



Protocol

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Site Number

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Subject Number

Tobacco Implementation Guide-Concomitant Medications**Any Concomitant Medications**

Were any concomitant medications/products taken?

Indicate if the subject took any concomitant medications/products. If Yes, include the appropriate details where indicated on the CRF.

- ☐ No
☐ Yes

NOT SUBMITTED

CMYN

Medications

What is the category for the concomitant medication/product?

Record the medication category, if not pre-printed on the CRF.

CMCAT

CMCAT

What is the line number?

If collected on the CRF, applicant may insert instructions to ensure each record has a unique identifier.

CMSPID

CMSPID

What was the medication/product?

Record only one medication/product per line. Provide the full trade or proprietary name of the medication/product; otherwise, record the generic name

CMTRT

CMTRT

For what indication was the medication/product taken?

Record the reason the medication/product was taken based on clinical investigator's evaluation. If taken to treat a condition, and a diagnosis was made, the indication should be the diagnosis. If taken to treat a condition, and no diagnosis was made, the indication should be the signs and symptoms. If taken as prophylaxis, report as "Prophylaxis for " and include a description of the condition(s).

CMINDC

CMINDC

What was the individual dose of the medication/product?

Record the dose of medication/product.

CMDOSTXT or CMDOSE

CMDSTXT

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



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Tobacco Implementation Guide-Concomitant Medications**Medications**

What is the unit?

*Record the dose unit of the dose of medication/product taken (e.g., mg.).***CMDOSU**

CMDOSU

What was the dose form of the medication/product?

*Record the pharmaceutical dosage form (e.g., TABLET CAPSULE, SYRUP) of delivery for the medication/product taken***CMDOSFRM**

CMDOSFRM

What was the route of administration of the medication/product?

*Provide the route of administration for the medication/product.***CMROUTE**

CMROUTE

What was the frequency of the medication/product?

*Record how often the medication/product was taken (e.g., BID, PRN).***CMDOSFRQ**

CMDOSFRQ

What was the medication/product dose start date? (DD-MMM-YYYY)

Record the date the medication/product was first taken. If the subject has been taking the medication/product for a considerable amount of time prior to the start of the study, it is acceptable to have an incomplete date. Medication/product taken during the study are expected to have a complete start date. Prior medication/product that are exclusionary should have both a start and end date.

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CMSTDTC

CMSTDAT

Is the medication/product ongoing?

Record the medication/product as ongoing if the subject has not stopped taking the medication/product at [the timepoint defined by the study]. If the medication/product is ongoing, the end date should be left blank

- ☐ No
☐ Yes

CMENRF or CMENRTP

CMONGO

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



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Subject Number

Tobacco Implementation Guide-Concomitant Medications

Medications

What was the end date?
(DD-MMM-YYYY)

Record the date the medication/product was stopped. If the subject has not stopped taking the medication/product leave this field blank.

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CMENDTC

CMENDAT

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