Date of Exam:

1. Was a physical exam performed on the patient/participant? Yes (Specify results below)  No

If an abnormal result, please complete the corresponding ISCoS International SCI Data Sets elements, which are listed on the Clinical Assessment Form (F1716).

| Body System | Result[[1]](#footnote-1) | Describe Abnormality or Comment if Body System is Not Examined | If Abnormality, Clinically Significant? |
| --- | --- | --- | --- |
| Constitutional symptoms (e.g., fever, weight loss) | Normal  Abnormal  Not examined | Data to be entered by site | Clinically significant  Not clinically significant |
| Eyes | Normal  Abnormal  Not examined | Data to be entered by site | Clinically significant  Not clinically significant |
| Ears, Nose, Mouth, and Throat | Normal  Abnormal  Not examined | Data to be entered by site | Clinically significant  Not clinically significant |
| Cardiovascular**2** | Normal  Abnormal  Not examined | Data to be entered by site | Clinically significant  Not clinically significant |
| Respiratory**3** | Normal  Abnormal  Not examined | Data to be entered by site | Clinically significant  Not clinically significant |
| Gastrointestinal**4** | Normal  Abnormal  Not examined | Data to be entered by site | Clinically significant  Not clinically significant |
| Genitourinary**5** | Normal  Abnormal  Not examined | Data to be entered by site | Clinically significant  Not clinically significant |
| Musculoskeletal**6** | Normal  Abnormal  Not examined | Data to be entered by site | Clinically significant  Not clinically significant |
| Integumentary (skin and/or breast)**7** | Normal  Abnormal  Not examined | Data to be entered by site | Clinically significant  Not clinically significant |
| Neurological8 | Normal  Abnormal  Not examined | Data to be entered by site | Clinically significant  Not clinically significant |
| Psychiatric | Normal  Abnormal  Not examined | Data to be entered by site | Clinically significant  Not clinically significant |
| Endocrine**9** | Normal  Abnormal  Not examined | Data to be entered by site | Clinically significant  Not clinically significant |
| Hematologic/Lymphatic | Normal  Abnormal  Not examined | Data to be entered by site | Clinically significant  Not clinically significant |
| Allergic/Immunologic | Normal  Abnormal  Not examined | Data to be entered by site | Clinically significant  Not clinically significant |

**General Instructions**

The physical exam is generally administered at screening and/or baseline to determine study eligibility. It may also be administered at follow-up visits to track a patient/participant’s physical status.

Important note: None of the data elements included on this CRF are considered Core (i.e., strongly recommended for all studies to collect). These data elements are Supplemental, frequently collected on clinical trials, and should be collected if the research team considers them appropriate for their study.

**Specific Instructions**

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

* Date of Exam – Record the date (and time) the physical exam was performed. The date/time should be recorded to the level of granularity known (e.g., year, year and month, complete date plus hours and minutes, etc.) and in the format acceptable to the study database.
* Exam Performed – Choose one. Specify whether or not a physical exam was performed on the participant/subject.
* Body System – Each body system is pre-populated on the case report form.
* Result – Choose one. Indicate whether each body system examined had any abnormal findings. If an abnormal result, please complete the Clinical Assessment Form (F1716) which contains elements from the relevant ISCoS International SCI Data Sets (specified below).
* Description of Result – Provide a description of each abnormal result found during the physical exam, or provide an explanation of why the body system was not examined. See the data dictionary for additional information on coding the abnormality using the Systematized Nomenclature of Medicine-Clinical Terms (SNOMED CT).
* If Abnormality, Clinically Significant? – Choose one. If the body system had an abnormal finding, record whether the abnormality is Clinically Significant. Any Abnormal, Clinically Significant finding at screening should be recorded on the Medical History CRF as well.
* Special Note: Questions from the following ISCoS International SCI Data Sets have been included on this template CRF:

**2** [International SCI Cardiovascular Function Basic Data Set](http://www.iscos.org.uk/international-sci-cardiovascular-function-data-sets) (Version 1.1)

**3** [International SCI Pulmonary Function Basic Data Set](http://www.iscos.org.uk/international-sci-pulmonary-function-data-sets) (Version 1.0)

**4** [International SCI Bowel Function Basic Data Set](http://www.iscos.org.uk/international-sci-bowel-data-sets) (Version 1.0)

**5** [International SCI Lower Urinary Tract Function Basic Data Set](http://www.iscos.org.uk/international-sci-lower-urinary-tract-function-data-sets) (Version 1.0)

**6** [International SCI Musculoskeletal Basic Data Set](http://www.iscos.org.uk/international-sci-musculoskeletal-data-sets) (Version 1.0)

**7** [International SCI Skin and Thermoregulation Function Basic Data Set](http://www.iscos.org.uk/international-sci-skin-and-thermoregulation-function-data-sets) (Version 1.0)

8 [International Standards for Neurological Classification of SCI Worksheet](http://www.asia-spinalinjury.org/elearning/ISNCSCI.php)

9 [International SCI Endocrine and Metabolic Function Basic Data Set](http://www.iscos.org.uk/international-sci-endocrine-and-metabolic-function-data-sets) (Version 2.0)

1. Indicator is based on description of “Normal” for non-SCI population. [↑](#footnote-ref-1)