Site Number	Subject Number

Form IE - Inclusion/Exclusion Criteria Not Met

1   IE - Inclusion/Exclusion Criteria Not Met

1.1	Were all eligibility criteria met?	○ [N] No ○ [Y] Yes	*IEYN*
1.2	What was the date the eligibility criteria assessment was performed? (DD-MMM-YYYY)	|__|__|__|__|__|__|	*IEDAT*

IE - Inclusion/Exclusion Criteria Not Met

	What was the category of the criterion?	What was the identifier of the inclusion criterion the subject did not meet or the exclusion criterion the subject met?
2	○ [Inclusion] INCLUSION *IECAT* ○ [Exclusion] EXCLUSION	○ [INCL01] Inclusion 1 *IETESTCD* ○ [INCL02] Inclusion 2 ○ [INCL03] Inclusion 3 ○ [EXCL01] Exclusion 1 ○ [EXCL02] Exclusion 2 ○ [EXCL03] Exclusion 3
3	○ [Inclusion] INCLUSION ○ [Exclusion] EXCLUSION	○ [INCL01] Inclusion 1 ○ [INCL02] Inclusion 2 ○ [INCL03] Inclusion 3 ○ [EXCL01] Exclusion 1 ○ [EXCL02] Exclusion 2 ○ [EXCL03] Exclusion 3
4	○ [Inclusion] INCLUSION ○ [Exclusion] EXCLUSION	○ [INCL01] Inclusion 1 ○ [INCL02] Inclusion 2 ○ [INCL03] Inclusion 3 ○ [EXCL01] Exclusion 1 ○ [EXCL02] Exclusion 2 ○ [EXCL03] Exclusion 3