## CDEs

Date of Exam (month/day/year):

1. Hand preference\*: (Hand participant/subject uses predominantly, not necessarily hand he/she writes with exclusively)

[ ]  Left hand [ ]  Right hand [ ]  Both hands [ ]  Unknown

1. Was a physical exam performed on the participant/subject?

[ ]  Yes (Specify results below) [ ]  No

Table for Data Collection

| **Body System** | **Result** | **Describe Abnormality or Comment if Body System is Not Examined** | **If Abnormality, Clinically Significant?** |
| --- | --- | --- | --- |
| Allergic/Immunologic | [ ]  Normal[ ]  Abnormal[ ]  Not assessed | Data to be filled in by site | [ ]  Clinically significant[ ]  Not clinically significant |
| Cardiovascular | [ ]  Normal[ ]  Abnormal[ ]  Not assessed | Data to be filled in by site | [ ]  Clinically significant[ ]  Not clinically significant |
| Constitutional symptoms (e.g., fever, weight loss) | [ ]  Normal[ ]  Abnormal[ ]  Not assessed | Data to be filled in by site | [ ]  Clinically significant[ ]  Not clinically significant |
| Ears, Nose, Mouth, and Throat | [ ]  Normal[ ]  Abnormal[ ]  Not assessed | Data to be filled in by site | [ ]  Clinically significant[ ]  Not clinically significant |
| Endocrine | [ ]  Normal[ ]  Abnormal[ ]  Not assessed | Data to be filled in by site | [ ]  Clinically significant[ ]  Not clinically significant |
| Eyes | [ ]  Normal[ ]  Abnormal[ ]  Not assessed | Data to be filled in by site | [ ]  Clinically significant[ ]  Not clinically significant |
| Gastrointestinal | [ ]  Normal[ ]  Abnormal[ ]  Not assessed | Data to be filled in by site | [ ]  Clinically significant[ ]  Not clinically significant |
| Genitourinary | [ ]  Normal-[ ]  Abnormal[ ]  Not assessed | Data to be filled in by site | [ ]  Clinically significant[ ]  Not clinically significant |
| Hematologic/Lymphatic | [ ]  Normal[ ]  Abnormal[ ]  Not assessed | Data to be filled in by site | [ ]  Clinically significant[ ]  Not clinically significant |
| Integumentary (skin and/or breast) | [ ]  Normal[ ]  Abnormal[ ]  Not assessed | Data to be filled in by site | [ ]  Clinically significant[ ]  Not clinically significant |
| Musculoskeletal | [ ]  Normal[ ]  Abnormal[ ]  Not assessed | Data to be filled in by site | [ ]  Clinically significant[ ]  Not clinically significant |
| Neurological | [ ]  Normal[ ]  Abnormal[ ]  Not assessed | Data to be filled in by site | [ ]  Clinically significant[ ]  Not clinically significant |
| Psychiatric | [ ]  Normal[ ]  Abnormal[ ]  Not assessed | Data to be filled in by site | [ ]  Clinically significant[ ]  Not clinically significant |
| Respiratory | [ ]  Normal[ ]  Abnormal[ ]  Not assessed | Data to be filled in 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 participant’s/subject’s physical status.

## 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.
* Hand preference – Choose one - the hand which the participant/subject uses predominantly, not necessarily the hand the participant/subject writes with exclusively.
* 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.
* 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 as well.