cdisc

Protocol

Site Number

Subject Number

Tobacco Implementation Guide-Adverse Experiences

Record all adverse experiences (AEs) except [list of protocol-defined exceptions] on the AE CRF
All serious adverse experiences (SAEs), regardless of relationship to study product, must be reported via telephone or fax within 24 hours of discovery.
Safety information (e.g., AE, SAE) identified for all subjects must be recorded on source documents from the time informed consent is obtained.

Any Adverse Experiences

Were there any adverse experiences? *Indicate if the subject experienced any adverse experienes. If Yes, include the appropriate details where indicated on the CRF.*	○ No ○ Yes	NOT SUBMITTED AEYN

Adverse Experiences

What is the category of the adverse experience? *Record the adverse experience category, if not pre-printed on the CRF.*	Applicant Defined	AECAT AECAT
What is the subcategory of the adverse experience? *Record the adverse experience subcategory, if not pre-printed on the CRF.*	Applicant Defined	AESCAT AESCAT
What is the adverse experience identifier? *If collected on the CRF, the applicant may insert instructions to ensure each record has a unique identifier.*	_____	AESPID AESPID
What is the adverse experience term? *Record only 1 diagnosis, sign, or symptom per line (e.g., nausea and vomiting should not be recorded in the same entry, but as 2 separate entries). Using accepted medical terminology, enter the diagnosis (if known); otherwise, enter a sign or symptom.*		AETERM AETERM

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

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Adverse Experiences

What is the adverse experience start date? (DD-MMM-YYYY) *Record the start date of the Adverse Experience*		AESTDTC AESTDAT
Ongoing *Indicate if the adverse experience has not resolved at the time of data collection; leave the End Date blank.*		AEENRF or AEENRTPT AEONGO
What was the adverse experience end date? (DD-MMM-YYYY) *Record the date that the AE resolved*		AEENDTC AEENDAT
What is the severity of the adverse experience? *The reporting physician/healthcare professional will assess the severity of the adverse experience using applicant-defined categories. This assessment is subjective and the reporting physician/healthcare professional should use medical judgment to compare the reported AE to similar type experiences observed in clinical practice. Severity is not equivalent to seriousness.*	○ Mild ○ Moderate ○ Severe	AESEV AESEV
Was the experience serious?	○ No ○ Yes	AESER AESER
Did the adverse experience result in death?	○ No ○ Yes	AESDTH AESDTH

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Was the adverse experience life threatening?	○ Yes ○ No	AESLIFE AESLIFE
Did the adverse experience result in initial or prolonged hospitalization for the subject?	○ No ○ Yes	AESHOSP AESHOSP
Did the adverse experience result in disability or permanent damage?	○ No ○ Yes	AESDISAB AESDISAB
Was the adverse experience associated with a congenital anomaly or birth defect?	○ No ○ Yes	AESCONG AESCONG
Was the adverse experience a medically important event not covered by other "serious" criteria?	○ No ○ Yes	AESMIE AESMIE
Was this adverse experience related to study product? *Indicate if the cause of the adverse experience was related to the study product and cannot be reasonably explained by other factors (e.g., subject's clinical state, concomitant therapy, other interventions).*	○ Not-Related ○ Unlikely Related ○ Possibly Related ○ Related	AEREL AEREL

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Adverse Experiences

What action was taken with study product? *Record changes made to the study product resulting from the adverse experience.*	○ Product Increased ○ Product Not Changed ○ Product Reduced ○ Product Interrupted ○ Product Stopped ○ Not Applicable	AEACN AEACN
What other action was taken? *Record all other action(s) taken resulting from the adverse experience that are unrelated to study product given because of this adverse experience.*		AEACNOTH AEACNOTH
What was the action taken with a device? *Record any action taken with a tobacco device as the result of the adverse experience. The device may or may not be a device under study..*	○ Device Replaced ○ Battery Replaced ○ Calibration ○ Reprogramming	AEACNDEV AEACNDEV
What was the outcome of this adverse experience?	○ Fatal ○ Not Recovered or Not Resolved ○ Recovered or Resolved ○ Recovered or Resolved with Sequelae ○ Recovering or Resolving ○ Unknown	AEOUT AEOUT
Was this adverse experience related to a device?	○ Not-Related ○ Unlikely Related ○ Possibly Related ○ Related	AERLDEV AERLDEV

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