

MTN-020 (ASPIRE):

Concomitant Medication Coding FAQ

- Household products should not be reported as concomitant medications on the CM-1 Log CRF. Examples of household product include cleaners, solvents, Coke, or any other products used for at-home douching, saline sitz baths, or saline gargles.
- Traditional herbal medications should be reported as concomitant medications. If a medication includes more than one herb, list each herb separately on the CM-1 Log CRF.

Trade Name

- If possible, record the trade name of a medication on the CM-1 log CRF. If a trade name is not available or not reportable per national guidelines, please record the generic name of the medication. A combination medication can be recorded as one entry using the generic name.

If a combination medication does not have a generic name, or the generic name is unknown, *each* active ingredient must be reported as a separate entry in order to be accurately coded at SCHARP.

Example: A combination medication with an unknown generic name and active ingredients Chloramphenicol and Dexamethason should be recorded as two separate entries on the CM-1; one entry for each active ingredient.

- Minor spelling differences can affect the coding of these medications. Please ensure that the spelling of medications is both correct and consistently used throughout the study. For example, if a medication has multiple accepted spellings (such as Azithromycin Mylan and Azithromycine Mylan), be sure to use consistent spelling at each site throughout the study.

- If a medication's trade or generic name is unknown, record "unknown" and a description or drug class.

Examples: "unknown white tablet", "pink and white tablet name unknown", "unknown analgesic", "antibiotic unknown"

Date Started/Date Stopped

- The start date form instruction currently reads that when recording injectable medications, record each injection as a separate entry. This applies to contraceptive injectable medications only. Non-contraceptive injectables (like medications given in the hospital) may be recorded as a single entry.

Frequency and Route

- Note that if “once” is marked for a medication’s frequency, both a Date Started and a Date Stopped must be present, and these should be the same date.

- When recording intra-uterine contraceptive devices or contraceptive implants, record the date of insertion as the Date Started, and leave the Date Stopped blank (record a Date Stopped once the device or implant is removed). Mark “other, specify” for frequency and on the line provided, specify “continuous” as the frequency. When recording contraceptive implants, mark “other, specify” for route and on the line provided, specify “sub-dermal”.

Medication Taken for an AE

- If a medication is taken for an AE (i.e. Item 7 on AE is marked with ‘medications’), ensure that the medication taken is recorded on the CM-1 log CRF and the corresponding AE log page number is recorded.

- If a medication is taken for an AE and the corresponding AE is subsequently deleted or subsumed under a diagnostic AE, update the corresponding entry on the CM-1 by updating or lining through the deleted AE/GAE log page number and initial, date and refax to SCHARP.