

Myasthenia Gravis (MG) CDE Highlight Summary

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.

- National Institutes of Health (NIH) Toolbox
- Quality of Life in Neurological Disorders (Neuro-QOL)
- Patient-Reported Outcomes Measurement Information System (PROMIS)

Suicidal Ideation

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 Website](#)).

Disease/Domain	Recommendations and List of Forms
Myasthenia Gravis (MG)	<p>Core elements:</p> <p>See Start-Up Resource Listing document MG Start-Up Resource Listing (Myasthenia Gravis Start-Up Resource Listing)</p> <p>Supplemental – Highly Recommended instruments: None</p>
Participant/Subject Characteristics/Demographics	<p>Core: Demographics, General Core</p> <p>Supplemental – Highly Recommended: None</p> <p>Supplemental: Demographics</p> <p>Exploratory: None</p>
Participant / Subject Characteristics / Social Status	<p>Core: Social Status</p> <p>Supplemental – Highly Recommended: None</p> <p>Supplemental: None</p> <p>Exploratory: None</p>
Participant/Subject History and Family History/General Health History	<p>Core: Family History, Medical History</p> <p>Supplemental – Highly Recommended: None</p> <p>Supplemental: Family History, Medical History, Prenatal and Perinatal History, Surgical History</p> <p>Exploratory: None</p>

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Disease/Injury Events/History of Disease/Injury Event	<p>Core: Medical History of MG</p> <p>Supplemental – Highly Recommended: None</p> <p>Supplemental: Medical History of MG</p> <p>Exploratory: None</p>
Disease/Injury Related Events/Classification	<p>Core: Confirmatory Diagnostic Tests</p> <p>Supplemental – Highly Recommended: None</p> <p>Supplemental: None</p> <p>Exploratory: None</p>
Assessments and Examinations/Physical /Neurological Examination	<p>Core: None</p> <p>Supplemental – Highly Recommended: None</p> <p>Supplemental: Physical Examination, Polysomnography</p> <p>Exploratory: None</p>
Assessments and Examinations / Vital Signs and Other Body Measures	<p>Core: Vital Signs</p> <p>Supplemental – Highly Recommended: None</p> <p>Supplemental: Vital Signs</p> <p>Exploratory: None</p>
Assessments and Examinations / Laboratory Tests and Biospecimens / Biomarkers	<p>Core: Fat Aspirate Tissue Specimens, Muscle Biopsy and Autopsy Tissue, Peripheral Nerves – Biopsies and Autopsies, Skin Biopsies for Qualification of Intraepidermal Nerve Fibers, Laboratory Tests and Tracking</p> <p>Supplemental – Highly Recommended: None</p> <p>Supplemental: Biomarkers and Sample Data Guidelines, Biospecimen Collection Guidelines for Use, Fat Aspirate Tissue Specimens, Gene Table and Guidelines for Use, Laboratory Tests and Tracking, Laboratory Tests Recommendations Table and Guidelines for Use, Muscle Biopsy and Autopsy Tissue, Mutation Analysis, Skin Biopsies for Qualification of Intraepidermal Nerve Fibers, Peripheral Nerves – Biopsies and Autopsies</p> <p>Exploratory: None</p>

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Assessments and Examinations / Imaging Diagnostics	<p>Core: Chest Imaging - MG</p> <p>Supplemental – Highly Recommended: None</p> <p>Supplemental: Brain Magnetic Resonance Imaging (MRI), Cardiac Magnetic Resonance Imaging (MRI), Diffusion Tensor Imaging (DTI), Dual-Energy X-Ray Absorptiometry (DEXA), Echocardiogram, Magnetic Resonance Imaging (MRI), Magnetic Resonance Spectroscopy (MRS)</p> <p>Exploratory: None</p>
Assessments and Examinations/Non-Imaging Diagnostics	<p>Core: None</p> <p>Supplemental – Highly Recommended: None</p> <p>Supplemental: Electrocardiogram (ECG), Electrophysiology – MG, Holter Examination</p> <p>Exploratory: None</p>
Treatment / Intervention Data / Drugs	<p>Core: Prior and Current Treatments for MG</p> <p>Supplemental – Highly Recommended: None</p> <p>Supplemental: Prior and Current Treatments for MG</p> <p>Exploratory: None</p>
Treatment / Intervention Data / Surgeries and Other Procedures	<p>Core: Thymectomy</p> <p>Supplemental – Highly Recommended: None</p> <p>Supplemental: Thymectomy</p> <p>Exploratory: None</p>
Treatment / Intervention Data / Therapies	<p>Core: None</p> <p>Supplemental – Highly Recommended: None</p> <p>Supplemental: Gastrointestinal Therapies, Respiratory Interventions</p> <p>Exploratory: None</p>
Outcomes and Endpoints/Summary of All Outcome Recommendations	<p>Core: None</p> <p>Supplemental – Highly Recommended: None</p> <p>Supplemental: MG Clinical Outcomes Recommendations by Domain and Classification – MG</p> <p>Exploratory: None</p>

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Outcomes and Endpoints/Global Outcome	<p>Core: MG Composite, MG Status</p> <p>Supplemental – Highly Recommended: None</p> <p>Supplemental: MG Status</p> <p>Exploratory: None</p>
Outcomes and Endpoints/Emotional and Cognitive Status	<p>Core: None</p> <p>Supplemental – Highly Recommended: None</p> <p>Supplemental: Cognitive Guidelines for Use</p> <p>Exploratory: None</p>
Outcomes and Endpoints/End Points	<p>Core: None</p> <p>Supplemental – Highly Recommended: None</p> <p>Supplemental: Death Report</p> <p>Exploratory: None</p>
Outcomes and Endpoints/Functional Status	<p>Core: None</p> <p>Supplemental – Highly Recommended: None</p> <p>Supplemental: None</p> <p>Exploratory: Modified Rankin Scale (mRS)</p>
Outcomes and Endpoints / Pediatric	<p>Core: None</p> <p>Supplemental – Highly Recommended: None</p> <p>Supplemental: Pediatric Cognitive Instrument Recommendations by Domain and Classification, Pediatric Cognitive Instrument Table</p> <p>Exploratory: None</p>
Outcomes and Endpoints/Pulmonary Function Testing/Respiratory Status	<p>Core: None</p> <p>Supplemental – Highly Recommended: None</p> <p>Supplemental: Measures of Gas Exchange, Pulmonary Assessment Master Outline and Guidelines for Use, Pulmonary Function Testing</p> <p>Exploratory: None</p>

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Outcomes and Endpoints / Quality of Life	<p>Core: None</p> <p>Supplemental – Highly Recommended: None</p> <p>Supplemental: Myasthenia Gravis Quality of Life (MG-QOL), Myasthenia Gravis Quality of Life 15 (MG-QOL-15), Short Form-Item Health Survey (SF-36)</p> <p>Exploratory: None</p>