cdisc Protocol	Site Number	Subject Number

Tobacco Implementation Guide -Tobacco Device Product Events or Malfunctions

Any Product Device Events or Malfunctions

Were any tobacco product events or malfunctions experienced? *Indicate if the subject experienced any tobacco product device events or malfunctions. If Yes, include the appropriate details where indicated on the CRF*	○ No ○ Yes	NOT SUBMITTED EMYN
What was the tobacco product identifier? *Indicate the tobacco product device that was associated with the event.*		SPTOBID SPTOBID

Product Device Events or Malfunctions

What was the event associated with this device? *Record a description of the toboacco product device event that occurred. Record only 1 event or malfunction per line.*		EMTERM EMTERM
Start Date (DD-MMM-YYYY) *Record the date that the event or malfunction first occurred or was noted*	__ ___ ____	EMSTDTC EMSTDAT
What was the pattern of the event? *Iindicate the pattern of the event over time.*	○ Single Event ○ Intermittent ○ Continuous	EMPATT EMPATT
What action was taken with the device? *Record what action was taken with the device as a result of the event.*	○ Device Replaced ○ Battery Replaced ○ Calibration ○ Reprogramming	EMACNDEV EMACNDEV

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

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Product Device Events or Malfunctions

What was the identifier for the primary adverse experiene(s) associated with or related to this device event? *Record the ID of the primary AE associated with event, if any.*	ASSOCIATE WITH RELATED RECORD VIA RELREC EMAENO1
What was the identifier for the primary adverse experienc(s) associated with or related to this device event? *Record the ID of the primary AE associated with event, if any.*	ASSOCIATE WITH RELATED RECORD VIA RELREC EMAENO1

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