

Question 4.b

Records selection:					
Select unique records by USUBJID, FATPTREF, FAOBJ, FATPTNUM, GRADE, FAEVAL from FACE/FAAE					
Note: If STUDY SUBJECT and INVESTIGATOR have the same grade, then select STUDY SUBJECT					
Topline Records CE Mapping					
CE Variables	Case 1 No Event Occurred within 7 Days	Case 2 First Event occurred after missing reported Time Point	Case 3 Last Event occurred before missing reported Time Point	Case 4 Event occurred within day 7	Case 5 Ongoing
CEOCCUR	N	Y	Y	Y	Y
CETOXGR	0	Worse Grade	Worse Grade	Worse Grade	Worse Grade
CESTDTC		Null		First Event Date	First Event Date
CEENDTC			Null	Last Event Date	Last Event Date
CEENRTPT					Ongoing
CEENTPT					Day 7

CE Mapping Examples

CASE1: There is no event within day 7

CEOCCUR = N, CETOXGR=0, CESTDTC=NULL, CEENDTC=NULL, CEENRTPT=NULL, CEENTPT = NULL

	Unique Subject Identifier	Time Point Reference	Object of the Observa	Planned Time Point Name	TOXGR	Evaluator	Date/Time of Collection
25	mRNA-1273-P301-US300-2002	DOSE 1	Fatigue	DAY 1, 30 MINUTES AFTER VACCINATION (AT STUDY CLINIC)	0	STUDY SUBJECT	2020-07-27T12:28
26	mRNA-1273-P301-US300-2002	DOSE 1	Fatigue	DAY 1, AFTER VACCINATION (AT HOME)	0	STUDY SUBJECT	2020-07-27T23:21
27	mRNA-1273-P301-US300-2002	DOSE 1	Fatigue	DAY 2	0	STUDY SUBJECT	2020-07-28T23:02
28	mRNA-1273-P301-US300-2002	DOSE 1	Fatigue	DAY 3	0	STUDY SUBJECT	2020-07-29T22:13
29	mRNA-1273-P301-US300-2002	DOSE 1	Fatigue	DAY 4	0	STUDY SUBJECT	2020-07-31T00:37
30	mRNA-1273-P301-US300-2002	DOSE 1	Fatigue	DAY 5	0	STUDY SUBJECT	2020-08-01T08:51
31	mRNA-1273-P301-US300-2002	DOSE 1	Fatigue	DAY 6	0	STUDY SUBJECT	2020-08-01T22:41
32	mRNA-1273-P301-US300-2002	DOSE 1	Fatigue	DAY 7	0	STUDY SUBJECT	2020-08-02T22:28
105	mRNA-1273-P301-US300-2002	DOSE 2	Fatigue	DAY 1, 30 MINUTES AFTER VACCINATION (AT STUDY CLINIC)	0	STUDY SUBJECT	2020-08-26T11:27
106	mRNA-1273-P301-US300-2002	DOSE 2	Fatigue	DAY 1, AFTER VACCINATION (AT HOME)	0	STUDY SUBJECT	2020-08-26T22:14
107	mRNA-1273-P301-US300-2002	DOSE 2	Fatigue	DAY 2	0	STUDY SUBJECT	2020-08-27T22:09
108	mRNA-1273-P301-US300-2002	DOSE 2	Fatigue	DAY 3	0	STUDY SUBJECT	2020-08-28T22:19
109	mRNA-1273-P301-US300-2002	DOSE 2	Fatigue	DAY 4	0	STUDY SUBJECT	2020-08-29T22:08
110	mRNA-1273-P301-US300-2002	DOSE 2	Fatigue	DAY 5	0	STUDY SUBJECT	2020-08-30T22:24
111	mRNA-1273-P301-US300-2002	DOSE 2	Fatigue	DAY 6	0	STUDY SUBJECT	2020-08-31T21:49
112	mRNA-1273-P301-US300-2002	DOSE 2	Fatigue	DAY 7	0	STUDY SUBJECT	2020-09-01T21:48

CASE 2: If the first event occurred after missing reported time point then

CEOCCUR = Y, CETOXGR=1, CESTDTC=NULL, CEENDTC=2020-11-23T14:38, CEENRTPT=NULL, CEENTPT = NULL

	Unique Subject Identifier	Time Point Referenc	Planned Time Point Name	Object of the Observati	TOXG	Evaluator	Date/Time of Collection
106	mRNA-1273-P301-US399-2126	DOSE 2	DAY 1, AFTER VACCINATION (AT HOME)	Fatigue	0	STUDY SUBJECT	2020-11-17T14:02
107	mRNA-1273-P301-US399-2126	DOSE 2	DAY 2	Fatigue	0	STUDY SUBJECT	2020-11-18T23:22
108	mRNA-1273-P301-US399-2126	DOSE 2	DAY 3	Fatigue	0	STUDY SUBJECT	2020-11-20T07:18
109	mRNA-1273-P301-US399-2126	DOSE 2	DAY 4	Fatigue	0	STUDY SUBJECT	2020-11-21T00:39
110	mRNA-1273-P301-US399-2126	DOSE 2	DAY 5	Fatigue			
111	mRNA-1273-P301-US399-2126	DOSE 2	DAY 6	Fatigue	0	STUDY SUBJECT	2020-11-22T15:10
112	mRNA-1273-P301-US399-2126	DOSE 2	DAY 7	Fatigue	1	STUDY SUBJECT	2020-11-23T14:38

Case 3 if the last event occurred before missing reported time point

CEOCCUR = Y, CETOXGR=1, CESTDTC=2020-09-29T19:13, CEENDTC=NULL, CEENRTPT=NULL, CEENTPT = NULL

	Unique Subject Identifier	Time Point Reference	Planned Time Point Name	Object of the Observati	TOXGR	Evaluator	Date/Time of Collection
42	mRNA-1273-P301-US322-2650	DOSE 1	DAY 1, AFTER VACCINATION (AT HOME)	Myalgia	1	STUDY SUBJECT	2020-09-29T19:13
43	mRNA-1273-P301-US322-2650	DOSE 1	DAY 2	Myalgia			
44	mRNA-1273-P301-US322-2650	DOSE 1	DAY 3	Myalgia	0	STUDY SUBJECT	2020-10-01T15:40
45	mRNA-1273-P301-US322-2650	DOSE 1	DAY 4	Myalgia	0	STUDY SUBJECT	2020-10-02T13:48
46	mRNA-1273-P301-US322-2650	DOSE 1	DAY 5	Myalgia	0	STUDY SUBJECT	2020-10-03T12:11
47	mRNA-1273-P301-US322-2650	DOSE 1	DAY 6	Myalgia	0	STUDY SUBJECT	2020-10-04T13:36
48	mRNA-1273-P301-US322-2650	DOSE 1	DAY 7	Myalgia	0	STUDY SUBJECT	2020-10-05T12:54

CASE 4: The event was occurred within day 7

CEOCCUR = Y, CETOXGR=2, CESTDTC=2020-07-30-T14:51, CEENDTC=2020-08-05, CEENRTPT=NULL, CEENTPT = NULL

	Unique Subject Identifier	Time Point Reference	Object of the Observation	Planned Time Point Number	TOXGR	Evaluator	Date/Time of Collection
2	mRNA-1273-P301-US300-2048	DOSE 1	Arthralgia	1.2	0	STUDY SUBJECT	2020-07-29T20:01
3	mRNA-1273-P301-US300-2048	DOSE 1	Arthralgia	2	1	STUDY SUBJECT	2020-07-30T14:51
4	mRNA-1273-P301-US300-2048	DOSE 1	Arthralgia	3	2	STUDY SUBJECT	2020-07-31T15:55
5	mRNA-1273-P301-US300-2048	DOSE 1	Arthralgia	4	1	STUDY SUBJECT	2020-08-01T17:17
6	mRNA-1273-P301-US300-2048	DOSE 1	Arthralgia	5	0	STUDY SUBJECT	2020-08-02T17:38
7	mRNA-1273-P301-US300-2048	DOSE 1	Arthralgia	6	0	STUDY SUBJECT	2020-08-03T19:14
8	mRNA-1273-P301-US300-2048	DOSE 1	Arthralgia	6	1	INVESTIGATOR	2020-08-04
9	mRNA-1273-P301-US300-2048	DOSE 1	Arthralgia	7	1	INVESTIGATOR	2020-08-05
10	mRNA-1273-P301-US300-2048	DOSE 1	Arthralgia	7	1	STUDY SUBJECT	2020-08-04T16:38

CASE 5: Ongoing

CEOCCUR = Y, CETOXGR=1, CESTDTC=2020-10-01, CEENDTC=2020-10-02T22:25, CEENRTPT=ONGOING, CEENTPT = DAY 7

Note:

1. Per our CRF, "Ongoing" data was not captured, and it was derived based on Planned Time Point Number - >=8 with EVENT GRADE>0
2. CEENDTC will be derived based on last records with GRADE>0

	Unique Subject Identifier	Time Point Referenc	Planned Time Point Name	Object of the Observati	TOXGR	Evaluator	Date/Time of Collection	Planned Time Point Number
1	mRNA-1273-P301-US325-2565	DOSE 1	DAY 1, AFTER VACCINATION (AT HOME)	Fatigue	0	STUDY SUBJECT	2020-09-25T18:18	1.2
2	mRNA-1273-P301-US325-2565	DOSE 1	DAY 2	Fatigue	0	STUDY SUBJECT	2020-09-26T15:35	2
3	mRNA-1273-P301-US325-2565	DOSE 1	DAY 3	Fatigue	0	STUDY SUBJECT	2020-09-27T12:31	3
4	mRNA-1273-P301-US325-2565	DOSE 1	DAY 4	Fatigue	0	STUDY SUBJECT	2020-09-28T16:51	4
5	mRNA-1273-P301-US325-2565	DOSE 1	DAY 5	Fatigue	0	STUDY SUBJECT	2020-09-29T12:04	5
6	mRNA-1273-P301-US325-2565	DOSE 1	DAY 6	Fatigue	1	INVESTIGATOR	2020-10-01	6
7	mRNA-1273-P301-US325-2565	DOSE 1	DAY 7	Fatigue	1	STUDY SUBJECT	2020-10-01T23:01	7
8	mRNA-1273-P301-US325-2565	DOSE 1	DAY 8	Fatigue	1	STUDY SUBJECT	2020-10-02T22:25	8
9	mRNA-1273-P301-US325-2565	DOSE 1	DAY 9	Fatigue	0	STUDY SUBJECT	2020-10-04T00:03	9

Additional Comments for Q10

CEENDTC will be present after we update CE mapping logic (CASE 5), but date may not be the same as reported in SDTM.AE. Per our current mapping logic. AE Reactogenicity event to be included in FAE must meet following criteria:

1. AECAT="REACTOGENITICY"
2. AEDECOD should be matched by one of pre-specified symptom terms

The example provided from Q10: it met condition 1 → AECAT=REACTOGENICITY, but it did not meet condition 2 → AEDECOD (Lymphadenopathy) is not the same as CETERM (Underarm Gland Swelling or Tenderness). The issue could be resolved when lookup table updated

From SDTM.AE

AECAT	AETERM	AEDECOD	AEREFID	AESEV	AESTDTC	AEENDTC
REACTOGENICITY	UNDERARM GLAND SWELLING, LEFT ARM (VACCINATION ARM)	Lymphadenopathy	DOSE 1 - 2020-08-06T14:48	MODERATE	2020-08-11	2020-08-21

FAAE

	Unique Subject Identifier	Time Point Referenc	Planned Time Point Name	Object of the Observation	TOXGR	Evaluator	Date/Time of Collection
1	mRNA-1273-P301-US301-2053	DOSE 1	DAY 1, AFTER VACCINATION (AT HOME)	Underarm Gland Swelling or Tenderness	0	STUDY SUBJECT	2020-08-06T18:35
2	mRNA-1273-P301-US301-2053	DOSE 1	DAY 2	Underarm Gland Swelling or Tenderness	3	STUDY SUBJECT	2020-08-07T17:28
3	mRNA-1273-P301-US301-2053	DOSE 1	DAY 3	Underarm Gland Swelling or Tenderness	0	STUDY SUBJECT	2020-08-08T18:29
4	mRNA-1273-P301-US301-2053	DOSE 1	DAY 4	Underarm Gland Swelling or Tenderness	0	STUDY SUBJECT	2020-08-10T00:12
5	mRNA-1273-P301-US301-2053	DOSE 1	DAY 5	Underarm Gland Swelling or Tenderness	3	STUDY SUBJECT	2020-08-11T00:00
6	mRNA-1273-P301-US301-2053	DOSE 1	DAY 6	Underarm Gland Swelling or Tenderness	3	STUDY SUBJECT	2020-08-11T18:07
7	mRNA-1273-P301-US301-2053	DOSE 1	DAY 7	Underarm Gland Swelling or Tenderness	3	STUDY SUBJECT	2020-08-12T17:27
8	mRNA-1273-P301-US301-2053	DOSE 1	DAY 8	Underarm Gland Swelling or Tenderness	3	STUDY SUBJECT	2020-08-13T12:02
9	mRNA-1273-P301-US301-2053	DOSE 1	DAY 9	Underarm Gland Swelling or Tenderness	3	STUDY SUBJECT	2020-08-14T12:01
10	mRNA-1273-P301-US301-2053	DOSE 1	DAY 10	Underarm Gland Swelling or Tenderness	3	STUDY SUBJECT	2020-08-15T16:15
11	mRNA-1273-P301-US301-2053	DOSE 1	DAY 11	Underarm Gland Swelling or Tenderness	3	STUDY SUBJECT	2020-08-16T23:08
12	mRNA-1273-P301-US301-2053	DOSE 1	DAY 12	Underarm Gland Swelling or Tenderness	3	STUDY SUBJECT	2020-08-17T12:02
13	mRNA-1273-P301-US301-2053	DOSE 1	DAY 13	Underarm Gland Swelling or Tenderness	3	STUDY SUBJECT	2020-08-18T14:20
14	mRNA-1273-P301-US301-2053	DOSE 1	DAY 14	Underarm Gland Swelling or Tenderness	3	STUDY SUBJECT	2020-08-19T19:28
15	mRNA-1273-P301-US301-2053	DOSE 1	DAY 15	Underarm Gland Swelling or Tenderness	3	STUDY SUBJECT	2020-08-20T13:26
16	mRNA-1273-P301-US301-2053	DOSE 1	DAY 16	Underarm Gland Swelling or Tenderness			
17	mRNA-1273-P301-US301-2053	DOSE 1	DAY 17	Underarm Gland Swelling or Tenderness			