

Additional ADaM Definition

ModernaTX, Inc.

Study mRNA-1273-P201

Contents

1. ADAR.....	3
2. ADARSUM.....	6

1. ADAR

Variable Name	Variable Label	Type	Parameter Identifier	Controlled Terms	Controlled Term Name	Source	Derivation
PARAMCD	Parameter Code	Char	PARAMCD	RASH; RASHOCC; LYMPHOCC; LYMPH; PAIN; ERYTHDIA; SWELLDIA; HEADACHE; FATIGUE; MYALGIA; ARTHRALG; NAUSEA; CHILLS; FEVER	ARPARAMCD	Assigned	RASH if PARAM='Rash', RASHOCC if PARAM='Rash Occurrence', LYMPHOCC if PARAM='Lymphadenopathy Occurrence', LYMPH if PARAM='Lymphadenopathy', PAIN if PARAM='Pain', ERYTHDIA if PARAM='Erythema Longest Diameter (mm)', SWELLDIA if PARAM='Swelling Longest Diameter (mm)', HEADACHE if PARAM='Headache', FATIGUE if PARAM='Fatigue', MYALGIA if PARAM='Myalgia', ARTHRALG if PARAM='Arthralgia', NAUSEA if PARAM='Nausea/Vomiting', CHILLS if PARAM='Chills', FEVER if PARAM='Fever (C)'

PARAM	Parameter	Char	*ALL*		ARPARAM	Derived	
				Rash; Rash Occurrence; Lymphadenopathy Occurrence; Lymphadenopathy; Pain; Erythema Longest Diameter (mm); Swelling Longest Diameter (mm); Headache; Fatigue; Myalgia; Arthralgia; Nausea/Vomiting; Chills; Fever (C)			If source data are from FACE and FAOBJ='Rash', and FATESTCD ne 'SEV' then set to 'Rash Occurrence'; If source data are from FACE and FAOBJ='Solicited Rash', and FATESTCD = 'SEV' then set to 'Rash'; If source data are from FACE and FAOBJ='Underarm Gland Swelling or Tenderness' and FATESTCD = 'SEV', then set to 'Lymphadenopathy'; If source data are from FACE and FAOBJ='Nausea/Vomiting' and FATESTCD = 'SEV', then set to 'Nausea/Vomiting' If source data are from FACE and FAOBJ='Lymphadenopathy', then set to 'Lymphadenopathy Occurrence'. If source data are from FACE and FAOBJ = 'Erythema' or 'Swelling', and FATEST contains 'Occurrence' and FAORRES='NO', then set to FAOBJ ' Longest Diameter (mm)'; and assign AVAL=0 (see specs for AVAL). If source data are from FACE and FAOBJ = 'Erythema' or 'Swelling', and FATEST contains 'Intensity', then set to FAOBJ ' Longest Diameter (mm)'; If source data are from FACE and FAOBJ='Solicited Rash', then set to 'Rash'. If source data are from FACE and FAOBJ = 'Erythema' or 'Swelling', and FATEST='Longest Diameter', set to 'FAOBJ' ' ' FATEST ' ' '(' FAORRESU ')' If source data are from FACE and FAOBJ='Fever', then set to 'Fever (C)'. set to FAOBJ otherwise.

Study mRNA-1273-P201

Additional ADaM Definition

							if source data are from VS and VSTESTCD in ('TEMP' 'VSALL'), set to 'Fever' '(' VSSTRESU ')'. (please add space between the VSTEST and VS unit. If the VSSTRESU is missing, use non-missing VSSTRESU)
--	--	--	--	--	--	--	---

2. ADARSUM

Variable Name	Variable Label	Type	Parameter Identifier	Controlled Terms	Controlled Term Name	Source	Derivation
PARAMCD	Parameter Code	Char	PARAMCD	RASHDUR; LYMPHDUR; PAINDUR; ERYTHDUR; SWELLDUR; HEADADUR; FATIGDUR; MYALGDUR; ARTHRDUR; NAUSEDUR; CHILLDUR; FEVERDUR; HPRASDUR; HPLYMDUR; ANYDUR; LOCDUR; SYSDUR; RASHOCYN; LYMOCCYN; WRASH; WLYMPH; WPAIN; WERYTH; WSWELL; WHEAD; WFATIGUE; WMYALGIA; WARTHUR; WNAUSEA; WCHILLS;	ARSPARCD	Assigned	RASHDUR if PARAM='Number of Days for Rash', LYMPHDUR if PARAM='Number of Days for Lymphadenopathy', PAINDUR if PARAM='Number of Days for Pain', ERYTHDUR if PARAM='Number of Days for Erythema', SWELLDUR if PARAM='Number of Days for Swelling', HEADADUR if PARAM='Number of Days for Headache', FATIGDUR if PARAM='Number of Days for Fatigue', MYALGDUR if PARAM='Number of Days for Myalgia', ARTHRDUR if PARAM='Number of Days for Arthralgia', NAUSEDUR if PARAM='Number of Days for Nausea', CHILLSDUR if PARAM='Number of Days for Chills', FEVERDUR if PARAM='Number of Days for Fever', HPRASDUR if PARAM='Number of Days for Rash by Health Provider', HPLYMDUR if PARAM='Number of Days for Lymphadenopathy by Health Provider', ANYDUR if PARAM='Number of Days

				WFEVER; WSAR; WSLAR; WSSAR			for Any Solicited AR ; LOCDUR if PARAM='Number of Days for Local Solicited AR ; SYSDUR if PARAM='Number of Days for Systemic Solicited AR ; RASHOCYN if PARAM='Rash Occurrence between Day 1 and Day 7'; LYMOCCYN if PARAM='Lymphadenopathy Occurrence between Day 1 and Day 7'; WRASH if PARAM='Worst Analysis Toxicity Grade for Rash between Day 1 and Day 7'; WLYMPH if PARAM='Worst Analysis Toxicity Grade for Lymphadenopathy between Day 1 and Day 7'; WPAIN if PARAM='Worst Analysis Toxicity Grade for Pain between Day 1 and Day 7'; WERYTH if PARAM='Worst Analysis Toxicity Grade for Erythema between Day 1 and Day 7'; WSWELL if PARAM='Worst Analysis Toxicity Grade for Swelling between Day 1 and Day 7'; WHEAD if PARAM='Worst Analysis Toxicity Grade for Headache between Day 1 and Day 7'; WFATIGUE if PARAM='Worst Analysis Toxicity Grade for Fatigue between Day 1 and Day 7'; WMYALGIA if PARAM='Worst
--	--	--	--	-------------------------------------	--	--	---

							Analysis Toxicity Grade for Myalgia between Day 1 and Day 7'; WARTH if PARAM='Worst Analysis Toxicity Grade for Arthralgia between Day 1 and Day 7'; WNAUSEA if PARAM='Worst Analysis Toxicity Grade for Nausea between Day 1 and Day 7'; WCHILLS if PARAM='Worst Analysis Toxicity Grade for Chills between Day 1 and Day 7'; WFEVER if PARAM='Worst Analysis Toxicity Grade for Fever between Day 1 and Day 7'; WSAR if PARAM='Worst Analysis Toxicity Grade for Any Solicited AR between Day 1 and Day 7'; WSLAR if PARAM='Worst Analysis Toxicity Grade for Any Solicited Local AR between Day 1 and Day 7'; WSSAR if PARAM='Worst Analysis Toxicity Grade for Any Solicited Systemic AR between Day 1 and Day 7';
--	--	--	--	--	--	--	---

PARAM	Parameter	Char	*ALL*	RASHDUR if PARAM='Number of Days for Rash', LYMPHDUR if PARAM='Number of Days for Lymphadenopathy', PAINDUR if PARAM='Number of Days for Pain', ERYTHDUR if PARAM='Number of Days for Erythema ', SWELLDUR if PARAM='Number of Days for Swelling', HEADADUR if PARAM='Number of Days for Headache', FATIGDUR if PARAM='Number of Days for Fatigue', MYALGDUR if PARAM='Number of Days for Myalgia', ARTHRDUR if PARAM='Number of Days for Arthralgia', NAUSEDUR if PARAM='Number of Days for Nausea', CHILLSDUR if PARAM='Number of Days for Chills', FEVERDUR if PARAM='Number of Days for Fever'; HPRASDUR if PARAM='Number of Days for	ARSPARAM	Assigned	Assign the PARAM to each subject and each ATPREF (i.e., Vaccination 1, Vaccination 2)
-------	-----------	------	-------	--	----------	----------	---

				Rash by Health Provider'; HPLYMDUR if PARAM='Number of Days for Lymphadenopathy by Health Provider'; ANYDUR if PARAM='Number of Days for Any Solicited AR ; LOCDUR if PARAM='Number of Days for Local Solicited AR ; SYSDUR if PARAM='Number of Days for Systemic Solicited AR ; RASHOCYN if PARAM='Rash Occurrence between Day 1 and Day 7'; LYMOCCYN if PARAM='Lymphadenopathy Occurrence between Day 1 and Day 7'; WRASH if PARAM='Worst Analysis Toxicity Grade for Rash between Day 1 and Day 7'; WLYMPH if PARAM='Worst Analysis Toxicity Grade for Lymphadenopathy between Day 1 and Day 7'; WPAIN if PARAM='Worst Analysis Toxicity Grade for Pain between Day 1 and Day 7'; WERYTH if PARAM='Worst Analysis Toxicity Grade for Erythema between Day 1 and			
--	--	--	--	--	--	--	--

				Day 7'; WSWELL if PARAM='Worst Analysis Toxicity Grade for Swelling between Day 1 and Day 7'; WHEAD if PARAM='Worst Analysis Toxicity Grade for Headache between Day 1 and Day 7'; WFATIGUE if PARAM='Worst Analysis Toxicity Grade for Fatigue between Day 1 and Day 7'; WMYALGIA if PARAM='Worst Analysis Toxicity Grade for Myalgia between Day 1 and Day 7'; WARTHHR if PARAM='Worst Analysis Toxicity Grade for Arthralgia between Day 1 and Day 7'; WNAUSEA if PARAM='Worst Analysis Toxicity Grade for Nausea between Day 1 and Day 7'; WCHILLS if PARAM='Worst Analysis Toxicity Grade for Chills between Day 1 and Day 7'; WFEVER if PARAM='Worst Analysis Toxicity Grade for Fever between Day 1 and Day 7'; WSAR if PARAM='Worst			
--	--	--	--	--	--	--	--

Study mRNA-1273-P201

Additional ADaM Definition

				Analysis Toxicity Grade for Any Solicited AR between Day 1 and Day 7'; WSLAR if PARAM='Worst Analysis Toxicity Grade for Any Solicited Local AR between Day 1 and Day 7'; WSSAR if PARAM='Worst Analysis Toxicity Grade for Any Solicited Systemic AR between Day 1 and Day 7';			
--	--	--	--	--	--	--	--