



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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<p>What is the unit? <i>Record the dose unit of the dose of medication/product taken (e.g., mg.).</i></p>	<p><b>CMDOSU</b> CMDOSU</p>											
<p>What was the dose form of the medication/product? <i>Record the pharmaceutical dosage form (e.g., TABLET CAPSULE, SYRUP) of delivery for the medication/product taken</i></p>	<p><b>CMDOSFRM</b> CMDOSFRM</p>											
<p>What was the route of administration of the medication/product? <i>Provide the route of administration for the medication/product.</i></p>	<p><b>CMROUTE</b> CMROUTE</p>											
<p>What was the frequency of the medication/product? <i>Record how often the medication/product was taken (e.g., BID, PRN).</i></p>	<p><b>CMDOSFRQ</b> CMDOSFRQ</p>											
<p>What was the medication/product dose start date? (DD-MMM-YYYY) <i>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.</i></p>	<table border="1" style="width: 100%; height: 30px;"> <tr> <td style="width: 10%;"></td><td style="width: 10%;"></td> </tr> </table> <p><b>CMSTDTC</b> CMSTDAT</p>											
<p>Is the medication/product ongoing? <i>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</i></p>	<p><input type="radio"/> No <input type="radio"/> Yes</p> <p><b>CMENRF or CMENRPT</b> CMONGO</p>											

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### 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).*