Tobacco Implementation Guide-Protocol Deviations

Any Protocol Deviations

Were there any protocol deviations? *Enter Yes if a protocol deviation occurred and No if none occurred. Ensure that any adverse event which triggers a protocol deviation (e.g., concomitant medication use, newly discovered medical history) is noted on the respective CRF.*	○ No **Not Submitted** ○ Yes DVYN

Protocol Deviations

What is the protocol deviation identifier? (DD-MMM-YYYY) *If collected on the CRF, applicant may insert instructions to ensure each record has a unique identifier.*	DVSPID DVSPID
What was the protocol deviation? *Record protocol deviations identified and/or select the appropriate code from the list of protocol deviation terms.*	○ Prohibited Medications DVDECOD ○ Informed Consent Issues DVDECOD ○ Inclusion Exclusion Criteria Violations ○ Adverse Event Not Reported in Timeline ○ Procedure not performed per protocol ○ Visit out of window ○ Other
What was the protocol deviation term? *Record the protocol deviation*	DVTERM DVTERM
What was the protocol deviation start date? (DD-MMM-YYYY) *Record the start date for the protocol deviation using this format. This should be the start or occurrence of the protocol deviation, not the date it was discovered or reported.*	DVSTDTC DVSTDAT

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

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Protocol Deviations

What was the protocol deviation end date? (DD-MMM-YYYY) *Record the end date for the protocol deviation using this format. This should be the date the protocol deviation stopped, not the date it was discovered or reported.*	DVSTDTC DVSTDAT

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