomarkers	Pregnancy test qualitative result value	C01710
Assessments and Examinations; Laboratory Tests and Biospecimens/Biomarkers	Lab test result unit of measure	C01711
Assessments and Examinations; Laboratory Tests and Biospecimens/Biomarkers	Specimen source type	C12226
Assessments and Examinations; Laboratory Tests and Biospecimens/Biomarkers	Tissue specimen size measurement	C12229
Assessments and Examinations; Laboratory Tests and Biospecimens/Biomarkers	Tissue specimen collection date and time	C12230
Assessments and Examinations; Laboratory Tests and Biospecimens/Biomarkers	Preservation technique used type	C12233
Assessments and Examinations; Laboratory Tests and Biospecimens/Biomarkers	Histochemical stains used type	C12235

Summary of Core Recommendations: Myasthenia Gravis CDEs

Domain; Sub-Domain	Data element	CDE ID
Treatment/Intervention Data; Surgeries and Other Procedures	Thymectomy date and time	C12811
Treatment/Intervention Data; Surgeries and Other Procedures	Thymectomy technique type	C12812
Treatment/Intervention Data; Surgeries and Other Procedures	Thymectomy transcervical type	C12813
Treatment/Intervention Data; Surgeries and Other Procedures	Thymectomy videoscopic type	C12814
Treatment/Intervention Data; Surgeries and Other Procedures	Thymectomy transsternal type	C12815
Treatment/Intervention Data; Surgeries and Other Procedures	Thymus non-thymoma histology grade	C12816
Treatment/Intervention Data; Surgeries and Other Procedures	Thymoma histology grade	C12817
Assessments and Examinations; Vital Signs and Other Body Measures	Vital signs date and time	C01519
Assessments and Examinations; Vital Signs and Other Body Measures	Weight measurement	C01541
Assessments and Examinations; Vital Signs and Other Body Measures	Body mass index value	C11131

General Core for all Studies:

Investigators should review the FDA's "Guidance for Industry: Suicidal Ideation and Behavior: Prospective Assessment of Occurrence in Clinical Trials" for the most up-to-date information about suicidal ideation and behavior. One scale that FDA suggests is the Columbia Suicide Severity Rating Scale (C-SSRS) (available at Columbia Suicide Severity Rating Scale).

Core Myasthenia Gravis Instruments:

1. Myasthenia Gravis Composite (MGC)

2. Manual Muscle Testing

For the complete list of NINDS CDE recommendations for MG, please see the NINDS CDE website.