

Inclusion/Exclusion – Natural History Study

Page 1 of 1

[Study Name/ID pre-filled]

Site Name: _____

Date Form Completed: ___/___/___ (mm/dd/yyyy)

Subject ID: _____

Visit: [pre-populated by database]

Inclusion Criteria

1. Does the participant/subject clinically present with CMD to LGMD spectrum disorder? Yes No

[Additional inclusion/exclusion criteria may be added as needed based on the protocol]

Is the participant/subject eligible for study enrollment based on the above criteria?

Yes

No



If no, specify: Inclusion Criterion Number(s): _____ **and/or**

Exclusion Criterion Number(s): _____

GENERAL INSTRUCTIONS

The study inclusion and exclusion criteria specify the characteristics of potential study participants/subjects that must be met prior to enrollment. Criteria may specify the appropriate age range, symptoms, disease area, etc. Additionally, circumstances that may hamper adherence to the protocol may also be listed in the inclusion and exclusion criteria (e.g., patient has another life-threatening disease or does not understand English.)

All Inclusion Criteria must be answered YES and all Exclusion Criteria must be answered NO or N/A in order for the participant/subject to be considered eligible for study participation.

Data system edit checks may need to be implemented on a study by study basis for situations where participants/subjects do not meet the eligibility criteria, but are still enrolled in the study.

SPECIFIC INSTRUCTIONS

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

- **Is the participants/subject eligible for study enrollment based on the above criteria?** - The participants/subject is eligible for study enrollment if all the inclusion criteria are answered YES and all the exclusion criteria are answered NO or N/A.
- **Inclusion Criterion Number(s)** - Enter the number(s) for the inclusion criterion/criteria the participant/subject did not meet. Multiple numbers should be separated by a comma.
- **Exclusion Criterion Number(s)** - Enter the number(s) for the exclusion criterion/criteria the participant/subject did not meet. Multiple numbers should be separated by a comma.