1. Stiffness:

SYSTEM: Have you had stiffness within the last 24 hours?

Press 1 if Yes

Press 2 if No

If YES, on average, please rate your amount of stiffness from 1-9 with 1 being minimal and 9 being the worst stiffness you ever have.

1. Pain:

SYSTEM: Have you had pain within the last 24 hours?

Press 1 if Yes

Press 2 if No

If YES, on average, please rate your amount of pain from 1-9 with 1 being minimal and 9 being the worst pain you ever have.

1. Weakness:

SYSTEM: Have you had weakness within the last 24 hours?

Press 1 if Yes

Press 2 if No

If YES, on average, please rate your amount of weakness from 1-9 with 1 being minimal and 9 being the worst attacks of weakness you ever have.

1. Tiredness/Fatigue:

SYSTEM: Have you had tiredness/fatigue within the last 24 hours?

Press 1 if Yes,

Press 2 if No

If YES, on average, please rate your amount of tiredness/fatigue from 1-9 with 1 being minimal and 9 being the worst tiredness you ever have.

## General Instructions

Important note: None of the data elements included on this CRF Module are classified as Core (i.e., strongly recommended). All data elements are classified as Exploratory (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

Administration time: Approximately 5 minutes

Myotonic Muscular Dystrophy:

Patients will be asked to call a central automated telephone number daily for 30 days. At each call the participant will be asked to record the severity of myotonia and gastrointestinal symptoms.  Participants will test grip strength at home, using a digital grip dynamometer, and record a daily strength measurement during the IVRS call.

The scoring for this procedure is as follows. For each symptom (stiffness, pain, weakness, and tiredness/fatigue), the subject will respond either 0 for No or 1 for Yes. If 1 is pressed on the phone, then they asked to rate the severity of the symptom from 1-9, with 1 being minimal and 9 being the maximum amount.

An interactive voice response system technology needs to be developed for each study.

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

The CRF includes all instructions available for the data elements at this time. More detailed instructions will be added in future versions of this CRF Module.

References

Statland JM, Wang Y, Richesson R, Bundy B, Herbelin L, Gomes J, Trivedi J, et al. An interactive voice response diary for patients with non-dystrophic myotonia. Muscle & Nerve, Jul;44(1):30-5, 2011.