

SENTINEL SUMMARY TABLES PROGRAMMING PACKAGE V2

INVESTIGATOR RELEASE NOTES

Sentinel Operations Center

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Sentinel is sponsored by the [U.S. Food and Drug Administration \(FDA\)](#) to monitor the safety of FDA-regulated medical products. Sentinel is one piece of the [Sentinel Initiative](#), a multi-faceted effort by the FDA to develop a national electronic system that complements previously existing methods of safety surveillance. Sentinel Collaborators include Data and Academic Partners that provide access to health care data and ongoing scientific, technical, methodological, and organizational expertise. The Sentinel Coordinating Center is funded by the FDA through the Department of Health and Human Services (HHS) Contract number HHSF223201400030I.

I. OVERVIEW

The Summary Table SAS programming package was completely rewritten in Q4 of 2015. During that time, some business rules were clarified and/or changed from the v1 version.

II. CHANGES AFFECTING ALL TABLES

1. The time window for selecting records is more precise in v2 versus v1.
 - In v1, we ask Data Partners to manually enter values for start year and end year for data completeness and the program code assumes that data completeness starts on Jan 1 of the start year entered and ends on Dec 31 of the end year entered.
 - In v2, the program code uses the data completeness parameter values read directly from Common Components (i.e., DP_MinDate and DP_MaxDate).
2. The calculation of age is more precise in v2 versus v1.
 - In v1, age is calculated as the number of calendar year intervals between a person's birth date and an age-as-of-date. As a result, a person is considered a year older every time a new calendar year is encountered. For example, if a person is born on Nov 24, 2005 and the age-as-of-date is Jan 1, 2006, the person's age would be considered to be one rather than zero.
 - In v2, age is calculated precisely. That is, a person is considered a year older on the day of their birthday.
3. The calculation of enrollment days covered is more precise in v2 versus v1.
 - In v1, in cases where enrollment spans cover three or more calendar years, only the first year and last year get credited with enrollment, while the middle years incorrectly receive no credit at all. For example, an enrollment span with ENR_START=10/01/2010 and ENR_END=10/01/2012, would receive credit for 92 days of enrollment for calendar year 2010, 0 days for calendar year 2011, and 274 days for calendar year 2012.
 - In v2, the enrollment days covered for a calendar year is correctly calculated under all scenarios.

III. CHANGES BY SUMMARY TABLE

Age Groups

No changes were made.

Enrollment Summary Table

Time-period stratifications are added in v2 compared to v1.

- In v1, the time period stratification variable includes only values for year (i.e., YYYY).
- In v2, the time period stratification variable will include YYYY values, as before, as well as YYYYQ# values, where YYYY=the calendar year and #=the calendar quarter.

Age is calculated as of the beginning of time period (i.e., either YYYY or YYYYQ#). Note that a result of this rule is that the sum of distinct member counts across calendar year quarters within a given year will NOT equal the distinct member count for that year.

- ICD-9-CM Diagnosis Summary Table (3 digit)
- ICD-9-CM Diagnosis Summary Table (4 digit)
- ICD-9-CM Diagnosis Summary Table (5 digit)
- HCPCS Summary Table
- ICD-9-CM Procedure Summary Table (3 digit)
- ICD-9-CM Procedure Summary Table (4 digit)

Enrollment criteria are tightened for including a diagnosis or procedure event in v2 compared to v1.

- In v1, only medical enrollment for at least one day in the same calendar year as an event is required.
- In v2, at least one day of both medical and drug coverage is required. The medical and drug coverage may be on different days.

Drug Category/Class Summary Table

Ingredient/Generic Name Summary Table

1. Enrollment criteria are tightened for including a dispensing event in v2 compared to v1.
 - In v1, only drug enrollment for at least one day in the same calendar year as an event is required.
 - In v2, at least one day of both medical and drug coverage is required. The medical and drug coverage may be on different days.
2. Multiple valid drug class values kept per unique NDC in v2 compared to v1.
 - In v1 only one valid drug class is randomly kept per unique NDC, where valid is defined as non-missing and not coded as UNKNOWN.
 - In v2, we keep all valid drug classes per unique NDC, where valid is defined as non-missing and not coded as UNKNOWN.

Incident ICD-9-CM Diagnosis Summary Table (3 Digit)

The types of events counted changes in v2 compared to v1.

In v1, we identify a first incident diagnosis in a year. Incidence determination for the first incident diagnosis requires:

1. Continuous enrollment of both medical and drug coverage types during the requester-specified lookback window (i.e., 90, 180, and 270 days).
2. No evidence of previous diagnosis during the requester-specified lookback window (i.e., 90, 180, and 270 days).
3. Continuous enrollment of both medical and drug coverage types looking *forward* the same number of days as the requester-specified lookback window.

Once the first incident diagnosis in a year is identified, the program looks *forward* the same number of days as the requester-specified lookback window and counts the number of prevalent events. Output metrics in any given year included, therefore, one incident event + all subsequent prevalent events during the look forward period.

In v2, we identify all incident events only. Incidence determination for incident events requires:

1. Continuous enrollment of both medical and drug coverage types during the requester-specified lookback window (i.e., 90, 180, and 270 days).
2. No evidence of previous diagnosis during the requester-specified lookback window (i.e., 90, 180, and 270 days).

We only identify events that meet incidence criteria. Output metrics in any given year include, therefore, only all incident events and no prevalent events.

Incident Drug Category/Class Summary Table

Incident Ingredient/Generic Name Summary Table

1. Enrollment criteria are tightened for including dispensing events in the follow up period that are associated with the index event (i.e., the subsequent events that are part of the same treatment episode).
 - In v1, continuous enrollment for both medical and drug coverage are required during the lookback interval for defining an index dispensing event, but no enrollment requirements are in place for counting events from the index event date forward.
 - In v2, continuous enrollment for both medical and drug coverage are required during the lookback interval for defining an index dispensing event. We also require continuous enrollment for both medical and drug coverage in the follow up period used for counting events associated with the index event. We stop follow up at the end of the patient's enrollment coverage, the end of the index treatment episode, or the end of Data Partner data, whichever comes first.
2. Multiple valid drug class values kept per unique NDC in v2 compared to v1.
 - In v1 only one valid drug class is randomly kept per unique NDC, where valid is defined as non-missing and not coded as UNKNOWN.
 - As for the prevalent Drug Category/Class Summary and Ingredient/Generic Name Summary Tables noted above, in v2, we keep all valid drug classes per unique NDC, where valid is defined as non-missing and not coded as UNKNOWN.