To be completed at every study contact when the participant/subject is prescribed study drug. This form should be used in conjunction with the Study Drug Compliance form.

Table 1: Study Drug Compliance

| **Start Date (mm/dd/yyyy)** | **Start Time (HH:MM)** | **End Date (mm/dd/yyyy)** | **End Time (mm/dd/yyyy)** | **Dose** | **Dose Units** | **Dose Frequency** |
| --- | --- | --- | --- | --- | --- | --- |
|  | am  pm  24-hour clock |  | am  pm  24-hour clock |  |  |  |
|  | am  pm  24-hour clock |  | am  pm  24-hour clock |  |  |  |
|  | am  pm  24-hour clock |  | am  pm  24-hour clock |  |  |  |
|  | am  pm  24-hour clock |  | am  pm  24-hour clock |  |  |  |
|  | am  pm  24-hour clock |  | am  pm  24-hour clock |  |  |  |
|  | am  pm  24-hour clock |  | am  pm  24-hour clock |  |  |  |
|  | am  pm  24-hour clock |  | am  pm  24-hour clock |  |  |  |

## General Instructions

The Study Drug Dosing form tracks the study drug dosing regimen for an individual study participant/subject across the duration of the study in a log format. This form can also be used for biologics. Additional pages may be required to capture the number of doses included in each study. For this reason, page numbers should be recorded. The Study Drug Dosing form should be used in conjunction with the Study Drug Compliance form.

For each dosing record the Start Date and Time, Stop Date and Time, Dose, Dose Unit, and Frequency should be recorded. Start Time and Stop Time may be important for some studies but not applicable in others; these data elements should be included or excluded from the Study Drug Dosing form as appropriate for the study.

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 and should be collected on clinical trials and only 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.*

* **Start Date and Time** – Record the date (and time) the participant/subject was prescribed to start taking study drug. 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. The Start Time column should be removed from the template form for those studies that do not need to collect time.
* **End Date** **and Time**– Record the date (and time) the participant/subject was prescribed to stop taking study drug. 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. The End Time column should be removed from the template form for those studies that do not need to collect time.
* **Dose** – Record the dose of study drug the participant/subject was prescribed to take.
* **Dose Unit** – Record the unit for dose of study drug the participant/subject was prescribed to take. See the data dictionary for information on coding the dose unit of measure using Unified Code for Units of Measure (UCUM).
* **Dose Frequency** – Record the frequency participant/subject was prescribed to take the dose of study drug. See the data dictionary for information on coding frequency using CDISC SDTM terminology.