

Form 44 Current Medication Data

Collection Time points

WHI Clinical Centers were required to collect Form 44 – Current Medication on Clinical Trial (CT) participants at baseline and years 1, 3, 6 and 9. For Observational Study (OS) participants, collection was required at baseline and year 3.

Baseline collection of current medication data was expected to be done at the first screening visit. However, each participant was asked to bring any new medications that she started since her first screening visit to her third screening visit, so they could also be recorded.

Protocol Section 4.4.5.4 Current Medications Update

A participant will bring to the SV3 any new medications that are prescribed or that she started taking since SV1. Enter any new medications into the database as done at SV1 (see Section 4.2.4.6 – Current Medications and Current Supplements Inventory Review) as a new encounter. You only need to enter medications that are “new” to the participant since the SV1 interview. You do not need to re-enter the medications entered at SV1 nor delete any medications that the participant discontinued since the SV1.

This protocol implies that one needs to look at medications collected at all Screening Visits to get an accurate picture of the medications a participant was taking during the screening period.

Changes in Data Collection Over Time

- Initial Implementation (Pre Medi-Span) Clinical Centers enter the product name or generic name of the medication, the prescribed dose and frequency, the actual dose and frequency, the duration, and excluded class information.
- February 1, 1994 (Medi-Span Implemented) Clinical Centers look up medications using a subset of information from the Master Drug Database (MDDDB®) supplied by the Medi-Span Division of Wolters Kluwer Health. The National Drug Code (NDC) for the medication is entered and the product name and generic name come from a lookup to the Medi-Span database. An oral corticosteroid flag data item is added to replace the excluded class data item.

Pre Medi-Span data is hand assigned an appropriate NDC by the CCC based on the medication data that was previously entered.

- September 1, 1994 (Dose and Frequency Removed) The prescribed dose and frequency, and actual dose and frequency are no longer entered. An oral daily corticosteroid flag is added to replace the oral corticosteroid flag.

Medication National Drug Codes (NDCs)

WHI used a subset of information from the Master Drug Database (MDDB®) supplied by the Medi-Span Division of Wolters Kluwer Health. WHI tried to limit the number of medications the Clinical Centers had to choose from by collapsing identical medications (e.g. generic versions of a medication like Acetaminophen Tab 500mg) into one NDC.

When WHI first started using Medi-Span, it did not include Herbal Estrogen medications, therefore WHI added their own NDC called “HERBAL EST”. Clinical Centers could use this NDC to indicate a participant was taking an Herbal Estrogen. Later Medi-Span added Herbal Estrogens into their database.

Main Medication Data File

The main F44 data file (f44_os_pub) includes information about the medication(s) recorded at a visit for a participant (e.g. NDC, duration of use, medication therapeutic class). If a participant was not taking any medications at a visit, there is one row of data for the participant visit with missing values for the medication data. If a participant was taking one or more medications at a visit, there is a row of data for each medication the participant was taking. Details about the medications themselves can be found by merging or referring to one or more of the reference files discussed below.

Reference File descriptions

f44ref_meds (dat,pdf,sas): Medication description, including National Drug Code (NDC), product name, generic name, strength, dosage form, administration route, and therapeutic class code. Merge to main F44 data file using the MEDNDC (Medication National Drug Code) variable.

f44ref_med_classes (dat,pdf,sas): Medication therapeutic class description. Includes medication therapeutic class code and name. Merge to main F44 data file or f44_ref_meds using the TCCODE (Medication Therapeutic Class Code) variable.

f44ref_med_ingredients (dat,pdf,sas): Medication ingredients. Includes NDC, ingredient name, and ingredient strength. Each medication may have none, one, or more than one ingredient associated with it. Merge to main F44 data file or f44ref_meds using the MEDNDC (Medication National Drug Code) variable.

f44ref_therclas.pdf: Medication Therapeutic Class list. Visually displays the hierarchy of drug groups, drug classes, and drug subclasses. The first 2 digits of the Therapeutic Class Code represent the Drug Group. The next 2 digits represent the Drug Class within the Drug Group. The last 2 digits represent the Drug Subclass within the Drug Class.

EXAMPLE: Drug Group: 270000 Antidiabetic
 Drug Class: 271000 Insulin
 Drug Subclass: 271010 Mixed Insulin
 271020 Beef Insulin
 271030 Pork Insulin
 271040 Human Insulin
 Drug Class: 272000 Sulfonylureas
 Drug Subclass: 272099 Sulfonylurea Combinations
 Drug Class: 272500 Biguanides
 Drug Class: 272800 Meglitinide Analogues
 Drug Class: 273000 Diabetic Other
 Drug Subclass: 273099 Diabetic Combinations

Using the Medications Data

Using the medications data can be challenging. A few points to keep in mind:

- To get an accurate picture of medication use for a participant at baseline, you will need to take into consideration medication data from each of the screening visits at which medication data was collected. This is not true of follow-up visits, where medications should only have been recorded once for any one Annual Visit. In the case of follow-up visits consider using the “Closest to visit within visit type and number” variable to restrict your selection of medications to a particular follow-up visit.
- Participants could be taking none, one, or more than one medication at a visit. Each medication taken by a participant is listed in the data file. Sometimes the same medication will be listed more than once for a participant, this is the way it was entered by the Clinical Center, and therefore it is that way in the data file.
- The easiest and most common way to look at medication use is by therapeutic class. For example, if you want to look at participants taking any type of Antidiabetic, you could look at those participants taking medications in a therapeutic class between 270000 and 279999 (TCCODE >= 270000 and TCCODE <= 279999).
- Often participants will be taking more than one medication in a therapeutic class at a visit. To derive a single value for a participant’s duration of use within a therapeutic class, you could take the duration of the medication taken the longest.
- Analyses that are more complicated can be done by using the reference files. For example, you can look at participants taking medications containing a particular ingredient or use of specific medications within a therapeutic class.