Creating a Study Drug Diary

Introduction

- A study drug diary is a tool used to communicate essential drug information relating to dosing requirements and to capture participant self-administration information. Use of a drug diary is encouraged, but not mandatory, to monitor participant use and tolerance of at home medications. (NOTE: Refer to *DF/HCC INV-103: Protocol Mandated Drug Taken at Home* for other methods to document the administration of at home medications.)
- If the Sponsor is not providing a participant drug diary, the study team will need to submit a dosing instruction sheet for the participants to take home.
- The following information is intended to assist study teams in creating a study drug diary when one is not provided by the study sponsor. Recommended Drug Diary Templates can be found on the DF/HCC website:
  - Excel Drug Diary Template - Multiple Drugs
  - Excel Drug Diary Template - Single Drug
  - Word Drug Diary Template with Instructions

Essential Information

- **FORMAT**
  The diary may be several pages in length. The text used should minimally be in 12 pt font.

- **STUDY DRUG**
  The diary must contain the name of the study drug(s). Please remember to clearly label the diary.

- **DF/HCC PROTOCOL NUMBER**
  Please include the DF/HCC protocol number once it has been assigned. If the study drug diary is submitted with a New Protocol Submission, this may be left blank and can be filled in prior to use.

- **PARTICIPANT IDENTIFIER**
  Include a space to record the study participant's identifier. For example: name, initials, study ID number or medical record number.

- **CYCLE**
  Please allow space to capture the current dosing cycle. This should be left blank and filled in prior to participant use.

- **SELF-ADMINISTRATION DATE**
  This date will be filled in by the participant to reflect the actual date the study drug was taken. Please make sure the space provided matches the dosing days for that cycle.

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- **AMOUNT TAKEN**
  Provide adequate space for the study participant to record drug information per dosing. It is preferable that the study participant record the actual amount of pills/capsules/tablets. Include a column for time of day for study drugs that must be taken more than once a day.

- **COMMENTS**
  Include a comment area for the study participant to record ancillary information related to study drug administration (e.g., vomited doses, why the dose was missed, etc).

- **STUDY DRUG AND SPECIAL INSTRUCTIONS**
  Describe in lay language: 1) how and when to take the study drug; 2) exclusionary food or beverage items; 3) storage requirements; 4) mixing instructions if capsules can be opened or medication can be crushed; 5) what to do in the event of late, missed or vomited doses: When a sponsor states that a vomited dose may be re-taken, please have them verify that the dose may be re-taken only if the capsule/tablet is seen in the emesis 6) information relating to safety concerns (i.e. safe handling practices, child-proofing provisions, etc.); and 7) when and how to return unused and/or empty drug containers.

- **STUDY CONTACT FOR QUESTIONS**
  Please indicate whom the participant should contact with questions. Remember to include a telephone or pager number that is monitored 24 hours a day.

  Please Note: DF/HCC Lead Sites should leave the contact information lines blank so that each respective institution can fill in the appropriate contact information.

- **PARTICIPANT/CAREGIVER INITIALS AND DATE LINE**
  A study drug diary becomes source documentation and therefore it should be initialed and dated by the study participant or caregiver completing it. Please include an area for study participant initials and a date line.

- **DRUG ACCOUNTABILITY**
  A drug diary can be used as a method to document the return of unused study drug from the study participant if it captures: 1) who is acknowledging the return of study drug; 2) date study drug was dispensed to study participant or date study participant started this cycle of study drug; 3) date study drug was returned; 4) number of pills/capsules/tablets dispensed; 5) number of pills/capsules/tablets returned; and 6) any discrepancies in compliance calculations.

Optional Information

- **SYMPTOMS/SIDE EFFECTS**
  Provide space for the study participant to capture side effects that may occur during the cycle. Symptoms should capture the date the particular symptom started and when it ended. If

participants are expected to evaluate the severity of symptoms, please use the definitions listed below.

Mild: Awareness of sign or symptom; easily tolerated and did not affect ability to perform normal daily activities. Symptoms did not require medication or therapeutic intervention.

Moderate: Significant discomfort which interfered with ability to perform normal daily activities. Symptom was easily resolved with at home medication or simple therapeutic intervention.

Severe: Marked discomfort with an inability to carry out normal daily activities. Symptom required new medication and/or therapeutic intervention in order to resolve.

Please Note: This section may be combined with a general comments section (as noted above) or can be a separate section of the diary.

- **OTHER MEDICATIONS TAKEN**
  It is optional to include a section for other medications taken concurrently with the study drug. This section may include the medication name, dose, start and stop dates, and the reason the other medication was taken.