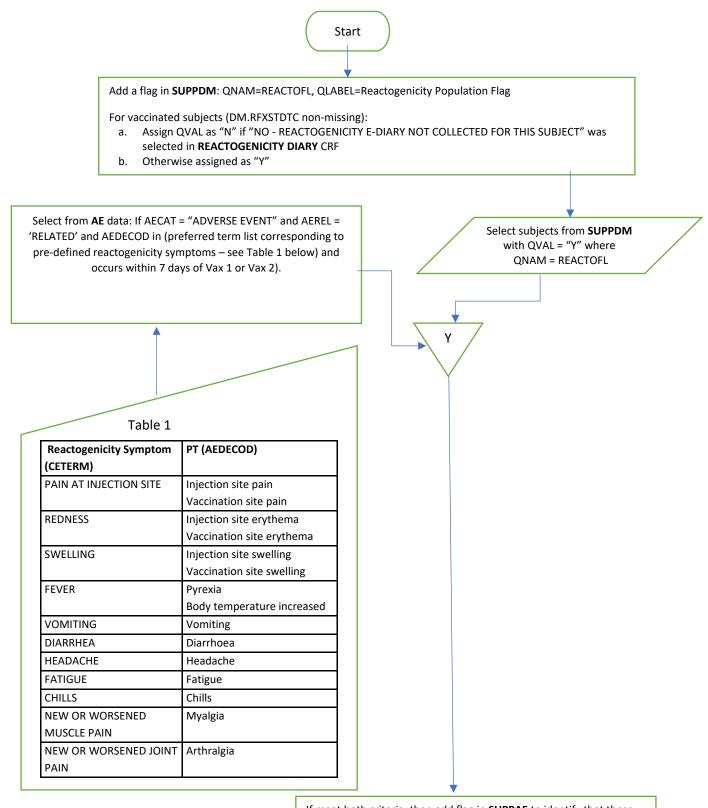
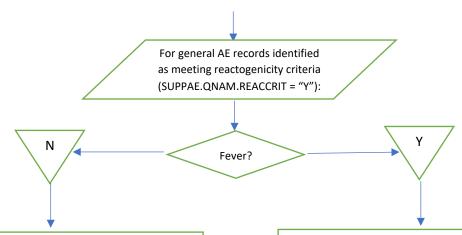
C4591001: Roadmap for Event Selection and SDTM Dataset Updates for Reactogenicity

Background: As discussed with the Agency on 08 April 2021, any events reported in the general adverse event data (AE domain) which meet criteria for reactogenicity have been added to the FACE and VS domains and used to update the summary records in the CE domain, as described below.



If meet both criteria, then add flag in **SUPPAE** to identify that these meet reactogenicity criteria (QVAL = "Y" where QNAM = "REACCRIT")



Add records to FACE for investigator's assessment from AE form:

- a. For each day AE overlaps with diary period, insert a pair of records for FATESTCD = 'OCCUR' (set to 'Y') and FATESTCD = 'SEV' (from AETOXGR, converted to severity according to Table 2 below) for that date (FADTC).
- Assign FAOBJ based on the symptom corresponding to AEDECOD (CETERM from Table 1).
- FACAT = "REACTOGENICITY ADVERSE EVENT".
- d. FASCAT ("SYSTEMIC" or "ADMINISTRATION SITE") assigned based on FAOBJ.
- e. FASPID is assigned the value of AESPID from source AE record.
- f. FAEVAL = 'INVESTIGATOR'.

Add records to VS for investigator's assessment from AE form:

- For each day AE overlaps with diary period, insert a record for VSTESTCD = 'TEMP': VSORRES is null, VSSTRESC = "FEVER" for that date (VSDTC).
- b. VSDRVDL is set to "Y".
- vscat = "reactogenicity adverse event".
- d. VSSCAT = "SYSTEMIC".
- e. VSSPID is assigned the value of AESPID from source AE record.
- f. VSEVAL = 'INVESTIGATOR'.

Table 2

AETOXGR	Severity
1	MILD
2	MODERATE
3	SEVERE
4	POTENTIALLY LIFE THREATENING

When general AE data affects the corresponding summary event record in CE → CE/SUPPCE updates

- a. Flag in SUPPCE that event was modified based on AE data (QNAM = 'AE MOD')
- b. Create record in SUPPCE with QNAM = 'CEDIFFRS'/QLABEL = 'Reason Investigator Changed Assessment'.
- c. Assign SUPPCE.CEEVAL = "INVESTIGATOR".

Originally CEOCCUR was "Y"

Originally CEOCCUR was not "Y"

- Re-derive CESTDTC by taking the earliest of AESTDTC and original CESTDTC.
- Re-derive CEENDTC by taking the latest of AEENDTC and original CEENDTC.
- For any date changes, write original date to SUPPCE.CESTDTC1 and/or CEENDTC1.
- d. CESTDY/CEENDY/CEDUR are updated based on any changes to CESTDTC/CEENDTC.
- e. Re-derive CESEV by taking the maximum severity from AETOXGR (mapped to severity according to Table 2) or original CESEV. If AE severity is worse than original CESEV, then write out original value to SUPPCE where QNAM = CESEV1. Note: Severity is not assigned for Fever events.
- f. If stop date is after diary period, then assign
 CEENRTPT = "ONGOING" and CEENTPT = "DAY 7".

- Assign CEOCCUR= "Y" and set
 CESTAT/CEREASND/CEDRVFL to null.
- b. Populate CESTDTC/CEENDTC with AESTDTC/AEENDTC.
- c. Derive CESTDY/CEENDY and CEDUR.
- d. Set CESEV based on AETOXGR, mapped to severity values in Table 2.
- e. If stop date is after diary period, then assign CEENRTPT = "ONGOING" and CEENTPT = "DAY 7".

