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### ADSL.EUAVACDT

Derivate EUAVACDT in the following steps:

1. If subject has CM/SUPPCM record(s) where CMTRT or CMINDC contains 'COVID' or 'CORONAVIRUS' in upper case and SUPPCM.QVAL contains 'VACCINE' in upper case where QNAM='ATCLEV3T', set to date part of CM.CMSTDTC. When CMSTDTC is missing or partial, impute it as below:
  - (1) When only Day is missing, use the 1st day of the month.
  - (2) When Day and Month are both missing, use the 1st day of the year.
  - (3) When Day, Month, and Year are all missing, use 11DEC2020.In case subject has multiple such CM records, use the earliest CMSTDTC.
2. When subject has no such CM record, if the subject has SUPPDV.QVAL='9 - Will be handled by statistical analysis; Pfizer EUA' or '13 - Will be handled by statistical analysis; Unknown EUA Vaccine' then set to 11DEC2020; if the subject has QVAL='10 - Will be handled by statistical analysis; Moderna EUA' then set to 18DEC2020; if the subject has QVAL='11 - Will be handled by statistical analysis; J&J EUA' then set to 27FEB2021. If the subject has multiple records with the mentioned QVAL, set to the earlier EUA issued date. For example, if a subject has QVAL='10 - ...' and QVAL='11 - ...', set to 18DEC2020.
3. When subject has the mentioned records in CM and SUPPDV, if the date from CM is not imputed then use the date, else if the date from CM is imputed then use the later date from CM and the date from step 2. For example, if a subject has 01DEC2020 (imputed) from CM and 11DEC2020 from SUPPDV, use 11DEC2020.

### ADAE.ASTDT

If AESTDTC is partial or missing, apply the following imputation rule:

- If only DAY is missing:  
If the AE end date (AEENDTC) is after the date of first vaccination (ADSL.TR01SDT) or is missing AND the start month and year of the AE (AESTDTC) coincide with the start month and year of the first vaccination (ADSL.TR01SDT), use the date of first vaccination, Otherwise, use the first day of the month

If DAY and Month are both missing:

- If the AE end date is after the date of first vaccination or is missing AND the start year of the AE coincides with the start year of the first vaccination, use the date of first vaccination, Otherwise, use the first day of the year
- If DAY, Month and Year are all missing, the date will not be imputed

Note: if AEENDTC is partial:

- If only day is missing, month and year coincide with or after the month and year of TR01SDT, treat AESTDTC as after TR01SDT, otherwise treat AESTDTC as before TR01SDT
- If month is missing (regardless of day is missing or not), if year coincides with or after the year of TR01SDT, treat AESTDTC as after TR01SDT, otherwise treat AESTDTC as before TR01SDT
- If year is missing (regardless of day and month), treat AESTDTC as after TR01SDT

After above steps, set ASTDT to AENDT if ASTDT is greater than non-missing AENDT

### ADCM.ASTDT

- If only DAY is missing,  
If the CM end date (CMENDTC) is after the date of first vaccination (ADSL.TR01SDT) or is missing AND the start month and year of the CM (CMSTDTC) coincide with the start month and year of the first vaccination (ADSL.TR01SDT), use the date of first vaccination;  
Otherwise, use the first day of the month
- If DAY and Month are both missing,  
If the CM end date is after the date of first vaccination or is missing AND the start year of the CM coincides with the start year of the first vaccination, use the date of first vaccination  
Otherwise, use the first day of the year
- If DAY, Month and Year are all missing, the date will not be imputed. blank otherwise

Note: if CMENDTC is partial:

- If only day is missing, month and year coincide with or after the month and year of TR01SDT, treat

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CMENDTC as after TR01SDT, otherwise treat CMENDTC as before TR01SDT

- If month is missing (regardless of day is missing or not), if year coincides with or after the year of TR01SDT, treat CMENDTC as after TR01SDT, otherwise treat CMENDTC as before TR01SDT. If year is missing (regardless of day and month), treat CMENDTC as after TR01SDT

After above steps, set ASTDT to AENDT if ASTDT is greater than non-missing AENDT

### ADIS.AVISIT

Set to 'Baseline' if ABLFL='Y'

If ADY>1 and VISIT does not contain "UNSCHED":

- Set to "Day xx" part of VISIT for VISITNUM=2, 6, 10, 15, 21, 32,
- Set to "Illness Visit Day 1" where VISITNUM=33,
- Set to "Illness Visit Day 28" where VISITNUM=35,
- Set to VISIT where VISIT="Participant Decision Visit / OL-D1",
- Set to "Open Label Day 29" where VISIT="OL-D29",
- Set to "Open Label Day 57" for VISIT="OL-D57",

If a subject has multiple scheduled Illness Visit Day 1 with different date part of ISDTC, sort these Illness Visit Day 1 records by date part of ISDTC and rename Illness Visit Day 1 to Illness Visit y Day 1 starting from 2nd record and y=2,3,4...

Set AVISIT as following visit window below if ADY>1 and VISIT contains "UNSCHED":

If VISIT contains "Illness Visit Day" or "Convalescence Visit":

- Set to "Illness Visit Day 1" if the visit date = VISIT Date where VISIT = "Illness Visit Day 1"
- Set to "Illness Visit Day 28" if  $2 \leq \text{ADT} - \text{ADT where VISIT} = \text{"Illness Visit Day 1"} \leq 34$
- Set to "Illness Visit" if  $\text{ADT} - \text{ADT where VISIT} = \text{"Illness Visit Day 1"} > 34$  or missing ADT where VISIT = "Illness Visit Day 1"

If ADSL.TR02SDT is not missing, ADSL.OLDOS2DT is missing:

- Set to "Participant Decision Visit / OL-D1" where  $\text{ADT} = \text{ADSL.TR02SDT}$
- Set to "Open Label Day 29" if  $1 \leq \text{ADT} - \text{ADSL.TR02SDT} \leq 42$

If ADSL.TR02SDT is not missing, ADSL.OLDOS2DT is not missing:

- Set to "Participant Decision Visit / OL-D1" if  $\text{ADT} = \text{ADSL.TR02SDT}$
- Set to "Open Label Day 29" if  $1 \leq \text{ADT} - \text{ADSL.TR02SDT} \leq 42$  (Q: if both TR02SDT and OLDOS2DT are not missing, do you consider checking Open-Label Day 29?)
- Set to "Open Label Day 57" if  $1 < \text{ADT} - \text{ADSL.TR02SDT} \leq 70$

Set to "Day 29" if  $2 \leq \text{ADY} \leq 43$

Set to "Day 57" if  $44 \leq \text{ADY} \leq 133$

Set to "Day 209" if  $134 \leq \text{ADY} \leq 301$

Set to "Day 394" if  $302 \leq \text{ADY} \leq 576$

Set to "Day 759" if  $577 \leq \text{ADY} \leq 773$

After the steps above, sort data by AVISITN and ADY, set the unscheduled visit (i.e., VISIT contains "Unsched") records to blank if AVISITN < 100 and AVISITN > any previous AVISITN AND ADY <= any previous ADY. For example, Scheduled Day 29 is with AVISITN=3 (Day 29) and ADY=46 and an unscheduled visit is with AVISITN=4 (Day 57) and ADY=44, set AVISIT to blank for this unscheduled visit.

After above steps, if AVISIT="Illness Visit Day x" or "Illness Visit y Day x" then set AVISIT="Illness Visit" or "Illness Visit y" and set ATPT="Day x"

### ADMB.AVISIT

If ABLFL='Y' then AVISIT='Baseline'

If ADY>1,

- Set to 'Day xx' part of VISIT if VISITNUM=2 or 6,
- Set to 'Illness Visit Day 1' if VISITNUM=33,
- Set to 'Illness Visit Day 3 – Day 21' if VISITNUM=34,

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- Set to 'Illness Visit Day 28' if VISITNUM=35,
- Set to VISIT for VISIT = 'Participant Decision Visit / OL-D1'

If a subject has multiple scheduled Illness Visit Day 1 with different MBDTC, sort these Illness Visit Day 1 records by MBDTC and rename 'Illness Visit Day 1' to 'Illness Visit y Day 1' starting from 2nd record and y=2,3,4.... For 'Illness Visit Day 3 – Day 21', set AVISIT to 'Illness Visit y Day 3 – Day 21' if the closest 'Illness Visit Day 1' has AVISIT='Illness Visit y Day 1'. Similar for 'Illness Visit Day 28'

Set AVISIT as follows using the visit window below if ADY>1 and VISIT contains 'UNSCHED' or is missing:

- Set to the AVISIT of that scheduled Illness Visit Day 1 if date part of MBDTC is the same as the date part of MBDTC for a scheduled Illness Visit Day 1
- Set AVISIT by using following visit window if ADT is within 34 days after an Illness Visit Day 1 where AVISIT = Illness Visit z Day 1 (z=., 2, 3, ...).  
*If the unscheduled visit is within 34 days of multiple Illness Visit Day 1, then apply the window to the latest Illness Visit Day 1*
- Set to 'Illness Visit z Day 3' if VISIT with  $1 \leq \text{ADT} - (\text{ADT where VISIT} = \text{'Illness Visit Day 1'}) \leq 2$
- Set to 'Illness Visit z Day 5' if VISIT with  $3 \leq \text{ADT} - (\text{ADT where VISIT} = \text{'Illness Visit Day 1'}) \leq 4$
- Set to 'Illness Visit z Day 7' if VISIT with  $5 \leq \text{ADT} - (\text{ADT where VISIT} = \text{'Illness Visit Day 1'}) \leq 6$
- Set to 'Illness Visit z Day 9' if VISIT with  $7 \leq \text{ADT} - (\text{ADT where VISIT} = \text{'Illness Visit Day 1'}) \leq 10$
- Set to 'Illness Visit z Day 14' if VISIT with  $11 \leq \text{ADT} - (\text{ADT where VISIT} = \text{'Illness Visit Day 1'}) \leq 16$
- Set to 'Illness Visit z Day 21' if VISIT with  $17 \leq \text{ADT} - (\text{ADT where VISIT} = \text{'Illness Visit Day 1'}) \leq 23$
- Set to 'Illness Visit z Day 28' if VISIT with  $24 \leq \text{ADT} - (\text{ADT where VISIT} = \text{'Illness Visit Day 1'}) \leq 34$

Set AVISIT to 'Illness Visit' if the unscheduled visit contains 'Illness Visit' and is not within 34 days after any Illness Visit Day 1 (VISIT='Illness Visit Day 1' is absent).

Set to 'Day 29' if VISIT with  $2 \leq \text{ADY} \leq 36$  if the unscheduled visit doesn't contain 'Illness Visit', doesn't have LOCALFL='Y', and is not within 34 days after any Illness Visit Day 1

After the steps above, sort data by AVISITN and ADY, set the unscheduled visit (i.e., VISIT in upper case contains "UNSCH") records to blank if AVISITN < 100 and AVISITN > any previous AVISITN AND ADY <= any previous ADY. For example, Scheduled Day 29 is with AVISITN=3 (Day 29) and ADY=46 and an unscheduled visit is with AVISITN=4 (Day 57) and ADY=44, set AVISIT to blank for this unscheduled visit

If AVISIT contains 'Illness Visit' but not 'Illness Visit y' then set AVISIT='Illness Visit'. If AVISIT contains 'Illness Visit y' then set AVISIT='Illness Visit y'

### ADMB.AWRANGE

'<=1 Pre-dose' for 'Baseline'  
'Day 2 – Day 36' for 'Day 29'  
'Participant Decision Visit / OL-D1' for 'Participant Decision Visit / OL-D1 Visit'  
'Illness Visit Day 1' for 'Illness Visit' and ATPT='Day 1'  
'Illness Visit y Day 1' for 'Illness Visit y' and ATPT='Day 1'  
'Illness Visit Day 2 - Illness Visit Day 3' for 'Illness Visit' and ATPT='Day 3'  
'Illness Visit y Day 2 - Illness Visit y Day 3' for 'Illness Visit y' and ATPT='Day 3'  
'Illness Visit Day 4 - Illness Visit Day 5' for 'Illness Visit' and ATPT='Day 5'  
'Illness Visit y Day 4 - Illness Visit y Day 5' for 'Illness Visit y' and ATPT='Day 5'  
'Illness Visit Day 6 - Illness Visit Day 7' for 'Illness Visit' and ATPT='Day 7'  
'Illness Visit y Day 6 - Illness Visit y Day 7' for 'Illness Visit y' and ATPT='Day 7'  
'Illness Visit Day 8 - Illness Visit Day 11' for 'Illness Visit' and ATPT='Day 9'  
'Illness Visit y Day 8 - Illness Visit y Day 11' for 'Illness Visit y' and ATPT='Day 9'  
'Illness Visit Day 12 - Illness Visit Day 17' for 'Illness Visit' and ATPT='Day 14'  
'Illness Visit y Day 12 - Illness Visit y Day 17' for 'Illness Visit y' and ATPT='Day 14'  
'Illness Visit Day 18 - Illness Visit Day 24' for 'Illness Visit' and ATPT='Day 21'  
'Illness Visit y Day 18 - Illness Visit y Day 24' for 'Illness Visit y' and ATPT='Day 21'  
'Illness Visit Day 25 - Illness Visit Day 35' for 'Illness Visit' and ATPT='Day 28'  
'Illness Visit y Day 25 - Illness Visit y Day 35' for 'Illness Visit y' and ATPT='Day 28'

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### ADMB.AWTARGET

Set to 1 for 'Baseline'  
 Set to Set to 29 for 'Day 29'  
 Set to ADY where AVISIT='Participant Decision Visit / OL-D1' for 'Participant Decision Visit / OL-D1'  
 Set to ADY where AVISIT='Illness Visit' for 'Illness Visit' and ATPT='Day 1'  
 Set to ADY where AVISIT='Illness Visit y' for 'Illness Visit y' and ATPT='Day 1'  
 Set to ADY + 2 where AVISIT='Illness Visit' for 'Illness Visit' and ATPT='Day 3'  
 Set to ADY + 2 where AVISIT='Illness Visit y' for 'Illness Visit y' and ATPT='Day 3'  
 Set to ADY + 4 where AVISIT='Illness Visit' for 'Illness Visit' and ATPT='Day 5'  
 Set to ADY + 4 where AVISIT='Illness Visit y' for 'Illness Visit y' and ATPT='Day 5'  
 Set to ADY + 6 where AVISIT='Illness Visit' for 'Illness Visit' and ATPT='Day 7'  
 Set to ADY + 6 where AVISIT='Illness Visit y' for 'Illness Visit y' and ATPT='Day 7'  
 Set to ADY + 8 where AVISIT='Illness Visit' for 'Illness Visit' and ATPT='Day 9'  
 Set to ADY + 8 where AVISIT='Illness Visit y' for 'Illness Visit y' and ATPT='Day 9'  
 Set to ADY + 13 where AVISIT='Illness Visit' for 'Illness Visit' and ATPT='Day 14'  
 Set to ADY + 13 where AVISIT='Illness Visit y' for 'Illness Visit y' and ATPT='Day 14'  
 Set to ADY + 20 where AVISIT='Illness Visit' for 'Illness Visit' and ATPT='Day 21'  
 Set to ADY + 20 where AVISIT='Illness Visit y' for 'Illness Visit y' and ATPT='Day 21'  
 Set to ADY + 27 where AVISIT='Illness Visit' for 'Illness Visit' and ATPT='Day 28'  
 Set to ADY + 27 where AVISIT='Illness Visit y' for 'Illness Visit y' and ATPT='Day 28'

### ADMB.ANL01FL

Set to 'Y' if ABLFL='Y'

For post-baseline assessments:

- Set to 'Y' if AVISIT is non-missing and AVALC = 'Negative' or 'Positive' per subject per parameter and per AVISIT

If AVISIT doesn't contains 'Illness Visit':

- Set to 'Y' where the assessment is scheduled visit if there is more than one post-baseline assessment found by subject, parameter and AVISIT
- Set to 'Y' to the assessment by selecting AVALC in the order of Positive > Negative if there are more than two assessments at scheduled visit by subject, parameter and AVISIT
- Set to 'Y' by selecting earliest assessment if there are 2 or more scheduled assessments with equal results

If AVISIT contains 'Illness Visit', regardless of scheduled visit or unscheduled visit

- Set to 'Y' by selecting AVALC in order of Positive > Negative if there is no scheduled visit
- Set to 'Y' to the earliest assessment if there are more than two assessment with the same result

### ADIS.AVISIT

If ABLFL='Y' then AVISIT='Baseline'

If ADY > 1 then

- set to 'Day xx' part of VISIT if VISITNUM=2, 6, 10, 15, 21, 32,
- set to 'Illness Visit Day 1' if VISITNUM=33
- set to 'Illness Visit Day 28' if VISITNUM=35
- set to VISIT if VISIT = 'Participant Decision Visit / OL-D1'
- set to 'Open Label Day 29' if VISIT='OL-D29'
- set to 'Open Label Day 57' if VISIT='OL-D57'

*If a subject has multiple scheduled Illness Visit Day 1 with different date part of ISDTC, sort these Illness Visit Day 1 records by date part of ISDTC and rename Illness Visit Day 1 to Illness Visit y Day 1 starting from 2nd record and y=2,3,4...*

Set AVISIT as follows using the visit window below if ADY > 1 and VISIT contains 'UNSCHED':

- Set to the AVISIT of that scheduled Illness Visit Day 1 if date part of ISDTC is the same as the date part of ISDTC for a scheduled Illness Visit Day 1
- Set to the corresponding AVISIT and substitute 'Day 1' with 'Day 28' if VISIT with  $2 \leq \text{ADT} - (\text{ADT where VISIT='Illness Visit Day 1'}) \leq 34$ . If there are multiple VISIT='Illness Visit Day 1' satisfy above window, choose the one with largest AVISITN
- Set to 'Illness Visit' if the unscheduled visit contains 'Illness Visit' and is not within 34 days after any Illness Visit Day

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1 (VISIT='Illness Visit Day 1' is absent)

If ADSL.TR02SDT is not missing, ADSL.OLDOS2DT is missing:

- Set to 'Participant Decision Visit / OL-D1' when VISIT is on the same date as VISIT='Participant Decision Visit / OL-D1'
- Set to 'Open Label Day 29' when VISIT is within [1, 42] days after VISIT='Participant Decision Visit / OL-D1' (ie, [ADT+1, ADT+42])

If ADSL.TR02SDT is not missing, ADSL.OLDOS2DT is not missing,

- Set to 'Participant Decision Visit / OL-D1' when VISIT is on the same date as VISIT='Participant Decision Visit / OL-D1',
- Set to 'Open Label Day 57' when VISIT is within [1, 70] days after VISIT='Participant Decision Visit / OL-D1' (ie, [ADT+1, ADT+70])

Set to 'Day 29' if VISIT with  $2 \leq \text{ADY} \leq 43$

Set to 'Day 57' if VISIT with  $44 \leq \text{ADY} \leq 133$

Set to 'Day 209' if VISIT with  $134 \leq \text{ADY} \leq 301$

Set to 'Day 394' if VISIT with  $302 \leq \text{ADY} \leq 576$

Set to 'Day 759' if VISIT with  $577 \leq \text{ADY} \leq 773$

After the steps above, sort data by AVISITN and ADY, set the unscheduled visit (i.e., VISIT contains 'Unsched') records to blank if AVISITN < 100 and AVISITN > any previous AVISITN and ADY <= any previous ADY).

For example, Scheduled Day 29 is with AVISITN = 3 (Day 29) and ADY = 46 and an unscheduled visit is with AVISITN = 4 (Day 57) and ADY = 44, set AVISIT to blank for this unscheduled visit.

After above steps,

set to 'Illness Visit' or 'Illness Visit y' and set ATPT='Day x' if AVISIT='Illness Visit Day x' or 'Illness Visit y Day x'

### **ADVS.AVISIT**

If ABLFL='Y' then set to 'Baseline'

If ADY > 1, then:

Set to 'Day xx' part of VISIT for VISITNUM=2, 6, 10, 15, 21, 32,

Set to 'Illness Visit Day 1' for VISITNUM=33,

Set to 'Illness Visit Day 28' for VISITNUM=35,

Set to VISIT for VISIT='Participant Decision Visit / OL-D1',

Set to 'Open Label Day 29' for VISIT='OL-D29',

Set to 'Open Label Day 57' for VISIT='OL-D57'

If a subject has multiple scheduled Illness Visit Day 1 with different date part of VSDTC, then sort these Illness Visit Day 1 records by date part of VSDTC and rename Illness Visit Day 1 to Illness Visit y Day 1 starting from 2nd record and y=2,3,4...

If (ADY=1 and ASTAGEN=1 or ADY>1) and VISIT contains 'Unscheduled', then set AVISIT as follows visit window below:

If date part of VSDTC is the same as the date part of VSDTC for a scheduled Illness Visit Day 1, then set to the AVISIT of that scheduled Illness Visit Day 1,

If VISIT with  $2 \leq \text{ADT} - (\text{ADT where VISIT='Illness Visit Day 1'}) \leq 34$ , then set to the corresponding AVISIT and substitute 'Day 1' with 'Day 28',

If there are multiple VISIT='Illness Visit Day 1' satisfy above window, choose the one with largest AVISITN,

If the unscheduled visit contains 'Illness Visit' and is not within 34 days after any Illness Visit Day, then Set to 'Illness Visit',

If ADSL.TR02SDT is not missing, ADSL.OLDOS2DT is missing:

when VISIT is on the same date as VISIT='Participant Decision Visit / OL-D1', then set to 'Participant Decision Visit / OL-D1',

when VISIT is within [1, 42] days after VISIT='Participant Decision Visit / OL-D1', then set to 'Open Label Day 29',

If ADSL.TR02SDT is not missing, ADSL.OLDOS2DT is not missing:

when VISIT is on the same date as VISIT='Participant Decision Visit / OL-D1', then set to

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'Participant Decision Visit / OL-D1',  
when VISIT is within [1, 42] days after VISIT='Participant Decision Visit / OL-D1', then set to  
'Open Label Day 29',  
when VISIT is within [43, 70] days after VISIT='Participant Decision Visit / OL-D1' then set to  
'Open Label Day 57',  
If VISIT with ADY=1, then set to 'Day 1';  
If VISIT with  $2 \leq \text{ADY} \leq 43$ , then set to 'Day 29';  
  
If VISIT with  $44 \leq \text{ADY} \leq 133$ , then set to 'Day 57';  
If VISIT with  $134 \leq \text{ADY} \leq 301$ , then set to 'Day 209';  
If VISIT with  $302 \leq \text{ADY} \leq 576$ , then set to 'Day 394';  
If VISIT with  $577 \leq \text{ADY} \leq 773$ , then set to 'Day 759';

After the steps above, sort data by AVISITN and ADY,  
set the unscheduled visit records to blank if AVISITN < 100 and AVISITN > any previous AVISITN AND  
ADY <= any previous ADY).  
For example, Scheduled Day 29 is with AVISITN=3 (Day 29) and ADY=46 and an unscheduled visit is with  
AVISITN=4 (Day 57) and ADY=44, set AVISIT to blank for this unscheduled visit.

After above steps, if AVISIT='Illness Visit Day x' or 'Illness Visit y Day x' then set AVISIT='Illness Visit' or 'Illness  
Visit y' and set ADVS.ATPT='Day x'.

### **ADVS.ASTAGE**

For subjects who received 2 injections in blinded phase (DOSE1FL='Y' and DOSE2FL='Y') and APERIOD=1, set  
to 'Vaccination stage' If  $.\text{ADSL}.\text{TR01SDTM} \leq \text{ADTM}$  and  $\text{ADT} \leq \text{earliest date of (date of Visit 3 (i.e. SV.SVSTDTC where SV.VISIT = 'Visit 3 Day 57'), ADSL.EOSDT, ADSL.DTHDT))}$ ; set to 'Follow up stage' if  
 $\text{ADT} > \text{non-missing date of Visit 3}$ . If date of Visit 3, ADSL.EOSDT, and ADSL.DTHDT are all unavailable, set to  
'Vaccination stage' for post baseline records. Else leave missing.

For subjects who received only 1 injection in blinded phase (DOSE1FL='Y' and DOSE2FL ne 'Y') and  
APERIOD=1, set to 'Vaccination stage' If  $.\text{ADSL}.\text{TR01SDTM} \leq \text{ADTM}$  and  $\text{ADT} \leq \text{earliest date of (date of Visit 2 (i.e. SV.SVSTDTC where SV.VISIT = 'Visit 2 Day 29'), ADSL.EOSDT, ADSL.DTHDT))}$ ; set to 'Follow up stage' if  
 $\text{ADT} > \text{non-missing date of Visit 2}$ . If date of Visit 2, ADSL.EOSDT, and ADSL.DTHDT are all  
unavailable, set to 'Vaccination stage' for post baseline records. Else leave missing.

For subjects who received 2 injections OL phase (OLDOS1FL='Y' and OLDOS2FL='Y') and APERIOD=2, set to  
'Vaccination stage' If  $.\text{ADSL}.\text{TR02SDTM} \leq \text{ADTM}$  and  $\text{ADT} \leq \text{earliest date of (date of OL-Day 57 (i.e. SV.SVSTDTC where SV.VISIT = 'OL-Day 57'), ADSL.EOSDT, ADSL.DTHDT))}$ ; set to 'Follow up stage' if  
 $\text{ADT} > \text{non-missing date of OL-Day 57}$ . If date of OL-Day 57, ADSL.EOSDT, and ADSL.DTHDT are all unavailable, set  
to 'Vaccination stage' for post baseline records. Else leave missing.

For subjects who received only 1 injection (OLDOS1FL='Y' and OLDOS2FL ne 'Y') and APERIOD=2, set to  
'Vaccination stage' If  $.\text{ADSL}.\text{TR02SDTM} \leq \text{ADTM}$  and  $\text{ADT} \leq \text{earliest date of (date of OL-Day 29 (i.e. SV.SVSTDTC where SV.VISIT = 'OL-Day 29'), ADSL.EOSDT, ADSL.DTHDT))}$ ; set to 'Follow up stage' if  
 $\text{ADT} > \text{non-missing date of OL-Day 29}$ . If date of OL-Day 29, ADSL.EOSDT, and ADSL.DTHDT are all unavailable,  
set to 'Vaccination stage' for post baseline records. Else leave missing.

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### ADTTE.ADT

PARAMCD	ADT
TTCVDC1 TTCVDC2 TTCVDC3 TTCVDC4 TTCVDC5 TTCVDC6	<p>Set to ADEFF.ADT if ADEFF.PARCAT1 = 'DERIVED PER SAP' and ADEFF.PARAMCD = 'COVIDS' and ADEFF.ANL01FL = 'Y' and APERIOD = 1 is found from ADEFF, ADEFF.ADT is on/before the earliest date of (ADSL.DTHDT, ADSL.EOSDT, ADSL.EFFCODT) and none of the following criteria is met:</p> <ol style="list-style-type: none"> <li>RT-PCR is positive at Day 29 prior to RT-PCR date based on which the COVID case is defined (no record found where MB.MBTESTCD = 'SARSCOV2' and MB.MBSTRESC in ('DETECTED', 'POSITIVE') and MB.VISIT = 'Visit 2 Day 29' and MB.MBDTC &lt; ADEFF.PCRDT),</li> <li>Elecsys is positive at Day 29, Day 57, or Day 209 prior to COVID onset date (no record found where IS.ISTESTCD = 'SARSCOV2' and IS.ISSTRESC = 'Positive' and IS.VISIT in ('Visit 2 Day 29', 'Visit 3 Day 57', 'Visit 4 Day 209') and IS.ISDTC &lt; ADEFF.PCRDT)</li> </ol> <p>Set to the date of earliest positive RT-PCR (MB.MBDTC) or Elecsys result (IS.ISDTC) if the above-mentioned record is found from ADEFF and any of the positive-test criteria is met, Set to earliest date of (ADSL.DTHDT, ADSL.EOSDT, ADSL.EFFCODT, ADSL.AP01EDT) if the above-mentioned record is not found from ADEFF</p>
TTCVDC9	<p>Set to ADEFF.ADT if ADEFF.PARCAT1 = 'DERIVED PER SAP' and ADEFF.PARAMCD = 'COVIDS' and ADEFF.ANL01FL = 'Y' is found from ADEFF, ADEFF.ADT is on/before the earliest date of (ADSL.DTHDT, ADSL.EOSDT, ADSL.EFFCODT) and none of the following criteria is met:</p> <ol style="list-style-type: none"> <li>RT-PCR is positive at Day 29 or participant decision visit prior to RT-PCR date based on which the COVID case is defined (no record found where MB.MBTESTCD = 'SARSCOV2', MB.MBSTRESC in ('DETECTED', 'POSITIVE'), MB.VISIT in ('Visit 2 Day 29', 'Participant Decision Visit/ OL-D1') and MB.MBDTC &lt; ADEFF.PCRDT)</li> <li>Elecsys is positive at Day 29, Day 57, Day 209, participant decision visit, OL-D29, or OL-D57 prior to COVID onset date (no record found where IS.ISTESTCD = 'SARSCOV2' and IS.ISSTRESC = 'Positive' and IS.VISIT in ('Visit 2 Day 29', 'Visit 3 Day 57', 'Visit 4 Day 209', 'Participant Decision Visit/ OL-D1', 'OL-D29', 'OL-D57') and IS.ISDTC &lt; ADEFF.PCRDT)</li> </ol> <p>Set to the date of earliest positive RT-PCR (MB.MBDTC) or Elecsys result (IS.ISDTC) if the above-mentioned record is found from ADEFF and any of the positive-test criteria is met, Set to earliest date of (ADSL.DTHDT, ADSL.EOSDT, ADSL.EFFCODT) if the above-mentioned record is not found from ADEFF</p>
TCVSDC1 TCVSDC2 TCVSDC3 TCVSDC4 TCVSDC5 TCVSDC6	<p>Set to ADEFF.ADT if ADEFF.PARCAT1='DERIVED PER SAP' and ADEFF.PARAMCD = 'COVIDSVS' and ADEFF.ANL01FL = 'Y' and APERIOD=1 is found from ADEFF and ADEFF.ADT is on/before the earliest date of (ADSL.DTHDT, ADSL.EOSDT, ADSL.EFFCODT) and none of the following criteria is met:</p> <ol style="list-style-type: none"> <li>RT-PCR Test is Positive at Day 29 prior to RT-PCR date based on which the severe COVID case is defined (no record found where MB.MBTESTCD = 'SARSCOV2' and MB.MBSTRESC in ('DETECTED', 'POSITIVE' and MB.VISIT = 'Visit 2 Day 2' and MB.MBDTC &lt; ADEFF.PCRDT)</li> <li>Positive Elecsys Test Result at Day 29, Day 57, or Day 209 prior to COVID onset date (no record found where IS.ISTESTCD = 'SARSCOV2' and IS.ISSTRESC = 'Positive' and IS.VISIT in ('Visit 2 Day 29', 'Visit 3 Day 57', 'Visit 4 Day 209') and IS.ISDTC &lt; ADEFF.PCRDT)</li> </ol> <p>Set to the date of earliest positive RT-PCR (MB.MBDTC) or Elecsys result (IS.ISDTC) if the above-mentioned record is found from ADEFF and any of the positive-test criteria is met Set to earliest date of (ADSL.DTHDT, ADSL.EOSDT, ADSL.EFFCODT, ADSL.AP01EDT) if the above-mentioned record is not found from ADEFF</p>



## Additional ADaM Variables definition

PARAMCD	ADT
TCVSDSC9	<p>Set to ADEFF.ADT if ADEFF.PARCAT1 = 'DERIVED PER SAP' and ADEFF.PARAMCD = 'COVIDSDS' and ADEFF.ANL01FL = 'Y' is found from ADEFF and ADEFF.ADT is on/before the earliest date of (ADSL.DTHDT, ADSL.EOSDT, ADSL.EFFCODT) and none of the following criteria is met:</p> <ol style="list-style-type: none"> <li>RT-PCR is positive at Day 29 or participant decision visit prior to RT-PCR date based on which the COVID (secondary definition) case is defined (no record is found where MB.MBTESTCD = 'SARSCOV2' and MB.MBSTRESC is in ('DETECTED', 'POSITIVE') and MB.VISIT is in ('Visit 2 Day 29', 'Participant Decision Visit / OL-D1') and MB.MBDTC &lt; ADEFF.PCRDT)</li> <li>Elecsys is positive at Day 29, Day 57, Day 209, participant decision visit, OL-D29, or OL-D57 prior to COVID onset date (no record is found where IS.ISTESTCD = 'SARSCOV2' and IS.ISSTRESC is 'Positive' and IS.VISIT is in ('Visit 2 Day 29', 'Visit 3 Day 57', 'Visit 4 Day 209', 'Participant Decision Visit / OL-D1', 'OL-D29', 'OL-D57') and IS.ISDTC &lt; ADEFF.PCRDT)</li> </ol> <p>Set to the date of earliest positive RT-PCR or Elecsys result (MB.MBDTC or IS.ISDTC) if the above mentioned record is found from ADEFF and any of the positive-test criteria is met Set to earliest date of (ADSL.DTHDT, ADSL.EOSDT, ADSL.EFFCODT).</p>
TCVDSVC1 TCVDSVC2 TCVDSVC3 TCVDSVC4 TCVDSVC5 TCVDSVC6	<p>Set to ADEFF.ADT if ADEFF.PARCAT1 = 'DERIVED PER SAP' and ADEFF.PARAMCD = 'COVIDSVS' and ADEFF.ANL01FL = 'Y' and APERIOD=1 is found from ADEFF where ADT is on/before the earliest date of (ADSL.DTHDT, ADSL.EOSDT, ADSL.EFFCODT) and none of the following criteria is met:</p> <ol style="list-style-type: none"> <li>RT-PCR is positive at Day 29 prior to RT-PCR date based on which the severe COVID case is defined (MB.MBTESTCD = 'SARSCOV2' and MB.MBSTRESC is in ('DETECTED', 'POSITIVE') and MB.VISIT = 'Visit 2 Day 29' and MB.MBDTC &lt; ADEFF.PCRDT)</li> <li>Elecsys is positive at Day 29, Day 57, or Day 209 prior to COVID onset date (IS.ISTESTCD = 'SARSCOV2' and IS.ISSTRESC = 'Positive' and IS.VISIT is in ('Visit 2 Day 29', 'Visit 3 Day 57', 'Visit 4 Day 209') and IS.ISDTC &lt; ADEFF.PCRDT)</li> </ol> <p>Else if the above-mentioned record is found from ADEFF and any of the positive-test criteria is met then set to the date of earliest positive RT-PCR or Elecsys result (MB.MBDTC or IS.ISDTC) Else if the above-mentioned record is not found from ADEFF then set to earliest date of (ADSL.DTHDT, ADSL.EOSDT, ADSL.EFFCODT, ADSL.AP01EDT)</p>
TCVDSVC9	<p>Set to ADEFF.ADT if ADEFF.PARCAT1 = 'DERIVED PER SAP' and ADEFF.PARAMCD = 'COVIDSVS' and ADEFF.ANL01FL = 'Y' is found from ADEFF and ADEFF.ADT is on/before the earliest date of (ADSL.DTHDT, ADSL.EOSDT, ADSL.EFFCODT) and none of the following criteria is met:</p> <ol style="list-style-type: none"> <li>RT-PCR is positive at Day 29 or participant decision visit prior to RT-PCR date based on which the severe COVID case is defined (no record was found where MB.MBTESTCD = 'SARSCOV2' and MB.MBSTRESC is in ('DETECTED', 'POSITIVE') and MB.VISIT is in ('Visit 2 Day 29', 'Participant Decision Visit / OL-D1') and MB.MBDTC &lt; ADEFF.PCRDT)</li> <li>Elecsys is positive at Day 29, Day 57, Day 209, participant decision visit, OL-D29, or OL-D57 prior to severe COVID onset date (no record is found where IS.ISTESTCD = 'SARSCOV2' and IS.ISSTRESC = 'Positive' and IS.VISIT is in ('Visit 2 Day 29', 'Visit 3 Day 57', 'Visit 4 Day 209', 'Participant Decision Visit / OL-D1', 'OL-D29' or 'OL-D57') and IS.ISDTC &lt; ADEFF.PCRDT)</li> </ol> <p>Set to the date of earliest positive RT-PCR (MB.MBDTC) or Elecsys result (IS.ISDTC) if the above mentioned record is found from ADEFF and any of the positive-test criteria is met Set to earliest date of (ADSL.DTHDT, ADSL.EOSDT, ADSL.EFFCODT)</p>
TTASYMP1 TTASYMP2 TTASYMP3 TTASYMP4 TTASYMP5 TTASYMP6 TTASYCR1 TTASYCR2 TTASYCR3 TTASYCR4 TTASYCR5 TTASYCR6	<p>Set to ADEFF.ADT if ADEFF.PARCAT1 = 'DERIVED PER SAP' and ADEFF.PARAMCD = 'ASYMPINF' and ADEFF.ANL01FL = 'Y' and APERIOD=1 is found from ADEFF and ADEFF.ADT is on/before the earliest date of (ADSL.DTHDT, ADSL.EOSDT, ADSL.EFFCODT)</p> <p>Set to earliest ADEFF.ADT if ADEFF.PARAMCD in ('COVIDS', 'COVIDSDS') and ADEFF.ANL01FL = 'Y' and APERIOD=1 is found from ADEFF and ADEFF.ADT is on/before the earliest date of (ADSL.DTHDT, ADSL.EOSDT, ADSL.EFFCODT)</p> <p>Set to earliest date of (ADSL.DTHDT, ADSL.EOSDT, ADSL.EFFCODT, ADSL.AP01EDT)</p>
TTASYMP9 TTASYCR9	<p>Set to ADEFF.ADT if ADEFF.PARCAT1 = 'DERIVED PER SAP' and ADEFF.PARAMCD = 'ASYMPINF' and ADEFF.ANL01FL = 'Y' is found from ADEFF and ADEFF.ADT is on/before the earliest date of (ADSL.DTHDT, ADSL.EOSDT, ADSL.EFFCODT)</p> <p>Set to earliest ADEFF.ADT if ADEFF.PARAMCD in ('COVIDS', 'COVIDSDS') and ADEFF.ANL01FL = 'Y' is found from ADEFF</p>

## Additional ADaM Variables definition

PARAMCD	ADT
	Set ADT to earliest date of (ADSL.DTHDT, ADSL.EOSDT, ADSL.EFFCODT)
TTINF1 TTINF2 TTINF3 TTINF4 TTINF5 TTINF6	Set to ADEFF.ADT if ADEFF.PARCAT1 = 'DERIVED PER SAP' and ADEFF.PARAMCD = 'INFECT' and ADEFF.ANL01FL = 'Y' and APERIOD=1 is found from ADEFF and ADEFF.ADT is on/before the earliest date of (ADSL.DTHDT, ADSL.EOSDT, and ADSL.EFFCODT)  Set ADT to earliest date of (ADSL.DTHDT, ADSL.EOSDT, ADSL.EFFCODT, ADSL.AP01EDT)
TTINF9	Set to ADEFF.ADT if ADEFF.PARCAT1 = 'DERIVED PER SAP' and ADEFF.PARAMCD = 'INFECT' and ADEFF.ANL01FL = 'Y' is found from ADEFF and ADEFF.ADT is on/before the earliest date of (ADSL.DTHDT, ADSL.EOSDT, ADSL.EFFCODT)  Set to earliest date of (ADSL.DTHDT, ADSL.EOSDT, ADSL.EFFCODT)
TTDTHCV1 TTDTHCV2 TTDTHCV3 TTDTHCV4 TTDTHCV5 TTDTHCV6	Set to ADEFF.ADT if ADEFF.PARCAT1 = 'DERIVED PER SAP' and ADEFF.PARAMCD = 'DEATHCVD' and ADEFF.ANL01FL = 'Y' and APERIOD=1 is found from ADEFF and ADEFF where ADT is on/before the earliest date of (ADSL.DTHDT, ADSL.EOSDT, ADSL.EFFCODT)  Set to earliest date of (ADSL.DTHDT, ADSL.EOSDT, ADSL.EFFCODT, ADSL.AP01EDT)
TTDTHCV9	Set to ADEFF.ADT if ADEFF.PARCAT1 = 'DERIVED PER SAP' and ADEFF.PARAMCD = 'DEATHCVD' and ADEFF.ANL01FL = 'Y' is found from ADEFF and ADEFF.ADT is on/before the earliest date of (ADSL.DTHDT, ADSL.EOSDT, ADSL.EFFCODT)  Set to earliest date of (ADSL.DTHDT, ADSL.EOSDT, ADSL.EFFCODT)
TTDEATH	Set to the earliest date of (ADSL.DTHDT, ADSL.EOSDT, ADSL.EFFCOD, ADSL.AP01EDT) if ADSL.DTHDT is non-missing and ADSL.AP02SDT is missing
TTDEATH9	Set to the earliest date of (ADSL.DTHDT, ADSL.EOSDT, ADSL.EFFCODT) if ADSL.DTHDT is not missing and ADSL.AP02SDT is not missing

### ADTTE.CNSR

PARAMCD	CNSR
TTCVDC1 TTCVDC2 TTCVDC3 TTCVDC4 TTCVDC5 TTCVDC6	<p>If ADEFF.PARCAT1 = 'DERIVED PER SAP' and ADEFF.PARAMCD = 'COVIDS' and ANL01FL = 'Y' and APERIOD=1 is found from ADEFF, ADEFF.ADT is on/before the earliest date of (ADSL.DTHDT, ADSL.EOSDT, ADSL.EFFCODT) and none of the following criteria is met:</p> <ol style="list-style-type: none"> <li>RT-PCR is positive at Day 29 prior to RT-PCR date based on which the COVID case is defined (no record is found where MB.MBTESTCD = 'SARSCOV2' and MB.MBSTRESC is in ('DETECTED', 'POSITIVE') and MB.VISIT is 'Visit 2 Day 29' and MB.MBDTC &lt; ADEFF.PCRDT)</li> <li>Elecsys is positive at Day 29, Day 57, or Day 209 prior to COVID onset date (no record is found where IS.ISTESTCD = 'SARSCOV2' and IS.ISSTRESC = 'Positive' and IS.VISIT in ('Visit 2 Day 29', 'Visit 3 Day 57', 'Visit 4 Day 209') and IS.ISDTC &lt; ADEFF.PCRDT)</li> </ol> <p>Then</p> <ul style="list-style-type: none"> <li>Set to 0 if PARAMCD='TTCVDC1' and ADT &gt;= ADSL.DOSE2DT (non-missing) + 14, else set to 1</li> <li>Set to 0 if PARAMCD='TTCVDC2' and ADT &gt;= ADSL.DOSE2DT (non-missing), else set to 1</li> <li>Set to 0 if PARAMCD='TTCVDC3' and ADT &gt;= ADSL.TRT01SDT (non-missing) + 14, else set to 1</li> <li>Set to 0 if PARAMCD='TTCVDC4' and ADT &gt;= ADSL.TRT01SDT (non-missing), else set to 1</li> <li>Set to 0 if PARAMCD='TTCVDC5' and ADT &gt;= ADSL.RANDDT (non-missing), else set to 1</li> <li>Set to 0 if PARAMCD='TTCVDC6' and ADT &gt;= ADSL.DOSE2DT (non-missing) + 35, else set to 1</li> </ul> <p>Else set to 1</p>

## Additional ADaM Variables definition

PARAMCD	CNSR
TTCVDC9	<p>Set to 0 if ADEFF.PARCAT1 = 'DERIVED PER SAP' and ADEFF.PARAMCD = 'COVIDS' and ANL01FL = 'Y' and APERIOD = 2 is found from ADEFF and ADEFF.ADT is on/before the earliest date of (ADSL.DTHDT, ADSL.EOSDT, ADSL.EFFCODT) and none of the following criteria is met:</p> <ol style="list-style-type: none"> <li>RT-PCR is positive at Day 29 or participant decision visit prior to RT-PCR date based on which the COVID case is defined (no record is not found where MB.MBTESTCD = 'SARSCOV2' and MB.MBSTRESC is in ('DETECTED', 'POSITIVE'), MB.VISIT in ('Visit 2 Day 29', 'Participant Decision Visit / OL-D1') and MB.MBDTC &lt; ADEFF.PCRDT)</li> <li>Elecsys is positive at Day 29, Day 57, Day 209, participant decision visit, OL-D29, or OL-D57 prior to COVID onset date (no record is not found where IS.ISTESTCD = 'SARSCOV2' and IS.ISSTRESC = 'Positive' and IS.VISIT in ('Visit 2 Day 29', 'Visit 3 Day 57', 'Visit 4 Day 209', 'Participant Decision Visit / OL-D1', 'OL-D29' or 'OL-D57') and IS.ISDTC &lt; ADEFF.PCRDT)</li> </ol> <p>Set to 1, otherwise</p>
TCVDSVC1 TCVDSVC2 TCVDSVC3 TCVDSVC4 TCVDSVC5 TCVDSVC6	<p>If ADEFF.PARCAT1 = 'DERIVED PER SAP' and ADEFF.PARAMCD = 'COVIDSVS' and ANL01FL = 'Y' and APERIOD = 1 is found from ADEFF and ADEFF.ADT is on/before the earliest date of (ADSL.DTHDT, ADSL.EOSDT, ADSL.EFFCODT) and none of the following criteria is met:</p> <ol style="list-style-type: none"> <li>positive RT-PCR at Day 29 prior to RT-PCR date based on which the severe COVID case is defined (MB.MBTESTCD="SARSCOV2", MB.MBSTRESC is "DETECTED" or 'POSITIVE' in upper case, MB.VISIT="Visit 2 Day 29", and MB.MBDTC&lt;ADEFF.PCRDT)</li> <li>positive Elecsys at Day 29, Day 57, or Day 209 prior to COVID onset date (IS.ISTESTCD="SARSCOV2", IS.ISSTRESC="Positive", IS.VISIT="Visit 2 Day 29" or 'Visit 3 Day 57' or 'Visit 4 Day 209', and IS.ISDTC&lt;ADEFF.PCRDT)</li> </ol> <p>then</p> <p>Set to 0 if PARAMCD='TCVCSVC1' and ADT &gt;= ADSL.DOSE2DT (non-missing) + 14, else set to 1</p> <p>Set to 0 if PARAMCD='TCVCSVC2' and ADT &gt;= ADSL.DOSE2DT (non-missing), else set to 1</p> <p>Set to 0 if PARAMCD='TCVCSVC3' and ADT &gt;= ADSL.TRT01SDT (non-missing) + 14, else set to 1</p> <p>Set to 0 if PARAMCD='TCVCSVC4' and ADT &gt;= ADSL.TRT01SDT (non-missing), else set to 1</p> <p>Set to 0 if PARAMCD='TCVCSVC5' and ADT &gt;= ADSL.RANDDT (non-missing), else set to 1</p> <p>Set to 0 if PARAMCD='TCVCSVC6' and ADT &gt;= ADSL.DOSE2DT (non-missing) + 35, else set to 1</p> <p>Set to 1, otherwise</p>
TCVDSVC9	<p>If ADEFF.PARCAT1 = 'DERIVED PER SAP' and ADEFF.PARAMCD = 'COVIDSVS' and ANL01FL = 'Y' and APERIOD=2 is found from ADEFF and ADEFF.ADT is on/before the earliest date of (ADSL.DTHDT, ADSL.EOSDT, ADSL.EFFCODT) and none of the following criteria is met:</p> <ol style="list-style-type: none"> <li>RT-PCR is positive at Day 29 or participant decision visit prior to RT-PCR date based on which the COVID case is defined ( no record is found where MB.MBTESTCD = 'SARSCOV2' and MB.MBSTRESC is in ('DETECTED', 'POSITIVE') and MB.VISIT in ('Visit 2 Day 29', 'Participant Decision Visit / OL-D1') and MB.MBDTC &lt; ADEFF.PCRDT)</li> <li>Elecsys is positive at Day 29, Day 57, Day 209, participant decision visit, OL-D29, or OL-D57 prior to severe COVID onset date ( no record is found where IS.ISTESTCD = 'SARSCOV2', IS.ISSTRESC = 'Positive' and IS.VISIT in ('Visit 2 Day 29', 'Visit 3 Day 57', 'Visit 4 Day 209', 'Participant Decision Visit / OL-D1', 'OL-D29' or 'OL-D57') and IS.ISDTC &lt; ADEFF.PCRDT)</li> </ol> <p>then set to 0</p> <p>else set to 1</p>
TCVSDC1 TCVSDC2 TCVSDC3 TCVSDC4 TCVSDC5 TCVSDC6	<p>If ADEFF.PARCAT1 = 'DERIVED PER SAP' and ADEFF.PARAMCD = 'COVIDSDS' and ANL01FL = 'Y' and APERIOD=1 is found from ADEFF and ADEFF.ADT is on/before the earliest date of (ADSL.DTHDT, ADSL.EOSDT, ADSL.EFFCODT) and none of the following criteria is met:</p> <ol style="list-style-type: none"> <li>RT-PCR is positive at Day 29 prior to RT-PCR date based on which the COVID (secondary definition) case is defined (no record is found where MB.MBTESTCD = 'SARSCOV2' and MB.MBSTRESC is in ('DETECTED', 'POSITIVE') and MB.VISIT = 'Visit 2 Day 29' and MB.MBDTC &lt; ADEFF.PCRDT)</li> <li>Elecsys is positive at Day 29, Day 57, or Day 209 prior to COVID onset date (no record is not found where IS.ISTESTCD = 'SARSCOV2' and IS.ISSTRESC = 'Positive' and IS.VISIT in ('Visit 2 Day 29', 'Visit 3 Day 57', 'Visit 4 Day 209') and IS.ISDTC &lt; ADEFF.PCRDT)</li> </ol> <p>then</p> <p>Set to 0 if PARAMCD='TCVCSDC1' and ADT &gt;= ADSL.DOSE2DT (non-missing) + 14, else set to 1</p> <p>Set to 0 if PARAMCD='TCVCSDC2' and ADT &gt;= ADSL.DOSE2DT (non-missing), else set to 1</p> <p>Set to 0 if PARAMCD='TCVCSDC3' and ADT &gt;= ADSL.TRT01SDT (non-missing) + 14, else set to 1</p> <p>Set to 0 if PARAMCD='TCVCSDC4' and ADT &gt;= ADSL.TRT01SDT (non-missing), else set to 1</p> <p>Set to 0 if PARAMCD='TCVCSDC5' and ADT &gt;= ADSL.RANDDT (non-missing), else set to 1</p> <p>Set to 0 if PARAMCD='TCVCSDC6' and ADT &gt;= ADSL.DOSE2DT (non-missing) + 35, else set to 1</p> <p>Else set to 1</p>

## Additional ADaM Variables definition

PARAMCD	CNSR
TCVSDC9	<p>If ADEFF.PARCAT1 = 'DERIVED PER SAP' and ADEFF.PARAMCD = 'COVIDSDS' and ANL01FL = 'Y' and APERIOD=2 is found from ADEFF and ADEFF.ADT is on/before the earliest date of (ADSL.DTHDT, ADSL.EOSDT, ADSL.EFFCODT) and none of the following criteria is met:</p> <ol style="list-style-type: none"> <li>RT-PCR is positive at Day 29 or participant decision visit prior to RT-PCR date based on which the COVID case is defined (no record is not found where MB.MBTESTCD = 'SARSCOV2', MB.MBSTRESC is in ('DETECTED', 'POSITIVE') and MB.VISIT in ('Visit 2 Day 29', 'Participant Decision Visit / OL-D1') and MB.MBDTC &lt; ADEFF.PCRDT)</li> <li>Elecsys is positive at Day 29, Day 57, Day 209, participant decision visit, OL-D29, or OL-D57 prior to severe COVID onset date (no record is found where IS.ISTESTCD = 'SARSCOV2' and IS.ISSTRESC = 'Positive' and IS.VISIT in ('Visit 2 Day 29', 'Visit 3 Day 57', 'Visit 4 Day 209', 'Participant Decision Visit / OL-D1', 'OL-D29' or 'OL-D57') and IS.ISDTC &lt; ADEFF.PCRDT)</li> </ol> <p>then set to 0 else set to 1</p>
TTASYMP1 TTASYMP2 TTASYMP3 TTASYMP4 TTASYMP5 TTASYMP6	<p>If ADEFF.PARCAT1 = 'DERIVED PER SAP' and ADEFF.PARAMCD = 'ASYMPINF' and ANL01FL = 'Y' and APERIOD=1 is found from ADEFF and ADEFF.ADT is on/before the earliest date of (ADSL.DTHDT, ADSL.EOSDT, ADSL.EFFCODT) then</p> <ul style="list-style-type: none"> <li>Set to 0 if PARAMCD='TTASYMP1' and ADT &gt;= ADSL.DOSE2DT (non-missing) + 14, else set to 1</li> <li>Set to 0 if PARAMCD='TTASYMP2' and ADT &gt;= ADSL.DOSE2DT (non-missing), else set to 1</li> <li>Set to 0 if PARAMCD='TTASYMP3' and ADT &gt;= ADSL.TRT01SDT (non-missing) + 14, else set to 1</li> <li>Set to 0 if PARAMCD='TTASYMP4' and ADT &gt;= ADSL.TRT01SDT (non-missing), else set to 1</li> <li>Set to 0 if PARAMCD='TTASYMP5' and ADT &gt;= ADSL.RANDDT (non-missing), else set to 1</li> <li>Set to 0 if PARAMCD='TTASYMP6' and ADT &gt;= ADSL.DOSE2DT (non-missing) + 35, else set to 1</li> </ul> <p>Else set to 1</p>
TTASYMP9	<p>Set to 0 if ADEFF.PARCAT1 = 'DERIVED PER SAP' and ADEFF.PARAMCD = 'ASYMPINF' and ANL01FL = 'Y' and APERIOD=2 is found from ADEFF and ADEFF.ADT is on/before the earliest date of (ADSL.DTHDT, ADSL.EOSDT, ADSL.EFFCODT) Set to 1, otherwise</p>
TTASYCR1 TTASYCR2 TTASYCR3 TTASYCR4 TTASYCR5 TTASYCR6	<p>If ADEFF.PARCAT1 = 'DERIVED PER SAP' and ADEFF.PARAMCD = 'ASYMPINF' and ANL01FL = 'Y' and APERIOD = 1 is found from ADEFF and ADEFF.ADT is on/before the earliest date of (ADSL.DTHDT, ADSL.EOSDT, ADSL.EFFCODT) then</p> <ul style="list-style-type: none"> <li>Set to 0 if PARAMCD='TTASYCR1' and ADT &gt;= ADSL.DOSE2DT (non-missing) + 14, else set to 1</li> <li>Set to 0 if PARAMCD='TTASYCR2' and ADT &gt;= ADSL.DOSE2DT (non-missing), else set to 1</li> <li>Set to 0 if PARAMCD='TTASYCR3' and ADT &gt;= ADSL.TRT01SDT (non-missing) + 14, else set to 1</li> <li>Set to 0 if PARAMCD='TTASYCR4' and ADT &gt;= ADSL.TRT01SDT (non-missing), else set to 1</li> <li>Set to 0 if PARAMCD='TTASYCR5' and ADT &gt;= ADSL.RANDDT (non-missing), else set to 1</li> <li>Set to 0 if PARAMCD='TTASYCR6' and ADT &gt;= ADSL.DOSE2DT (non-missing) + 35, else set to 1</li> </ul> <p>Else If ADEFF.PARCAT1 = 'DERIVED PER SAP' and ADEFF.PARAMCD in ('COVIDS', 'COVIDSDS') and ANL01FL = 'Y' and APERIOD=1 is found from ADEFF and ADEFF.ADT is on/before the earliest date of (ADSL.DTHDT, ADSL.EOSDT, ADSL.EFFCODT) then set to 2 Else set to 1</p>
TTASYCR9	<p>Set to 0 if ADEFF.PARCAT1 = 'DERIVED PER SAP' and ADEFF.PARAMCD = 'ASYMPINF' and ANL01FL = 'Y' and APERIOD = 2 is found from ADEFF, ADEFF.ADT is on/before the earliest date of (ADSL.DTHDT, ADSL.EOSDT, ADSL.EFFCODT) Set to 2 if ADEFF.PARCAT1 = 'DERIVED PER SAP' and ADEFF.PARAMCD in ('COVIDS', 'COVIDSDS') and ANL01FL = 'Y' and APERIOD = 2 is found from ADEFF and ADEFF.ADT is on/before the earliest date of (ADSL.DTHDT, ADSL.EOSDT, ADSL.EFFCODT) Set to 1</p>
TTINF1 TTINF2 TTINF3 TTINF4 TTINF5 TTINF6	<p>If ADEFF.PARCAT1 = 'DERIVED PER SAP' and ADEFF.PARAMCD = 'INFECT' and ANL01FL = 'Y' and APERIOD=1 is found from ADEFF and ADEFF.ADT is on/before the earliest date of (ADSL.DTHDT, ADSL.EOSDT, ADSL.EFFCODT) then</p> <ul style="list-style-type: none"> <li>Set to 0 if PARAMCD='TTINF1' and ADT &gt;= ADSL.DOSE2DT (non-missing) + 14, else set to 1</li> <li>Set to 0 if PARAMCD='TTINF2' and ADT &gt;= ADSL.DOSE2DT (non-missing), else set to 1</li> <li>Set to 0 if PARAMCD='TTINF3' and ADT &gt;= ADSL.TRT01SDT (non-missing) + 14, else set to 1</li> <li>Set to 0 if PARAMCD='TTINF4' and ADT &gt;= ADSL.TRT01SDT (non-missing), else set to 1</li> <li>Set to 0 if PARAMCD='TTINF5' and ADT &gt;= ADSL.RANDDT (non-missing), else set to 1</li> <li>Set to 0 if PARAMCD='TTINF6' and ADT &gt;= ADSL.DOSE2DT (non-missing) + 35, else set to 1</li> </ul> <p>Else set to 1</p>
TTINF9	<p>Set to 0 if ADEFF.PARCAT1='DERIVED PER SAP' and ADEFF.PARAMCD = 'INFECT' and ANL01FL = 'Y' and APERIOD = 2 is found from ADEFF and ADEFF.ADT is on/before the earliest date of (ADSL.DTHDT, ADSL.EOSDT, ADSL.EFFCODT), otherwise Set to 1</p>

## Additional ADaM Variables definition

PARAMCD	CNSR
TTDTHCV1 TTDTHCV2 TTDTHCV3 TTDTHCV4 TTDTHCV5 TTDTHCV6	<p>If ADEFF.PARCAT1 = 'DERIVED PER SAP' and ADEFF.PARAMCD = 'DEATHCVD' and ANL01FL = 'Y' and APERIOD = 1 is found from ADEFF and ADEFF.ADT is on/before the earliest date of (ADSL.DTHDT, ADSL.EOSDT, ADSL.EFFCODT) then</p> <ul style="list-style-type: none"> <li>Set to 0 if PARAMCD='TTDTHCV1' and ADT &gt;= ADSL.DOSE2DT (non-missing) + 14, else set to 1</li> <li>Set to 0 if PARAMCD='TTDTHCV2' and ADT &gt;= ADSL.DOSE2DT (non-missing), else set to 1</li> <li>Set to 0 if PARAMCD='TTDTHCV3' and ADT &gt;= ADSL.TRT01SDT (non-missing) + 14, else set to 1</li> <li>Set to 0 if PARAMCD='TTDTHCV4' and ADT &gt;= ADSL.TRT01SDT (non-missing), else set to 1</li> <li>Set to 0 if PARAMCD='TTDTHCV5' and ADT &gt;= ADSL.RANDDT (non-missing), else set to 1</li> <li>Set to 0 if PARAMCD='TTDTHCV6' and ADT &gt;= ADSL.DOSE2DT (non-missing) + 35, else set to 1</li> </ul> <p>Else set to 1</p>
TTDTHCV9	<p>Set to 0 if ADEFF.PARCAT1 = 'DERIVED PER SAP' and ADEFF.PARAMCD = 'DEATHCVD' and ANL01FL = 'Y' and APERIOD = 2 is found from ADEFF and ADEFF.ADT is on/before the earliest date of ADSL.DTHDT, ADSL.EOSDT, ADSL.EFFCODT), otherwise</p> <p>Set to 1</p>
TTDEATH	<p>Set to 0 If ADSL.DTHDT is not missing and on/before ADSL.EOSDT, ADSL.EFFCODT, and ADSL.AP01EDT, and ADSL.AP02SDT is missing, otherwise,</p> <p>Set to 1</p>
TTDEATH9	<p>Set to 0 if ADSL.DTHDT is not missing and on/before ADSL.EOSDT and ADSL.EFFCODT, and ADSL.AP02SDT is not missing, otherwise,</p> <p>Set to 1</p>

### ADTTE.EVNTDESC

PARAMCD	EVNTDESC
TTCVDC1 TTCVDC2 TTCVDC3 TTCVDC4 TTCVDC5 TTCVDC6	<p>If ADEFF.PARCAT1 = 'DERIVED PER SAP' and ADEFF.PARAMCD = 'COVIDS' and ANL01FL = 'Y' and APERIOD = 1 is found from ADEFF, ADEFF.ADT is on/before the earliest date of (ADSL.DTHDT, ADSL.EOSDT, ADSL.EFFCODT) and none of the following criteria is met:</p> <ol style="list-style-type: none"> <li>RT-PCR is positive at Day 29 prior to RT-PCR date based on which the COVID case is defined (no record is found where MB.MBTESTCD = 'SARSCOV2' and MB.MBSTRESC is in ('DETECTED', 'POSITIVE') and MB.VISIT = 'Visit 2 Day 29' and MB.MBDTC &lt; ADEFF.PCRDT)</li> <li>Elecsys is positive at Day 29, Day 57, or Day 209 prior to COVID onset date (no record is found where IS.ISTESTCD = 'SARSCOV2' and IS.ISTRESC = 'Positive' and IS.VISIT in ('Visit 2 Day 29', 'Visit 3 Day 57', 'Visit 4 Day 209' and IS.ISDTC &lt; ADEFF.PCRDT)</li> </ol> <p>then</p> <ul style="list-style-type: none"> <li>Set to PARAM if PARAMCD='TTCVDC1' and ADT &gt;= ADSL.DOSE2DT (non-missing) + 14, else concatenate 'Early ' with PARAM</li> <li>Set to PARAM if PARAMCD='TTCVDC2' and ADT &gt;= ADSL.DOSE2DT (non-missing), else concatenate 'Early ' with PARAM</li> <li>Set to PARAM if PARAMCD='TTCVDC3' and ADT &gt;= ADSL.TRT01SDT (non-missing) + 14, else concatenate 'Early ' with PARAM</li> <li>Set to PARAM if PARAMCD='TTCVDC4' and ADT &gt;= ADSL.TRT01SDT (non-missing), else concatenate 'Early ' with PARAM</li> <li>Set to PARAM if PARAMCD='TTCVDC5' and ADT &gt;= RANDDT (non-missing), else concatenate 'Early ' with PARAM</li> <li>Set to PARAM if PARAMCD='TTCVDC6' and ADT &gt;= ADSL.DOSE2DT (non-missing) + 35, else concatenate 'Early ' with PARAM</li> </ul> <p>Else if the above-mentioned record is found from ADEFF and any of the positive-test criteria is met then concatenate 'Infection Prior to ' with PARAM</p> <p>Else concatenate 'No ' with PARAM</p>

## Additional ADaM Variables definition

PARAMCD	EVNTDESC
TTCVDC9	<p>If ADEFF.PARCAT1 = 'DERIVED PER SAP' and ADEFF.PARAMCD = 'COVIDS' and ANL01FL = 'Y' is found from ADEFF, ADEFF.ADT is on/before the earliest date of (ADSL.DTHDT, ADSL.EOSDT, ADSL.EFFCODT) and none of the following criteria is met:</p> <ol style="list-style-type: none"> <li>1. RT-PCR is positive at Day 29 or participant decision visit prior to RT-PCR date based on which the COVID case is defined (no record is found where MB.MBTESTCD = 'SARSCOV2' and MB.MBSTRESC is in ('DETECTED', 'POSITIVE') and MB.VISIT in ('Visit 2 Day 29', 'Participant Decision Visit / OL-D1') and MB.MBDTC &lt; ADEFF.PCRDT)</li> <li>2. Elecsys is positive at Day 29, Day 57, Day 209, participant decision visit, OL-D29, or OL-D57 prior to COVID onset date (no record is found where IS.ISTESTCD = 'SARSCOV2' and IS.ISSTRESC = 'Positive' and IS.VISIT in ('Visit 2 Day 29', 'Visit 3 Day 57', 'Visit 4 Day 209', 'Participant Decision Visit / OL-D1', 'OL-D29' or 'OL-D57') and IS.ISDTC &lt; ADEFF.PCRDT)</li> </ol> <p>then set to PARAM if ADEFF.APERIOD = 2, else concatenate 'Early ' with PARAM Else if the above mentioned record is found from ADEFF and any of the positive-test criteria is met then concatenate 'Infection Prior to ' with PARAM Else concatenate 'No ' with PARAM</p>
TCVDSVC1 TCVDSVC2 TCVDSVC3 TCVDSVC4 TCVDSVC5 TCVDSVC6	<p>If ADEFF.PARCAT1 = 'DERIVED PER SAP' and ADEFF.PARAMCD = 'COVIDSVS' and ANL01FL = 'Y' and APERIOD = 1 is found from ADEFF, ADEFF.ADT is on/before the earliest date of (ADSL.DTHDT, ADSL.EOSDT, ADSL.EFFCODT) and none of the following criteria is met:</p> <ol style="list-style-type: none"> <li>1. RT-PCR is positive at Day 29 prior to RT-PCR date based on which the severe COVID case is defined (no record is found where MB.MBTESTCD = 'SARSCOV2' and MB.MBSTRESC in ('DETECTED', 'POSITIVE')) and MB.VISIT = 'Visit 2 Day 29' and MB.MBDTC &lt; ADEFF.PCRDT)</li> <li>2. Elecsys is positive at Day 29, Day 57, or Day 209 prior to COVID onset date (no record is found where IS.ISTESTCD = 'SARSCOV2' and IS.ISSTRESC = 'Positive' and IS.VISIT in ('Visit 2 Day 29', 'Visit 3 Day 57', 'Visit 4 Day 209' and IS.ISDTC &lt; ADEFF.PCRDT)</li> </ol> <p>then</p> <ul style="list-style-type: none"> <li>• Set to PARAM if PARAMCD='TTCVDSVC1' and ADT &gt;= ADSL.DOSE2DT (non-missing) + 14, else concatenate 'Early ' with PARAM</li> <li>• Set to PARAM if PARAMCD='TTCVDSVC2' and ADT &gt;= ADSL.DOSE2DT (non-missing), else concatenate 'Early ' with PARAM</li> <li>• Set to PARAM if PARAMCD='TTCVDSVC3' and ADT &gt;= ADSL.TRT01SDT (non-missing) + 14, else concatenate 'Early ' with PARAM</li> <li>• Set to PARAM if PARAMCD='TTCVDSVC4' and ADT &gt;= ADSL.TRT01SDT (non-missing), else concatenate 'Early ' with PARAM</li> <li>• Set to PARAM if PARAMCD='TTCVDSVC5' and ADT &gt;= RANDDT (non-missing), else concatenate 'Early ' with PARAM</li> <li>• Set to PARAM if PARAMCD='TTCVDSVC6' and ADT &gt;= ADSL.DOSE2DT (non-missing) + 35, else concatenate 'Early ' with PARAM</li> </ul> <p>Else if the above-mentioned record is found from ADEFF and any of the positive-test criteria is met then concatenate 'Infection Prior to ' with PARAM Else concatenate 'No ' with PARAM</p>
TCVDSVC9	<p>If ADEFF.PARCAT1 = 'DERIVED PER SAP' and ADEFF.PARAMCD = 'COVIDSVS' and ANL01FL = 'Y' is found from ADEFF, ADEFF.ADT is on/before the earliest date of (ADSL.DTHDT, ADSL.EOSDT, ADSL.EFFCODT) and none of the following criteria is met:</p> <ol style="list-style-type: none"> <li>1. RT-PCR is positive at Day 29 or participant decision visit prior to RT-PCR date based on which the COVID case is defined (no record is found where MB.MBTESTCD = 'SARSCOV2' and MB.MBSTRESC in ('DETECTED', 'POSITIVE') and MB.VISIT in ('Visit 2 Day 29', 'Participant Decision Visit / OL-D1') and MB.MBDTC &lt; ADEFF.PCRDT)</li> <li>2. Elecsys is positive at Day 29, Day 57, Day 209, participant decision visit, OL-D29, or OL-D57 prior to severe COVID onset date (no record is found where IS.ISTESTCD = 'SARSCOV2' and IS.ISSTRESC = 'Positive' and IS.VISIT in ('Visit 2 Day 29', 'Visit 3 Day 57', 'Visit 4 Day 209', 'Participant Decision Visit / OL-D1', 'OL-D29' or 'OL-D57') and IS.ISDTC &lt; ADEFF.PCRDT)</li> </ol> <p>then Set to PARAM if ADEFF.APERIOD=2, else concatenate 'Early ' with PARAM Else if the above mentioned record is found from ADEFF and any of the positive-test criteria is met then concatenate 'Infection Prior to ' with PARAM Else concatenate 'No ' with PARAM</p>

## Additional ADaM Variables definition

PARAMCD	EVNTDESC
TCVSDSDC1 TCVSDSDC2 TCVSDSDC3 TCVSDSDC4 TCVSDSDC5 TCVSDSDC6	<p>If ADEFF.PARCAT1 = 'DERIVED PER SAP' and ADEFF.PARAMCD = 'COVIDSDS' and ANL01FL = 'Y' and APERIOD=1 is found from ADEFF, ADEFF.ADT is on/before the earliest date of (ADSL.DTHDT, ADSL.EOSDT, ADSL.EFFCODT) and none of the following criteria is met:</p> <ol style="list-style-type: none"> <li>RT-PCR is positive at Day 29 prior to RT-PCR date based on which the COVID case is defined (no record is found where MB.MBTESTCD="SARSCOV2", MB.MBSTRESC is "DETECTED" or 'POSITIVE' in upper case, MB.VISIT='Visit 2 Day 29', and MB.MBDTC&lt;ADEFF.PCRDT)</li> <li>Elecsys is positive at Day 29, Day 57, or Day 209 prior to COVID onset date (no record is found where IS.ISTESTCD = 'SARSCOV2' and IS.ISSTRESC = 'Positive' and IS.VISIT in ('Visit 2 Day 29', 'Visit 3 Day 57', 'Visit 4 Day 209') and IS.ISDTC &lt; ADEFF.PCRDT)</li> </ol> <p>then</p> <ul style="list-style-type: none"> <li>Set to PARAM if PARAMCD='TCVSDSDC1' and ADT &gt;= ADSL.DOSE2DT (non-missing) + 14, else concatenate 'Early ' with PARAM</li> <li>Set to PARAM if PARAMCD='TCVSDSDC2' and ADT &gt;= ADSL.DOSE2DT (non-missing), else concatenate 'Early ' with PARAM</li> <li>Set to PARAM if PARAMCD='TCVSDSDC3' and ADT &gt;= ADSL.TRT01SDT (non-missing) + 14, else concatenate 'Early ' with PARAM</li> <li>Set to PARAM if PARAMCD='TCVSDSDC4' and ADT &gt;= ADSL.TRT01SDT (non-missing), else concatenate 'Early ' with PARAM</li> <li>Set to PARAM if PARAMCD='TCVSDSDC5' and ADT &gt;= RANDDT (non-missing), else concatenate 'Early ' with PARAM</li> <li>Set to PARAM if PARAMCD='TCVSDSDC6' and ADT &gt;= ADSL.DOSE2DT (non-missing) + 35, else concatenate 'Early ' with PARAM</li> </ul> <p>Else if the above-mentioned record is found from ADEFF and any of the positive-test criteria is met then concatenate 'Infection Prior to ' with PARAM Else concatenate 'No ' with PARAM</p>
TCVSDSDC9	<p>If ADEFF.PARCAT1 = 'DERIVED PER SAP' and ADEFF.PARAMCD = 'COVIDSDS' and ANL01FL = 'Y' is found from ADEFF, ADEFF.ADT is on/before the earliest date of (ADSL.DTHDT, ADSL.EOSDT, ADSL.EFFCODT) and none of the following criteria is met:</p> <ol style="list-style-type: none"> <li>RT-PCR is positive at Day 29 or participant decision visit prior to RT-PCR date based on which the COVID case is defined (no record is found where MB.MBTESTCD="SARSCOV2", MB.MBSTRESC in ('DETECTED', 'POSITIVE') and MB.VISIT in ('Visit 2 Day 29', 'Participant Decision Visit / OL-D1') and MB.MBDTC &lt; ADEFF.PCRDT)</li> <li>Elecsys is positive at Day 29, Day 57, Day 209, participant decision visit, OL-D29, or OL-D57 prior to severe COVID onset date (no record is found where IS.ISTESTCD = 'SARSCOV2' and IS.ISSTRESC = 'Positive' and IS.VISIT in ('Visit 2 Day 29', 'Visit 3 Day 57', 'Visit 4 Day 209', 'Participant Decision Visit / OL-D1' or 'OL-D29' or 'OL-D57') and IS.ISDTC &lt; ADEFF.PCRDT)</li> </ol> <p>then set to PARAM if ADEFF.APERIOD = 2, else concatenate 'Early ' with PARAM Else if the above mentioned record is found from ADEFF and any of the positive-test criteria is met then concatenate 'Infection Prior to ' with PARAM Else concatenate 'No ' with PARAM</p>
TTASYMP1 TTASYMP2 TTASYMP3 TTASYMP4 TTASYMP5 TTASYMP6	<p>If ADEFF.PARCAT1 = 'DERIVED PER SAP' and ADEFF.PARAMCD = 'ASYMPINF' and ADEFF.ANL01FL = 'Y' and APERIOD=1 is found from ADEFF, and ADEFF.ADT is on/before the earliest date of (ADSL.DTHDT, ADSL.EOSDT, ADSL.EFFCODT) then</p> <ul style="list-style-type: none"> <li>Set to PARAM if PARAMCD='TTASYMP1' and ADT &gt;= ADSL.DOSE2DT (non-missing) + 14, else concatenate 'Early ' with PARAM</li> <li>Set to PARAM if PARAMCD='TTASYMP2' and ADT &gt;= ADSL.DOSE2DT (non-missing), else concatenate 'Early ' with PARAM</li> <li>Set to PARAM if PARAMCD='TTASYMP3' and ADT &gt;= ADSL.TRT01SDT (non-missing) + 14, else concatenate 'Early ' with PARAM</li> <li>Set to PARAM if PARAMCD='TTASYMP4' and ADT &gt;= ADSL.TRT01SDT (non-missing), else concatenate 'Early ' with PARAM</li> <li>Set to PARAM if PARAMCD='TTASYMP5' and ADT &gt;= RANDDT (non-missing), else concatenate 'Early ' with PARAM</li> <li>Set to PARAM if PARAMCD='TTASYMP6' and ADT &gt;= ADSL.DOSE2DT (non-missing) + 35, else concatenate 'Early ' with PARAM</li> </ul> <p>Else if ADEFF.PARAMCD in ('COVIDS', 'COVIDSDS') and ADEFF.ANL01FL = 'Y' is found from ADEFF then set to 'Symptomatic SARS-CoV-2 Infection' Else set to 'No '    PARAM</p>

## Additional ADaM Variables definition

PARAMCD	EVNTDESC
TTASYMP9	If ADEFF.PARCAT1 = 'DERIVED PER SAP' and ADEFF.PARAMCD = 'ASYMPINF' and ADEFF.ANL01FL = 'Y' is found from ADEFF, and ADEFF.ADT is on/before the earliest date of (ADSL.DTHDT, ADSL.EOSDT, ADSL.EFFCODT) then set to PARAM if ADEFF.APERIOD=2, else concatenate 'Early ' with PARAM Else if ADEFF.PARAMCD in ('COVIDS', 'COVIDSDS') and ADEFF.ANL01FL = 'Y' is found from ADEFF then set to 'Symptomatic SARS-CoV-2 Infection' Else set to 'No '    PARAM
TTASYCR1 TTASYCR2 TTASYCR3 TTASYCR4 TTASYCR5 TTASYCR6	If ADEFF.PARCAT1 = 'DERIVED PER SAP' and ADEFF.PARAMCD = 'ASYMPINF' and ADEFF.ANL01FL = 'Y' and APERIOD = 1 is found from ADEFF, and ADEFF.ADT is on/before the earliest date of (ADSL.DTHDT, ADSL.EOSDT, ADSL.EFFCODT) then <ul style="list-style-type: none"> <li>Set to PARAM if PARAMCD='TTASYCR1' and ADT &gt;= ADSL.DOSE2DT (non-missing) + 14, else concatenate 'Early ' with PARAM</li> <li>Set to PARAM if PARAMCD='TTASYCR2' and ADT &gt;= ADSL.DOSE2DT (non-missing), else concatenate 'Early ' with PARAM</li> <li>Set to PARAM if PARAMCD='TTASYCR3' and ADT &gt;= ADSL.TRT01SDT (non-missing) + 14, else concatenate 'Early ' with PARAM</li> <li>Set to PARAM if PARAMCD='TTASYCR4' and ADT &gt;= ADSL.TRT01SDT (non-missing), else concatenate 'Early ' with PARAM</li> <li>Set to PARAM if PARAMCD='TTASYCR5' and ADT &gt;= RANDDT (non-missing), else concatenate 'Early ' with PARAM</li> <li>Set to PARAM if PARAMCD='TTASYCR6' and ADT &gt;= ADSL.DOSE2DT (non-missing) + 35, else concatenate 'Early ' with PARAM</li> </ul> Else if ADEFF.PARAMCD in ('COVIDS', 'COVIDSDS') and ADEFF.ANL01FL = 'Y' is found from ADEFF then set to 'COVID-19 or Second Definition of COVID-19' Else set to 'No '    PARAM
TTASYCR9	If ADEFF.PARCAT1 = 'DERIVED PER SAP' and ADEFF.PARAMCD = 'ASYMPINF' and ADEFF.ANL01FL = 'Y' is found from ADEFF, and ADEFF.ADT is on/before the earliest date of (ADSL.DTHDT, ADSL.EOSDT, ADSL.EFFCODT) then set to PARAM if ADEFF.APERIOD=2, else concatenate 'Early ' with PARAM Else if ADEFF.PARAMCD in ('COVIDS', 'COVIDSDS') and ADEFF.ANL01FL = 'Y' is found from ADEFF then set to 'COVID-19 or Second Definition of COVID-19' Else set to 'No '    PARAM
TTINF1 TTINF2 TTINF3 TTINF4 TTINF5 TTINF6	If ADEFF.PARCAT1 = 'DERIVED PER SAP' and ADEFF.PARAMCD = 'INFECT' and ANL01FL = 'Y' and APERIOD = 1 is found from ADEFF and ADEFF.ADT is on/before the earliest date of (ADSL.DTHDT, ADSL.EOSDT, ADSL.EFFCODT) then <ul style="list-style-type: none"> <li>Set to PARAM if PARAMCD='TTINF1' and ADT &gt;= ADSL.DOSE2DT (non-missing) + 14, else concatenate 'Early ' with PARAM</li> <li>Set to PARAM if PARAMCD='TTINF2' and ADT &gt;= ADSL.DOSE2DT (non-missing), else concatenate 'Early ' with PARAM</li> <li>Set to PARAM if PARAMCD='TTINF3' and ADT &gt;= ADSL.TRT01SDT (non-missing) + 14, else concatenate 'Early ' with PARAM</li> <li>Set to PARAM if PARAMCD='TTINF4' and ADT &gt;= ADSL.TRT01SDT (non-missing), else concatenate 'Early ' with PARAM</li> <li>Set to PARAM if PARAMCD='TTINF5' and ADT &gt;= RANDDT (non-missing), else concatenate 'Early ' with PARAM</li> <li>Set to PARAM if PARAMCD='TTINF6' and ADT &gt;= ADSL.DOSE2DT (non-missing) + 35, else concatenate 'Early ' with PARAM</li> </ul> Else set to 'No '    PARAM
TTINF9	If ADEFF.PARCAT1 = 'DERIVED PER SAP' and ADEFF.PARAMCD = 'INFECT' and ANL01FL = 'Y' is found from ADEFF and ADEFF.ADT is on/before the earliest date of ADSL.DTHDT, ADSL.EOSDT, ADSL.EFFCODT) then Set to PARAM if ADEFF.APERIOD = 2, else concatenate 'Early ' with PARAM Else set to 'No '    PARAM
TTDTHCV1 TTDTHCV2 TTDTHCV3 TTDTHCV4 TTDTHCV5 TTDTHCV6	If ADEFF.PARCAT1 = 'DERIVED PER SAP' and ADEFF.PARAMCD = 'DEATHCVD' and ANL01FL = 'Y' and APERIOD = 1 is found from ADEFF and ADEFF.ADT is on/before the earliest date of (ADSL.DTHDT, ADSL.EOSDT, ADSL.EFFCODT) then <ul style="list-style-type: none"> <li>Set to PARAM if PARAMCD='TTDTHCV1' and ADT &gt;= ADSL.DOSE2DT (non-missing) + 14, else concatenate 'Early ' with PARAM</li> <li>Set to PARAM if PARAMCD='TTDTHCV2' and ADT &gt;= ADSL.DOSE2DT (non-missing), else concatenate 'Early ' with PARAM</li> <li>Set to PARAM if PARAMCD='TTDTHCV3' and ADT &gt;= ADSL.TRT01SDT (non-missing) + 14, else concatenate 'Early ' with PARAM</li> <li>Set to PARAM if PARAMCD='TTDTHCV4' and ADT &gt;= ADSL.TRT01SDT (non-missing), else concatenate 'Early ' with PARAM</li> </ul>



## Additional ADaM Variables definition

PARAMCD	EVNTDESC
	<ul style="list-style-type: none"> <li>Set to PARAM if PARAMCD='TTDTHCV5' and ADT &gt;= RANDDT (non-missing), else concatenate 'Early ' with PARAM</li> <li>Set to PARAM if PARAMCD='TTDTHCV6' and ADT &gt;= ADSL.DOSE2DT (non-missing) + 35, else concatenate 'Early ' with PARAM</li> </ul> <p>Else set to 'No '    PARAM</p>
TTDTHCV9	<p>If ADEFF.PARCAT1 = 'DERIVED PER SAP' and ADEFF.PARAMCD = 'DEATHCVD' and ANL01FL = 'Y' is found from ADEFF, and ADEFF.ADT is on/before the earliest date of (ADSL.DTHDT, ADSL.EOSDT, ADSL.EFFCODT) then</p> <p>Set to PARAM if ADEFF.APERIOD = 2, else concatenate 'Early ' with PARAM</p> <p>Else set to 'No '    PARAM</p>
TTDEATH	<p>If ADSL.DTHDT is not missing and on/before ADSL.EOSDT, ADSL.EFFCODT, and ADSL.AP01EDT, and ADSL.AP02SDT is missing, then Set to 'All-Cause Death', else Set to 'No All-Cause Death'</p>
TTDEATH9	<p>If ADSL.DTHDT is not missing and on/before ADSL.EOSDT and ADSL.EFFCODT, and ADSL.AP02SDT is not missing, then Set to 'All-Cause Death', else Set to 'No All-Cause Death'</p>

### ADTTEA.ADT

PARAMCD	ADT
TTCVDC1 TTCVDC2 TTCVDC3 TTCVDC4 TTCVDC5 TTCVDC6	<p>Set to ADEFF.ADT if ADEFF.PARCAT1 = 'DERIVED PER ADJUDICATION' and ADEFF.PARAMCD = 'COVIDA' and ADEFF.ANL01FL = 'Y' and APERIOD=1 is found from ADEFF, ADEFF.ADT is on/before the earliest date of (ADSL.DTHDT, ADSL.EOSDT, ADSL.EFFCODT) and none of the following criteria is met:</p> <ol style="list-style-type: none"> <li>RT-PCR is positive at Day 29 prior to the COVID-19 onset date per adjudication (MB.MBTESTCD = 'SARSCOV2' and MB.MBSTRESC is in ('DETECTED', 'POSITIVE') and MB.VISIT = 'Visit 2 Day 29' and MB.MBDTC &lt; ADT) and a record with ADEFF.PARCAT1 = 'DERIVED PER SAP' and ADEFF.PARAMCD = 'COVIDS' and PCRD29FL = 'Y' is not found from ADEFF</li> <li>Elecsys is positive at Day 29, Day 57, or Day 209 prior to COVID onset date (IS.ISTESTCD = 'SARSCOV2' and IS.ISSTRESC = 'Positive' and IS.VISIT in ('Visit 2 Day 29', 'Visit 3 Day 57', 'Visit 4 Day 209') and IS.ISDTC &lt; ADT)</li> </ol> <p>Set to the date of earliest positive RT-PCR (MB.MBDTC) or Elecsys result (IS.ISDTC) if the above-mentioned record is found from ADEFF and any of the positive-test criteria is met</p> <p>Set to earliest date of (ADSL.DTHDT, ADSL.EOSDT, ADSL.EFFCODT, ADSL.AP01EDT) if the above-mentioned record is not found from ADEFF</p> <p>Note: Set to RANDDT if ADT &lt; ADSL.RANDDT</p>
TTCVDC9	<p>Set to ADEFF.ADT if ADEFF.PARCAT1 = 'DERIVED PER ADJUDICATION' and ADEFF.PARAMCD = 'COVIDA' and ADEFF.ANL01FL = 'Y' is found from ADEFF, ADEFF.ADT is on/before the earliest date of ADSL.DTHDT, ADSL.EOSDT, and ADSL.EFFCODT, and none of the following criteria is met:</p> <ol style="list-style-type: none"> <li>RT-PCR is positive at Day 29 or participant decision visit prior to COVID-19 onset date per adjudication (MB.MBTESTCD = 'SARSCOV2' and MB.MBSTRESC is in ('DETECTED', 'POSITIVE') and MB.VISIT in ('Visit 2 Day 29', 'Participant Decision Visit / OL-D1') and MB.MBDTC &lt; ADT) and a record with ADEFF.PARCAT1 = 'DERIVED PER SAP' and ADEFF.PARAMCD = 'COVIDS' and PCRD29FL = 'Y' is not found from ADEFF</li> <li>Elecsys is positive at Day 29, Day 57, or Day 209, participant decision visit, OL-D29, or OL-D57 prior to the severe COVID onset date (IS.ISTESTCD = 'SARSCOV2') and IS.ISSTRESC = 'Positive' and IS.VISIT in ('Visit 2 Day 29', 'Visit 3 Day 57', 'Visit 4 Day 209', 'Participant Decision Visit / OL-D1', 'OL-D29', 'OL-D57') and IS.ISDTC &lt; ADT)</li> </ol> <p>Set to the date of earliest positive RT-PCR or Elecsys result (MB.MBDTC or IS.ISDTC) if the above-mentioned record is found from ADEFF and any of the positive-test criteria is met</p> <p>Set to earliest date of ADSL.DTHDT, ADSL.EOSDT, and ADSL.EFFCODT Else if the above-mentioned record is not found from ADEFF</p> <p>Note: Set to AP02SDT if ADT &lt; ADSL.AP02SDT</p>

## Additional ADaM Variables definition

PARAMCD	ADT
TCVDSVC1 TCVDSVC2 TCVDSVC3 TCVDSVC4 TCVDSVC5 TCVDSVC6	<p>Set to ADEFF.ADT if ADEFF.PARCAT1='DERIVED PER ADJUDICATION' and ADEFF.PARAMCD = 'COVIDSVA' and ADEFF.ANL01FL = 'Y' and APERIOD=1 is found from ADEFF, ADT is on/before the earliest date of (ADSL.DTHDT, ADSL.EOSDT, ADSL.EFFCODT) and none of the following criteria is met:</p> <ol style="list-style-type: none"> <li>RT-PCR is positive at Day 29 prior to the severe COVID-19 onset date per adjudication (MB.MBTESTCD = 'SARSCOV2' and MB.MBSTRESC is in ('DETECTED', 'POSITIVE') and MB.VISIT = 'Visit 2 Day 29' and MB.MBDTC &lt; ADT) and a record with ADEFF.PARCAT1='DERIVED PER SAP' and ADEFF.PARAMCD = 'COVIDS' and PCRD29FL='Y' is not found from ADEFF</li> <li>Elecsys is positive at Day 29, Day 57, or Day 209 prior to the severe COVID onset date (IS.ISTESTCD = 'SARSCOV2' and IS.ISSTRESC = 'Positive' and IS.VISIT in ('Visit 2 Day 29', 'Visit 3 Day 57', 'Visit 4 Day 209') and IS.ISDTC &lt; ADT)</li> </ol> <p>Set to the date of earliest positive RT-PCR or Elecsys result (MB.MBDTC or IS.ISDTC) if the above-mentioned record is found from ADEFF and any of the positive-test criteria is met</p> <p>Set to earliest date of (ADSL.DTHDT, ADSL.EOSDT, ADSL.EFFCODT, ADSL.AP01EDT) if the above-mentioned record is not found from ADEFF</p> <p>Note: Set to RANDDT if ADT &lt; ADSL.RANDDT</p>
TCVDSVC9	<p>Set to ADEFF.ADT if ADEFF.PARCAT1='DERIVED PER ADJUDICATION' and ADEFF.PARAMCD = 'COVIDSVA' and ADEFF.ANL01FL = 'Y' is found from ADEFF, ADEFF.ADT is on/before the earliest date of ADSL.DTHDT, ADSL.EOSDT, and ADSL.EFFCODT, and none of the following criteria is met:</p> <ol style="list-style-type: none"> <li>RT-PCR is positive at Day 29 or participant decision visit prior to the severe COVID-19 onset date per adjudication (MB.MBTESTCD = 'SARSCOV2' and MB.MBSTRESC is in ('DETECTED', 'POSITIVE') and MB.VISIT in ('Visit 2 Day 29', 'Participant Decision Visit / OL-D1') and MB.MBDTC&lt;ADT) and a record with ADEFF.PARCAT1= 'DERIVED PER SAP' and ADEFF.PARAMCD = 'COVIDS' and PCRD29FL='Y' is not found from ADEFF</li> <li>Elecsys is positive at Day 29, Day 57, or Day 209, participant decision visit, OL-D29, or OL-D57 prior to the severe COVID onset date (IS.ISTESTCD = 'SARSCOV2') and IS.ISSTRESC = 'Positive' and IS.VISIT in ('Visit 2 Day 29', 'Visit 3 Day 57', 'Visit 4 Day 209', 'Participant Decision Visit / OL-D1', 'OL-D29', 'OL-D57') and IS.ISDTC &lt; ADT)</li> </ol> <p>Set to the date of earliest positive RT-PCR ((MB.MBDTC) or Elecsys result (IS.ISDTC) if the above-mentioned record is found from ADEFF and any of the positive-test criteria is met</p> <p>Set to earliest date of (ADSL.DTHDT, ADSL.EOSDT, ADSL.EFFCODT) if the above-mentioned record is not found from ADEFF</p> <p>Note: Set to AP02SDT if ADT &lt; ADSL.AP02SDT</p>

### ADTTEA.CNSR

PARAMCD	CNSR
TTCVDC1 TTCVDC2 TTCVDC3 TTCVDC4 TTCVDC5 TTCVDC6	<p>If ADEFF.PARCAT1 = 'DERIVED PER ADJUDICATION' and ADEFF.PARAMCD = 'COVIDA' and ANL01FL = 'Y' and APERIOD = 1 is found from ADEFF, ADEFF.ADT is on/before the earliest date of (ADSL.DTHDT, ADSL.EOSDT, ADSL.EFFCODT) and none of the following criteria is met:</p> <ol style="list-style-type: none"> <li>RT-PCR is positive at Day 29 prior to the COVID-19 onset date per adjudication (MB.MBTESTCD = 'SARSCOV2' and MB.MBSTRESC is in ('DETECTED', 'POSITIVE') and MB.VISIT = 'Visit 2 Day 29' and MB.MBDTC &lt; ADT) and a record with ADEFF.PARCAT1 = 'DERIVED PER SAP' and ADEFF.PARAMCD = 'COVIDS' and PCRD29FL = 'Y' is not found from ADEFF</li> <li>Elecsys is positive at Day 29, Day 57, or Day 209 prior to COVID onset date (IS.ISTESTCD = 'SARSCOV2' and IS.ISSTRESC = 'Positive' and IS.VISIT in ('Visit 2 Day 29', 'Visit 3 Day 57', 'Visit 4 Day 209') and IS.ISDTC &lt; ADT)</li> </ol> <p>Then</p> <ul style="list-style-type: none"> <li>Set to 0 if PARAMCD='TTCVDC1' and ADT &gt;= ADSL.DOSE2DT (non-missing) + 14, else Set to 1</li> <li>Set to 0 if PARAMCD='TTCVDC2' and ADT &gt;= ADSL.DOSE2DT (non-missing), else Set to 1</li> <li>Set to 0 if PARAMCD='TTCVDC3' and ADT &gt;= ADSL.TRT01SDT (non-missing) + 14, else Set to 1</li> <li>Set to 0 if PARAMCD='TTCVDC4' and ADT &gt;= ADSL.TRT01SDT (non-missing), else Set to 1</li> <li>Set to 0 if PARAMCD='TTCVDC5' and ADT &gt;= ADSL.RANDDT (non-missing), else Set to 1</li> <li>Set to 0 if PARAMCD='TTCVDC6' and ADT &gt;= ADSL.DOSE2DT (non-missing) + 35, else Set to 1</li> </ul> <p>Else Set to 1</p> <p style="text-align: right;">FDA-CBER-2022-1614-3820150</p>

## Additional ADaM Variables definition

PARAMCD	CNSR
TTCVDC9	<p>Set to 0 if ADEFF.PARCAT1 = 'DERIVED PER ADJUDICATION' and ADEFF.PARAMCD = 'COVIDA' and ANL01FL = 'Y' and APERIOD = 2 is found from ADEFF, ADEFF.ADT is on/before the earliest date of (ADSL.DTHDT, ADSL.EOSDT, ADSL.EFFCODT) and none of the following criteria is met:</p> <ol style="list-style-type: none"> <li>RT-PCR is positive at Day 29 or participant decision visit prior to COVID-19 onset date per adjudication (MB.MBTESTCD = 'SARSCOV2' and MB.MBSTRESC is in ('DETECTED', 'POSITIVE') and MB.VISIT in ('Visit 2 Day 29', 'Participant Decision Visit / OL-D1') and MB.MBDTC &lt; ADT) and a record with ADEFF.PARCAT1 = 'DERIVED PER SAP' and ADEFF.PARAMCD = 'COVIDS' and PCRD29FL = 'Y' is not found from ADEFF</li> <li>Elecsys is positive at Day 29, Day 57, or Day 209, participant decision visit, OL-D29, or OL-D57 prior to the severe COVID onset date (IS.ISTESTCD = 'SARSCOV2') and IS.ISSTRESC = 'Positive' and IS.VISIT in ('Visit 2 Day 29', 'Visit 3 Day 57', 'Visit 4 Day 209', 'Participant Decision Visit / OL-D1', 'OL-D29', 'OL-D57') and IS.ISDTC &lt; ADT)</li> </ol> <p>Set to 1, otherwise</p>
TCVDSVC1 TCVDSVC2 TCVDSVC3 TCVDSVC4 TCVDSVC5 TCVDSVC6	<p>If ADEFF.PARCAT1 = 'DERIVED PER ADJUDICATION' and ADEFF.PARAMCD = 'COVIDSVA' and ANL01FL = 'Y' and APERIOD=1 is found from ADEFF, ADEFF.ADT is on/before the earliest date of (ADSL.DTHDT, ADSL.EOSDT, ADSL.EFFCODT) and none of the following criteria is met:</p> <ol style="list-style-type: none"> <li>RT-PCR is positive at Day 29 prior to the severe COVID-19 onset date per adjudication (MB.MBTESTCD = 'SARSCOV2' and MB.MBSTRESC is in ('DETECTED', 'POSITIVE') and MB.VISIT = 'Visit 2 Day 29' and MB.MBDTC &lt; ADT) and a record with ADEFF.PARCAT1='DERIVED PER SAP' and ADEFF.PARAMCD = 'COVIDS' and PCRD29FL='Y' is not found from ADEFF</li> <li>Elecsys is positive at Day 29, Day 57, or Day 209 prior to the severe COVID onset date (IS.ISTESTCD = 'SARSCOV2' and IS.ISSTRESC = 'Positive' and IS.VISIT in ('Visit 2 Day 29', 'Visit 3 Day 57', 'Visit 4 Day 209') and IS.ISDTC &lt; ADT)</li> </ol> <p>Then</p> <ul style="list-style-type: none"> <li>Set to 0 if PARAMCD='TCVDSVC1' and ADT &gt;= ADSL.DOSE2DT (non-missing) + 14, else Set to 1</li> <li>Set to 0 if PARAMCD='TCVDSVC2' and ADT &gt;= ADSL.DOSE2DT (non-missing), else Set to 1</li> <li>Set to 0 if PARAMCD='TCVDSVC3' and ADT &gt;= ADSL.TRT01SDT (non-missing) + 14, else Set to 1</li> <li>Set to 0 if PARAMCD='TCVDSVC4' and ADT &gt;= ADSL.TRT01SDT (non-missing), else Set to 1</li> <li>Set to 0 if PARAMCD='TCVDSVC5' and ADT &gt;= ADSL.RANDDT (non-missing), else Set to 1</li> <li>Set to 0 if PARAMCD='TCVDSVC6' and ADT &gt;= ADSL.DOSE2DT (non-missing) + 35, else Set to 1</li> </ul> <p>Else Set to 1</p>
TCVDSVC9	<p>Set to 0 if ADEFF.PARCAT1 = 'DERIVED PER ADJUDICATION' and ADEFF.PARAMCD = 'COVIDSVA' and ANL01FL = 'Y' and APERIOD = 2 is found from ADEFF, ADEFF.ADT is on/before the earliest date of (ADSL.DTHDT, ADSL.EOSDT, ADSL.EFFCODT) and none of the following criteria is met:</p> <ol style="list-style-type: none"> <li>RT-PCR is positive at Day 29 or participant decision visit prior to the severe COVID-19 onset date per adjudication (MB.MBTESTCD = 'SARSCOV2' and MB.MBSTRESC is in ('DETECTED', 'POSITIVE') and MB.VISIT in ('Visit 2 Day 29', 'Participant Decision Visit / OL-D1') and MB.MBDTC &lt; ADT) and a record with ADEFF.PARCAT1= 'DERIVED PER SAP' and ADEFF.PARAMCD = 'COVIDS' and PCRD29FL='Y' is not found from ADEFF</li> <li>Elecsys is positive at Day 29, Day 57, or Day 209, participant decision visit, OL-D29, or OL-D57 prior to the severe COVID onset date (IS.ISTESTCD = 'SARSCOV2') and IS.ISSTRESC = 'Positive' and IS.VISIT in ('Visit 2 Day 29', 'Visit 3 Day 57', 'Visit 4 Day 209', 'Participant Decision Visit / OL-D1', 'OL-D29', 'OL-D57') and IS.ISDTC &lt; ADT)</li> </ol> <p>Set to 1, otherwise</p>

## Additional ADaM Variables definition

### ADTTEA.EVNTDESC

PARAMCD	EVNTDESC
TTCVDC1 TTCVDC2 TTCVDC3 TTCVDC4 TTCVDC5 TTCVDC6	<p>If ADEFF.PARCAT1 = 'DERIVED PER ADJUDICATION' and ADEFF.PARAMCD = 'COVIDA' and ANL01FL = 'Y' and APERIOD = 1 is found from ADEFF, ADEFF.ADT is on/before the earliest date of (ADSL.DTHDT, ADSL.EOSDT, ADSL.EFFCODT) and none of the following criteria is met:</p> <ol style="list-style-type: none"> <li>1. RT-PCR is positive at Day 29 prior to the COVID-19 onset date per adjudication (MB.MBTESTCD = 'SARSCOV2' and MB.MBSTRESC is in ('DETECTED', 'POSITIVE') and MB.VISIT = 'Visit 2 Day 29' and MB.MBDTC &lt; ADT) and a record with ADEFF.PARCAT1 = 'DERIVED PER SAP' and ADEFF.PARAMCD = 'COVIDS' and PCRD29FL = 'Y' is not found from ADEFF</li> <li>2. Elecsys is positive at Day 29, Day 57, or Day 209 prior to COVID onset date (IS.ISTESTCD = 'SARSCOV2' and IS.ISSTRESC = 'Positive' and IS.VISIT in ('Visit 2 Day 29', 'Visit 3 Day 57', 'Visit 4 Day 209') and IS.ISDTC &lt; ADT)</li> </ol> <p>then</p> <ul style="list-style-type: none"> <li>• Set to PARAM if PARAMCD='TTCVDC1' and ADT &gt;= ADSL.DOSE2DT (non-missing) + 14, else concatenate 'Early ' with PARAM</li> <li>• Set to PARAM if PARAMCD='TTCVDC2' and ADT &gt;= ADSL.DOSE2DT (non-missing), else concatenate 'Early ' with PARAM</li> <li>• Set to PARAM if PARAMCD='TTCVDC3' and ADT &gt;= ADSL.TRT01SDT (non-missing) + 14, else concatenate 'Early ' with PARAM</li> <li>• Set to PARAM if PARAMCD='TTCVDC4' and ADT &gt;= ADSL.TRT01SDT (non-missing), else concatenate 'Early ' with PARAM</li> <li>• Set to PARAM if PARAMCD='TTCVDC5' and ADT &gt;= RANDDT (non-missing), else concatenate 'Early ' with PARAM</li> <li>• Set to PARAM if PARAMCD='TTCVDC6' and ADT &gt;= ADSL.DOSE2DT (non-missing) + 35, else concatenate 'Early ' with PARAM</li> </ul> <p>Else if the above-mentioned record is found from ADEFF and any of the positive-test criteria is met then concatenate 'Infection Prior to ' with PARAM Else concatenate 'No ' with PARAM</p>
TTCVDC9	<p>If ADEFF.PARCAT1 = 'DERIVED PER ADJUDICATION' and ADEFF.PARAMCD = 'COVIDA' and ANL01FL = 'Y' is found from ADEFF, ADEFF.ADT is on/before the earliest date of (ADSL.DTHDT, ADSL.EOSDT, ADSL.EFFCODT) and none of the following criteria is met:</p> <ol style="list-style-type: none"> <li>1. RT-PCR is positive at Day 29 or participant decision visit prior to COVID-19 onset date per adjudication (MB.MBTESTCD = 'SARSCOV2' and MB.MBSTRESC is in ('DETECTED', 'POSITIVE') and MB.VISIT in ('Visit 2 Day 29', 'Participant Decision Visit / OL-D1') and MB.MBDTC &lt; ADT) and a record with ADEFF.PARCAT1 = 'DERIVED PER SAP' and ADEFF.PARAMCD = 'COVIDS' and PCRD29FL = 'Y' is not found from ADEFF</li> <li>2. Elecsys is positive at Day 29, Day 57, or Day 209, participant decision visit, OL-D29, or OL-D57 prior to the severe COVID onset date (IS.ISTESTCD = 'SARSCOV2') and IS.ISSTRESC = 'Positive' and IS.VISIT in ('Visit 2 Day 29', 'Visit 3 Day 57', 'Visit 4 Day 209', 'Participant Decision Visit / OL-D1', 'OL-D29', 'OL-D57') and IS.ISDTC &lt; ADT)</li> </ol> <p>Then Set to PARAM if ADEFF.APERIOD = 2, else concatenate 'Early ' with PARAM Else if the above-mentioned record is found from ADEFF and any of the positive-test criteria is met then concatenate 'Infection Prior to ' with PARAM Else concatenate 'No ' with PARAM</p>
TCVDSVC1 TCVDSVC2 TCVDSVC3 TCVDSVC4 TCVDSVC5 TCVDSVC6	<p>If ADEFF.PARCAT1 = 'DERIVED PER ADJUDICATION' and ADEFF.PARAMCD = 'COVIDSVA' and ANL01FL = 'Y' and APERIOD=1 is found from ADEFF, ADEFF.ADT is on/before the earliest date of (ADSL.DTHDT, ADSL.EOSDT, ADSL.EFFCODT) and none of the following criteria is met:</p> <ol style="list-style-type: none"> <li>1. RT-PCR is positive at Day 29 prior to the severe COVID-19 onset date per adjudication (MB.MBTESTCD = 'SARSCOV2' and MB.MBSTRESC is in ('DETECTED', 'POSITIVE') and MB.VISIT = 'Visit 2 Day 29' and MB.MBDTC &lt; ADT) and a record with ADEFF.PARCAT1='DERIVED PER SAP' and ADEFF.PARAMCD = 'COVIDS' and PCRD29FL='Y' is not found from ADEFF</li> <li>2. Elecsys is positive at Day 29, Day 57, or Day 209 prior to the severe COVID onset date (IS.ISTESTCD = 'SARSCOV2' and IS.ISSTRESC = 'Positive' and IS.VISIT in ('Visit 2 Day 29', 'Visit 3 Day 57', 'Visit 4 Day 209') and IS.ISDTC &lt; ADT)</li> </ol> <p>Then</p> <ul style="list-style-type: none"> <li>• Set to PARAM if PARAMCD='TTCVDSVC1' and ADT &gt;= ADSL.DOSE2DT (non-missing) + 14, else concatenate 'Early ' with PARAM</li> <li>• Set to PARAM if PARAMCD='TTCVDSVC2' and ADT &gt;= ADSL.DOSE2DT (non-missing), else concatenate 'Early ' with PARAM</li> </ul>

## Additional ADaM Variables definition

PARAMCD	EVNTDESC
	<ul style="list-style-type: none"> <li>Set to PARAM if PARAMCD='TTCVDSVC3' and ADT &gt;= ADSL.TRT01SDT (non-missing) + 14, else concatenate 'Early ' with PARAM</li> <li>Set to PARAM if PARAMCD='TTCVDSVC4' and ADT &gt;= ADSL.TRT01SDT (non-missing), else concatenate 'Early ' with PARAM</li> <li>Set to PARAM if PARAMCD='TTCVDSVC5' and ADT &gt;= RANDDT (non-missing), else concatenate 'Early ' with PARAM</li> <li>Set to PARAM if PARAMCD='TTCVDSVC6' and ADT &gt;= ADSL.DOSE2DT (non-missing) + 35, else concatenate 'Early ' with PARAM</li> </ul> <p>Else if the above-mentioned record is found from ADEFF and any of the positive-test criteria is met then concatenate 'Infection Prior to ' with PARAM Else concatenate 'No ' with PARAM</p>
TCVDSVC9	<p>If ADEFF.PARCAT1 = 'DERIVED PER ADJUDICATION' and ADEFF.PARAMCD = 'COVIDSVA' and ANL01FL = 'Y' is found from ADEFF, ADEFF.ADT is on/before the earliest date of (ADSL.DTHDT, ADSL.EOSDT, ADSL.EFFCODT) and none of the following criteria is met:</p> <ol style="list-style-type: none"> <li>RT-PCR is positive at Day 29 or participant decision visit prior to the severe COVID-19 onset date per adjudication (MB.MBTESTCD = 'SARSCOV2' and MB.MBSTRESC is in ('DETECTED', 'POSITIVE') and MB.VISIT in ('Visit 2 Day 29', 'Participant Decision Visit / OL-D1') and MB.MBDTC &lt; ADT) and a record with ADEFF.PARCAT1 = 'DERIVED PER SAP' and ADEFF.PARAMCD = 'COVIDS' and PCRD29FL = 'Y' is not found from ADEFF</li> <li>Elecsys is positive at Day 29, Day 57, or Day 209, participant decision visit, OL-D29, or OL-D57 prior to the severe COVID onset date (IS.ISTESTCD = 'SARSCOV2') and IS.ISSTRESC = 'Positive' and IS.VISIT in ('Visit 2 Day 29', 'Visit 3 Day 57', 'Visit 4 Day 209', 'Participant Decision Visit / OL-D1', 'OL-D29', 'OL-D57') and IS.ISDTC &lt; ADT)</li> </ol> <p>Then Set to PARAM if ADEFF.APERIOD=2, else concatenate 'Early ' with PARAM Else if the above mentioned record is found from ADEFF and any of the positive-test criteria is met then concatenate 'Infection Prior to ' with PARAM Else concatenate 'No ' with PARAM</p>

### ADTTE.ADT

PARAMCD	ADT
TASYCRB1 TASYCRB2 TASYCRB3 TASYCRB4 TASYCRB5	<p>Derive ADT in the following steps:</p> <ol style="list-style-type: none"> <li>Set to ADTTE.ADT where ADTTE.PARAMCD = 'TASYCR5' and (ADTTE.CNSR = 0 or ADTTE.CNSR = 2)</li> <li>Set to earlier date of following: <ol style="list-style-type: none"> <li>MB.MBDTC where MB.MBTESTCD = 'SARSCOV2' and MB.MBSTRESC is in ('DETECTED', 'POSITIVE') and VISIT = 'Participant Decision Visit / OL-D1'</li> <li>ADIS.ADT where ADIS.CRIT5FL = 'Y' and VISIT = 'Participant Decision Visit / OL-D1'</li> </ol> if the date is on/before the earliest date of (ADSL.DTHDT, ADSL.EOSDT, ADSL.EFFCODT) and has no prior COVID-19 symptoms (COVID-19 or secondary definition of COVID-19) </li> <li>Set to the earliest date of ADEFF.ADT where ADEFF.PARAMCD in ('COVIDS', 'COVIDSDS') and <ol style="list-style-type: none"> <li>MB.MBTESTCD = 'SARSCOV2' and MB.MBSTRESC is in ('DETECTED', 'POSITIVE') and VISIT = 'Participant Decision Visit / OL-D1' or</li> <li>ADIS.CRIT5FL = 'Y' and VISIT = 'Participant Decision Visit / OL-D1'</li> </ol> if the earlier date of MB.MBDTC and ADIS.ADT is on/before the earliest date of (ADSL.DTHDT, ADSL.EOSDT, ADSL.EFFCODT) and has prior COVID-19 symptoms COVID-19 or secondary definition of COVID-19) </li> <li>Set to the earliest date of (ADSL.DTHDT, ADSL.EOSDT, and ADSL.EFFCODT, ADSL.AP02SDT)</li> </ol>
TTINFB1 TTINFB2 TTINFB3 TTINFB4 TTINFB5	<p>Derive ADT in the following steps:</p> <ol style="list-style-type: none"> <li>Set to ADTTE.ADT where ADTTE.PARAMCD='TTINF5' and (ADTTE.PARAMCD = 'TTINF5' and ADTTE.CNSR=0)</li> <li>Set to earliest date of following: <ol style="list-style-type: none"> <li>MB.MBDTC where MB.MBTESTCD = 'SARSCOV2' and MB.MBSTRESC in upper case is in ('DETECTED', 'POSITIVE') and VISIT = 'Participant Decision Visit / OL-D1'</li> <li>ADIS.ADT where ADIS.CRIT5FL = 'Y' and VISIT = 'Participant Decision Visit / OL-D1'</li> </ol> if the date is on/before the earliest date of (ADSL.DTHDT, ADSL.EOSDT, ADSL.EFFCODT) </li> </ol>

## Additional ADaM Variables definition

PARAMCD	ADT
	3. Set to the earliest date of (ADSL.DTHDT, ADSL.EOSDT, ADSL.EFFCODT, ADSL.AP02SDT)

### **ADTTE.CNSR**

PARAMCD	CNSR
TASYCRB1 TASYCRB2 TASYCRB3 TASYCRB4 TASYCRB5	<p>For PARAMCD='TASYCRBX[1]', derive CNSR in the following steps:</p> <p>1. Set to ADTTE.CNSR where ADTTE.PARAMCD = 'TTASYCRX[1]' and (ADTTE.CNSR = 0 or (ADTTE.CNSR is not 0 and EVNTDESC in ('Early Asymptomatic SARS-CoV-2 Infection'[2], 'COVID-19 or Second Definition of COVID-19')))</p> <p>2. The earlier date of following:</p> <ol style="list-style-type: none"> <li>MB.MBTESTCD = 'SARSCOV2' and MB.MBSTRESC is in ('DETECTED', 'POSITIVE') and VISIT = 'Participant Decision Visit / OL-D1'</li> <li>ADIS.CRIT5FL = 'Y' and VISIT = 'Participant Decision Visit / OL-D1' is on/before the earliest date of (ADSL.DTHDT, ADSL.EOSDT, ADSL.EFFCODT), and There are no prior COVID-19 symptoms found: <ul style="list-style-type: none"> <li>For PARAMCD = 'TASYCRB1', if the earlier date of MB.MBDTC or ADIS.ADT is <math>\geq</math> ADSL.DOSE2DT (non-missing) + 14 then set to 0, else set to 1</li> <li>For PARAMCD = 'TASYCRB2', if the earlier date of MB.MBDTC or ADIS.ADT is <math>\geq</math> ADSL.DOSE2DT (non-missing) then set to 0, else set to 1</li> <li>For PARAMCD = 'TASYCRB3', if the earlier date of MB.MBDTC or ADIS.ADT is <math>\geq</math> ADSL.TRT01SDT (non-missing) + 14 then set to 0, else set to 1</li> <li>For PARAMCD = 'TASYCRB4', if the earlier date of MB.MBDTC or ADIS.ADT is <math>\geq</math> ADSL.TRT01SDT (non-missing) then set to 0, else set to 1</li> <li>For PARAMCD = 'TASYCRB5', if the earlier date of MB.MBDTC or ADIS.ADT is <math>\geq</math> ADSL.RANDT (non-missing) then set to 0, else set to 1</li> </ul> </li> </ol> <p>Set to 2 if there are prior COVID-19 symptoms found</p> <p>3. Set to ADTTE.CNSR where ADTTE.PARAMCD='TTASYCRX[1]'</p> <p>[1] X = 1, 2, 3, 4, or 5 [2] this condition applies only when X is not 5</p>
TTINFB1 TTINFB2 TTINFB3 TTINFB4 TTINFB5	<p>For PARAMCD='TTINFBX[1]', derive CNSR in the following steps:</p> <p>1. Set to ADTTE.CNSR where ADTTE.PARAMCD='TTINFX[1]' and (ADTTE.CNSR=0 or (ADTTE.CNSR = 1 and EVNTDESC='Early SARS-CoV-2 Infection Regardless of Symptomatology or Severity')[2])</p> <p>2. The earlier date of following:</p> <ol style="list-style-type: none"> <li>MB.MBTESTCD = 'SARSCOV2' and MB.MBSTRESC is in ('DETECTED', 'POSITIVE') and VISIT = 'Participant Decision Visit / OL-D1'</li> <li>ADIS.CRIT5FL = 'Y' and VISIT = 'Participant Decision Visit / OL-D1' is on/before the earliest date of (ADSL.DTHDT, ADSL.EOSDT, and ADSL.EFFCODT) <ul style="list-style-type: none"> <li>For PARAMCD = 'TTINFB1', if the earlier date of MB.MBDTC or ADIS.ADT is <math>\geq</math> ADSL.DOSE2DT (non-missing) + 14 then set CNSR to 0, else set to 1,</li> <li>For PARAMCD = 'TTINFB2', if the earlier date of MB.MBDTC or ADIS.ADT is <math>\geq</math> ADSL.DOSE2DT (non-missing) then set CNSR to 0, else set to 1,</li> <li>For PARAMCD = 'TTINFB3', if the earlier date of MB.MBDTC or ADIS.ADT is <math>\geq</math> ADSL.TRT01SDT (non-missing) + 14 then set CNSR to 0, else set to 1,</li> <li>For PARAMCD = 'TTINFB4', if the earlier date of MB.MBDTC or ADIS.ADT is <math>\geq</math> ADSL.TRT01SDT (non-missing) then set CNSR to 0, else set to 1,</li> <li>For PARAMCD = 'TTINFB5', if the earlier date of MB.MBDTC or ADIS.ADT is <math>\geq</math> ADSLRANDT then set CNSR to 0, else set to 1</li> </ul> </li> </ol> <p>3. Set CNSR to 1, otherwise</p> <p>[1] X = 1, 2, 3, 4, or 5 [2] this condition applies only when X is not 5</p>

### **ADTTE.EVNTDESC**

## Additional ADaM Variables definition

PARAMCD	EVNTDESC
TASYCRB1 TASYCRB2 TASYCRB3 TASYCRB4 TASYCRB5	<p>For PARAMCD = 'TASYCRBX'[1], derive EVNTDESC in the following steps:</p> <ol style="list-style-type: none"> <li>Set to 'Asymptomatic SARS-CoV-2 Infection in Blinded Phase' where ADTTE.PARAMCD = 'TTASYCRX'[1] and ADTTE.CNSR = 0</li> <li>Set to ADTTE.EVNTDESC where ADTTE.PARAMCD = 'TTASYCRX'[1] and ADTTE.CNSR is not 0 and ADTTE.EVNTDESC in ('Early Asymptomatic SARS-CoV-2 Infection'[2], 'COVID-19 or Second Definition of COVID-19')</li> <li>Earlier date of following: <ol style="list-style-type: none"> <li>MB.MBTESTCD = 'SARSCOV2' and MB.MBSTRESC is in ('DETECTED', 'POSITIVE') and VISIT = 'Participant Decision Visit / OL-D1'</li> <li>ADIS.CRIT5FL = 'Y' and VISIT = 'Participant Decision Visit / OL-D1'</li> </ol> if the data is on/before the earliest date of (ADSL.DTHDT, ADSL.EOSDT, ADSL.EFFCODT) and <p>Case 1 - no prior COVID-19 symptoms found:</p> <ul style="list-style-type: none"> <li>For PARAMCD = 'TASYCRB1', if the earliest date of MB.MBDTC or ADIS.ADT &gt;= ADSL.DOSE2DT (non-missing) + 14 then set to 'Asymptomatic SARS-CoV-2 Infection at PDV', else set to 'Early Asymptomatic SARS-CoV-2 Infection',</li> <li>For PARAMCD = 'TASYCRB2', if the earliest date of MB.MBDTC or ADIS.ADT &gt;= ADSL.DOSE2DT (non-missing) then set to 'Asymptomatic SARS-CoV-2 Infection at PDV', else set to 'Early Asymptomatic SARS-CoV-2 Infection',</li> <li>For PARAMCD = 'TASYCRB3', if the earliest date of MB.MBDTC or ADIS.ADT &gt;= ADSL.TRT01SDT (non-missing) + 14 then set to 'Asymptomatic SARS-CoV-2 Infection at PDV', else set to 'Early Asymptomatic SARS-CoV-2 Infection',</li> <li>For PARAMCD = 'TASYCRB4', if the earliest date of MB.MBDTC or ADIS.ADT &gt;= ADSL.TRT01SDT (non-missing) then set to 'Asymptomatic SARS-CoV-2 Infection at PDV', else set to 'Early Asymptomatic SARS-CoV-2 Infection',</li> <li>For PARAMCD = 'TASYCRB5', if the earliest date of MB.MBDTC or ADIS.ADT &gt;= ADSL.RANNDT (non-missing) then set to 'Asymptomatic SARS-CoV-2 Infection at PDV'</li> </ul> <p>CASE 2 - prior COVID-19 symptoms found: Set to 'COVID-19 or Second Definition of COVID-19'</p> </li> <li>Set to ADTTE.EVNTDESC where ADTTE.PARAMCD='TTASYCRX'[1]</li> </ol> <p>[1] X = 1, 2, 3, 4, or 5 [2] This condition applies only when X is not 5</p>
TTINFB1 TTINFB2 TTINFB3 TTINFB4 TTINFB5	<p>For PARAMCD='TTINFBX'[1], derive EVNTDESC in the following steps:</p> <ol style="list-style-type: none"> <li>Set to 'SARS-CoV-2 Infection Regardless of Symptomatology or Severity in Blinded Phase' where ADTTE.PARAMCD='TTINFX'[1] and ADTTE.CNSR=0</li> <li>Set to ADTTE.EVNTDESC where ADTTE.PARAMCD='TTINFX'[1] and ADTTE.CNSR=1 and EVNTDESC='Early SARS-CoV-2 Infection Regardless of Symptomatology or Severity'[2]</li> <li>Earlier date of following criteria met: <ol style="list-style-type: none"> <li>MB.MBTESTCD = 'SARSCOV2' and MB.MBSTRESC is in ('DETECTED', 'POSITIVE') and VISIT = 'Participant Decision Visit / OL-D1'</li> <li>ADIS.CRIT5FL = 'Y' and VISIT = 'Participant Decision Visit / OL-D1'</li> </ol> if the date is on/before the earliest date of (ADSL.DTHDT, ADSL.EOSDT, and ADSL.EFFCODT): <ul style="list-style-type: none"> <li>For PARAMCD = TTINFB1, if the earliest date of MB.MBDTC or ADIS.ADT &gt;= ADSL.DOSE2DT (non-missing) + 14 then set to 'SARS-CoV-2 Infection Regardless of Symptomatology or Severity at PDV', else set EVNTDESC to 'Early SARS-CoV-2 Infection Regardless of Symptomatology or Severity'</li> <li>For PARAMCD = TTINFB2, if the earliest date of MB.MBDTC or ADIS.ADT &gt;= ADSL.DOSE2DT (non-missing) then set to 'SARS-CoV-2 Infection Regardless of Symptomatology or Severity at PDV', else set EVNTDESC to 'Early SARS-CoV-2 Infection Regardless of Symptomatology or Severity'</li> <li>For PARAMCD = TTINFB3, if the earliest date of MB.MBDTC or ADIS.ADT &gt;= ADSL.TRT01SDT(non-missing) + 14 then set to 'SARS-CoV-2 Infection Regardless of Symptomatology or Severity at PDV', else set EVNTDESC to 'Early SARS-CoV-2 Infection Regardless of Symptomatology or Severity'</li> <li>For PARAMCD = TTINFB4, if the earliest date of MB.MBDTC or ADIS.ADT &gt;= ADSL.TRT01SDT (non-missing) then set to 'SARS-CoV-2 Infection Regardless of Symptomatology or Severity at PDV', else set EVNTDESC to 'Early SARS-CoV-2 Infection Regardless of Symptomatology or Severity'</li> <li>For PARAMCD = TTINFB5, if the earliest date of MB.MBDTC or ADIS.ADT &gt;= ADSL.RANDDT (non-missing) then set to 'SARS-CoV-2 Infection Regardless of Symptomatology or Severity'</li> </ul> </li> <li>Set to ADTTE.EVNTDESC where ADTTE.PARAMCD='TTINFX'[1]</li> </ol>

### Additional ADaM Variables definition

PARAMCD	EVNTDESC
	[1] X = 1, 2, 3, 4, or 5 [2] this condition applies only when X is not 5