**Purpose:** This template may be used to record and track concomitant medications.

**Responsibility:** To be used by Principal Investigators and study team members who record and track concomitant medications.

**Procedure:**

* This template contains two types of text: instruction/explanatory and example text.
* **Instruction/explanatory text** are indicated by italics and should be deleted. Footnotes to instructional text should also be deleted. This text provides information on the content that should be included.
* **Example text** is included to further aid in document development and should either be modified or deleted. Example text is indicated in [brackets in regular font]. Within example text, a need for insertion of specific information is notated by <angle brackets>. Example text can be incorporated as written or tailored to a particular document. If it is not appropriate to the document, however, it too should be deleted.

**Concomitant Medication Log Template**

**Study/Protocol ID:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Site Name/Number:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_ Subject ID:\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_\_**

*Customize the following according to the protocol*

*[Check if participant has not taken medications (including OTC) within 30 days of screening visit  None]*

*[Check if participant has not taken medications (including OTC) within 30 days of randomization visit  None]*

| Medication Name  (Generic name) | Indication  (If given for an AE, enter exact term from AE log) | Dose w/Units | Frequency | Route\* | Start Date  (mm/dd/yyyy) | End Date  (mm/dd/yyyy) | Given for an AE?  Y/N | Data Collected By (Initials & Date) | Investigator Initials & Date |
| --- | --- | --- | --- | --- | --- | --- | --- | --- | --- |
|  |  |  |  |  | \_\_\_/\_\_\_ /20\_\_\_ | \_\_\_/\_\_\_ /20\_\_\_  **Or**  Ongoing at End of Study |  |  |  |
|  |  |  |  |  | \_\_\_/\_\_\_ /20\_\_\_ | \_\_\_/\_\_\_ /20\_\_\_  **Or**  Ongoing at End of Study |  |  |  |
|  |  |  |  |  | \_\_\_/\_\_\_ /20\_\_\_ | \_\_\_/\_\_\_ /20\_\_\_  **Or**  Ongoing at End of Study |  |  |  |
|  |  |  |  |  | \_\_\_/\_\_\_ /20\_\_\_ | \_\_\_/\_\_\_ /20\_\_\_  **Or**  Ongoing at End of Study |  |  |  |
|  |  |  |  |  | \_\_\_/\_\_\_ /20\_\_\_ | \_\_\_/\_\_\_ /20\_\_\_  **Or**  Ongoing at End of Study |  |  |  |

*[Check at end of study if participant did not take medications (including OTC) throughout the course of the study*  *None]*

\*Route = Inhaled (RESP), Intramuscular (IM), Intravenous (IV), Nasal (NAS), Oral (PO), Rectal (REC), Topical (TOP), Subcutaneous (SC), Sublingual (SL), Transdermal (TDM), Unknown (UNK), or Other (specify).

*Customize the following according to the protocol*

*[  Medications Confirmed at Baseline by \_\_\_\_\_\_\_\_\_\_\_  Medications Confirmed at V1 by \_\_\_\_\_\_\_\_\_\_\_ ]*