## CDEs

**Date of Exam: (month/day/year)**

**Was a physical exam performed on the participant/subject?**

[ ]  Yes (Specify results below)

[ ]  No

Table 1: Data collection grid

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

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

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

## 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.

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