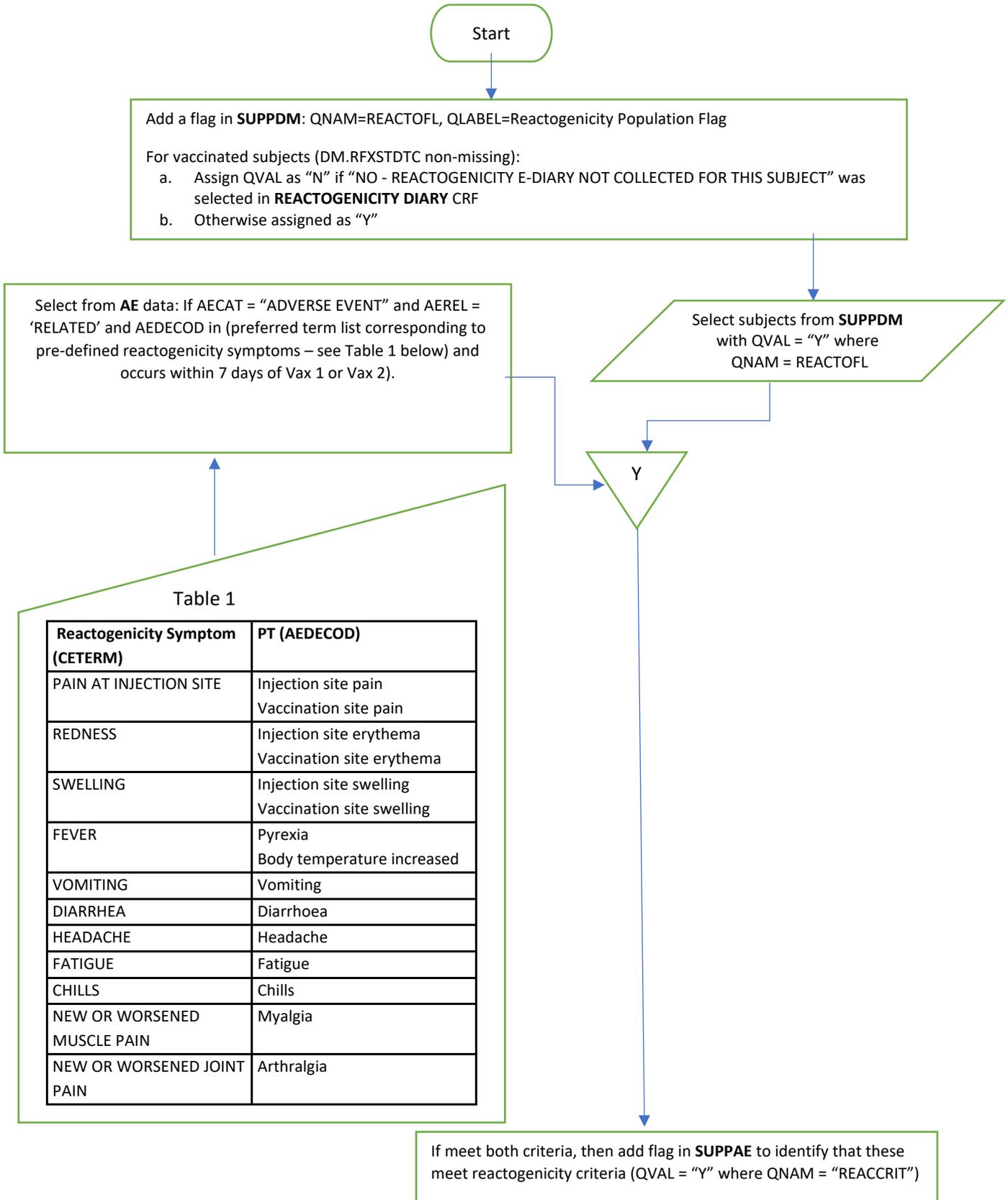


C4591001: Roadmap for Event Selection and SDTM Dataset Updates for Reactogenicity

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.



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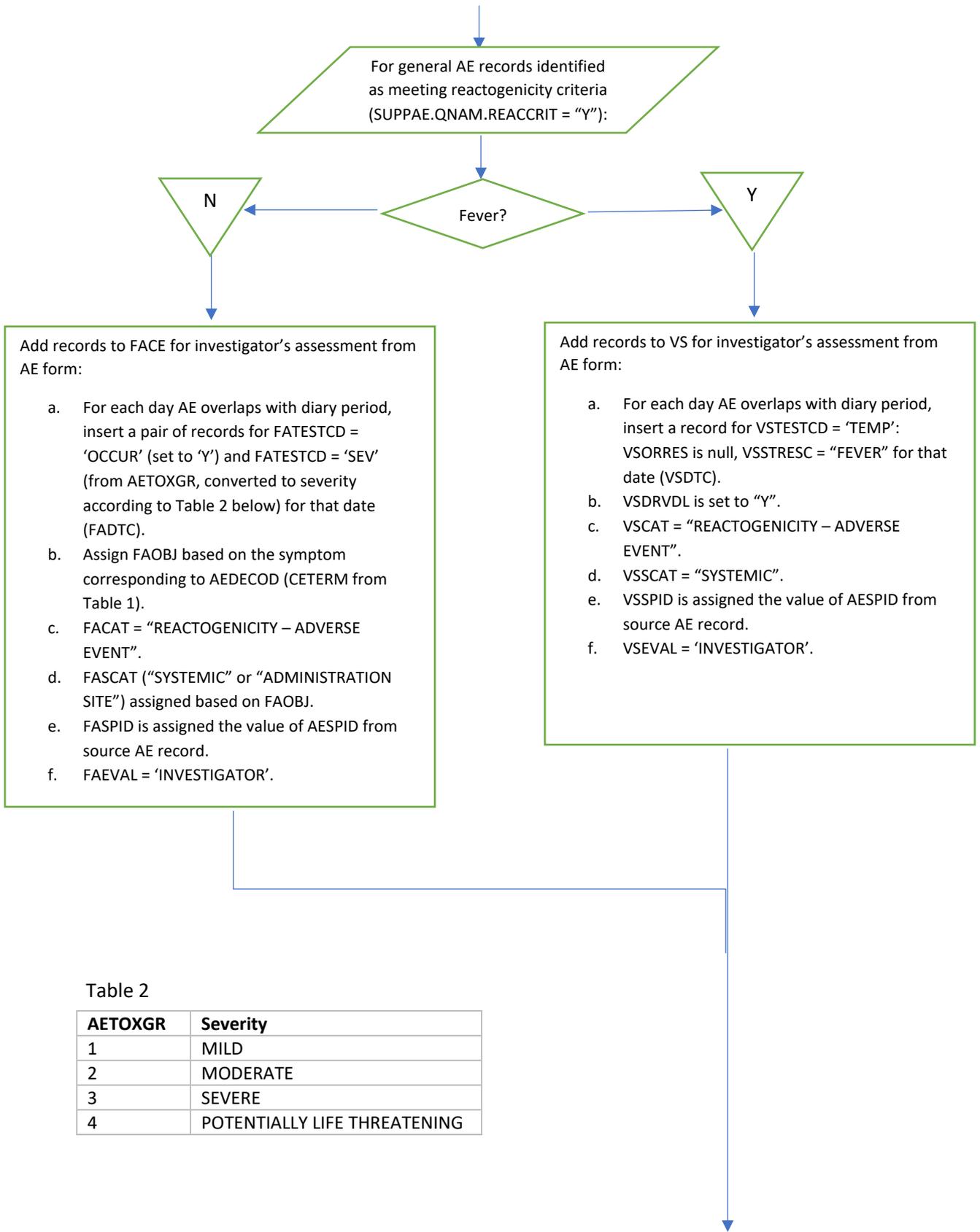


Table 2

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

