



Protocol

--	--	--

Site Number

--	--	--	--	--

Subject Number

Tobacco Implementation Guide-Inclusion/Exclusion

All procedures must be performed and the subject's eligibility determined within <protocol-specified time period prior to study medication administration>

(If applicable, include the following instructions) Complete the Inclusion/Exclusion Worksheet as source document by recording a "Yes" or "No" response to each criterion.

Record the criterion identification that was an exception.

Any Inc/Exc

Were all eligibility criteria met?

Record Yes if all eligibility criteria were met at the time the subject was enrolled. Record No if the subject did not meet all criteria at the time the subject was enrolled.

NOT SUBMITTED

IEYN

Inc/Exc Criteria

What was the category of the criterion?

Record whether the criterion exception was Inclusion or Exclusion.

IECAT

IECAT

What was the identifier of the inclusion criterion the subject did not meet or the exclusion criterion the subject met?

If the subject was not eligible, record the identifying code for each criterion that was an exception

IETESTCD

IETESTCD

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