To be completed at every study visit

1. \*Date of Visit (m m/d d/y y y y):
2. \*MGFA Post Intervention Status (choose only one):

CSR

PR

MM-0

MM-1

MM-2

MM-3

Improved[[1]](#footnote-1)

Unchanged[[2]](#footnote-2)

Worse[[3]](#footnote-3)

Exacerbation

Died of MG

1. INNCB MG Scale
   1. Total Score:
   2. Muscle Fatigability Score:
2. QMG Score:
3. MG-MMT Score:
4. \*MG Composite:
5. MG-ADL Score:
6. MG-QOL15 Score:
7. Global Impression of Change, Patient:
8. Global Impression of Change, Physician:
9. Other measures of severity specify:

\* Elements classified as Core

## General Instructions

Myasthenia gravis status data are collected to monitor the progression of Myasthenia Gravis in a participant/subject. The Myasthenia Gravis Status CRF is to be completed at every study visit.

Important note: The data elements with an asterisk on this CRF Module are classified as Core (i.e., strongly recommended for all Myasthenia Gravis clinical studies to collect). The remaining data elements are classified as supplemental (i.e., non Core) and should only be collected if the research team considers them appropriate for their study. Please see the Data Dictionary for element classifications.

## Specific Instructions

Please see the Data Dictionary for definitions for each of the data elements included in this CRF Module.

### MGFA Post Intervention Status

* + Complete Stable Remission (CSR) – The patient has no symptoms or signs of MG for at least 1 year and has received no therapy for MG during that time. There is no weakness of any muscle on careful examination by someone skilled in the evaluation of neuromuscular disease. Isolated weakness of eye closure is accepted.
  + Pharmacologic Remissions (PR) – The same criteria as for CSR except that the patient continues to take some form of therapy for MG. Patients taking cholinesterase inhibitors are excluded from this category because their use suggests the presence of weakness.
  + Minimal Manifestation (MM) – The patient has no symptoms or functional limitations from MG but has some weakness on examination of some muscles. This class recognizes that some patients who otherwise meet the definition of CSR or PR do have weakness that is only detectable by careful examination.
  + MM-0: The patient has received no MG treatment for at least [1 year]. The duration of post-intervention status of outcome is left to the discretion of the Investigator, but should be predetermined.
  + MM-1: The patient continues to receive some form of immunosuppression but no cholinesterase inhibitors or other symptomatic therapy
  + MM-2: The patient has received only low dose cholinesterase inhibitors (< 120 mg pyridostigmine per day), for at least [1 year]. The duration of post-intervention status of outcome is left to the discretion of the Investigator, but should be predetermined.
  + MM-3: Patient has received cholinesterase inhibitors or other symptomatic therapy and some form of immunosuppression during the past year.
  + Improved (I) – A substantial decrease in pre-treatment clinical manifestations or a sustained substantial reductions in MG medications as defined in the protocol. In prospective studies, this should be defined as a specific decrease in a predetermined quantitative score, if the patient has not met minimal manifestations or better.
  + Unchanged (U) – No substantial change in pre-treatment clinical manifestations or reduction in MG medications as defined in the protocol. In prospective studies, this should be defined in terms of a maximum change in a predetermined quantitative score, if the patient has not met minimal manifestations or better.
  + Worse (W) – A substantial increase in pre-treatment clinical manifestations or a substantial increase in MG medications as defined in the protocol. In prospective studies, this should be defined as a specific increase in a predetermined quantitative score.
  + Exacerbation (E) – Patients who have fulfilled criteria for CSR, PR, or MM but subsequently developed clinical findings greater than permitted by these criteria. In prospective studies, this should be defined in terms of a change in a predetermined quantitative score.
  + Died of MG (D of MG) – Patients who died of MG, of complications of MG therapy, or within 30 days after thymectomy. List the cause.

1. To be defined in the protocol [↑](#footnote-ref-1)
2. To be defined in the protocol [↑](#footnote-ref-2)
3. To be defined in the protocol [↑](#footnote-ref-3)