



Protocol

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Site Number

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Subject Number

Tobacco Implementation Guide -Disposition

Disposition

What was the category of the disposition?
If collected on the CRF, the applicant provides instructions to ensure the data is entered as intended.

DACAT
 DSDCAT

What is the study epoch for this disposition event?
Select the study epoch for which disposition is being recorded

- Screening
- Product Exposure
- Follow-up

EPOCH
 EPOCH

What was the subject's status?
Document the subject's status for the study or study period. If the subject discontinued prematurely, record the primary reason for discontinuation.

- Completed
- Adverse Experience
- Death
- Lost To Follow-up
- Protocol Deviation
- Screen Failure
- Site Terminated by Applicant
- Withdrawal by Subject
- Study Terminated by Applicant
- Other

DSDECOD
 DSDECOD

What was the verbatim reason for the subject status?
If Adverse Experiences, Death, Protocol Deviation or Other is selected from the Status list, provide the verbatim reason.

DSTERM
 DSTERM

What was the completion/discontinuation date?
 (DD-MMM-YYYY)
Record the date that the subject completed the study or study period using this format. If the subject did not complete the study or study period, record the date that the subject discontinued.

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DSSTDTC
 DSSTDAT

CRFs are annotated to show the collection variable (in Grey) and the tabulation target/mapping instructions (in Red).



Protocol

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Site Number

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Tobacco Implementation Guide -Disposition

Disposition

Will the subject continue into the next epoch?
Record if the subject will be continuing to the next study period of this study.

- No
 Yes

NOT SUBMITTED
DSCONT

What is the next epoch the subject will continue to enter?
Record the planned subsequent study epoch in which the subject intends to participate.

NOT SUBMITTED
DSNEXT

CRFs are annotated to show the collection variable (in Grey) and the tabulation target/mapping instructions (in Red).