

Additional ADaM Definition

ModernaTX, Inc.

Study mRNA-1273-P201 Part A

Contents

ADARSUMM.PARAMCD..... 3

ADARSUMM.PARAM..... 3

ADARSUMM.PARAMCD

Assigned PARAMCD as

RASHDUR for Number of Days for Rash
 LYMPHDUR for Number of Days for Underarm Gland Swelling or Tenderness,
 PAINDUR for Number of Days for Pain
 ERYTHDUR for Number of Days for Erythema
 SWELLDUR for Number of Days for Swelling
 HEADADUR for Number of Days for Headache
 FATIGDUR for Number of Days for Fatigue
 MYALGDUR for Number of Days for Myalgia
 ARTHRDUR for Number of Days for Arthralgia
 NAUSEDUR for Number of Days for Nausea
 CHILLSDUR for Number of Days for Chills
 FEVERDUR for Number of Days for Fever
 HPRASDUR for Number of Days for Rash by Health Provider
 HPLYMDUR for Number of Days for Lymphadenopathy by Health Provider
 ANYDUR for Number of Days for Any Solicited AR
 LOCDUR for Number of Days for Local Solicited AR
 SYSDUR for Number of Days for Systemic Solicited AR
 RASHOCYN for Rash Occurrence between Day 1 and Day 7
 LYMOCCYN for Lymphadenopathy Occurrence between Day 1 and Day 7
 WRASH for Worst Analysis Toxicity Grade for Rash between Day 1 and Day 7
 WLYMPH for Worst Analysis Toxicity Grade for Underarm Gland Swelling or Tenderness between Day 1 and Day 7
 WPAIN for Worst Analysis Toxicity Grade for Pain between Day 1 and Day 7
 WERYTH for Worst Analysis Toxicity Grade for Erythema between Day 1 and Day 7
 WSWELL for Worst Analysis Toxicity Grade for Swelling between Day 1 and Day 7
 WHEAD for Worst Analysis Toxicity Grade for Headache between Day 1 and Day 7
 WFATIGUE for Worst Analysis Toxicity Grade for Fatigue between Day 1 and Day 7
 WMYALGIA for Worst Analysis Toxicity Grade for Myalgia between Day 1 and Day 7
 WARTHRA for Worst Analysis Toxicity Grade for Arthralgia between Day 1 and Day 7
 WNAUSEA for Worst Analysis Toxicity Grade for Nausea between Day 1 and Day 7
 WCHILLS for Worst Analysis Toxicity Grade for Chills between Day 1 and Day 7
 WFEVER for Worst Analysis Toxicity Grade for Fever between Day 1 and Day 7
 WSAR for Worst Analysis Toxicity Grade for Any Solicited AR between Day 1 and Day 7
 WSLAR for Worst Analysis Toxicity Grade for Any Solicited Local AR between Day 1 and Day 7
 WSSAR for Worst Analysis Toxicity Grade for Any Solicited Systemic AR between Day 1 and Day 7

ADARSUMM.PARAM

Set to Number of Days for Rash if PARAMCD = RASHDUR
 Set to Number of Days for Underarm Gland Swelling or Tenderness if PARAMCD = LYMPHDUR
 Set to Number of Days for Pain if PARAMCD = PAINDUR
 Set to Number of Days for Erythema if PARAMCD = ERYTHDUR
 Set to Number of Days for Swelling if PARAMCD = SWELLDUR
 Set to Number of Days for Headache if PARAMCD = HEADADUR
 Set to Number of Days for Fatigue if PARAMCD = FATIGDUR
 Set to Number of Days for Myalgia if PARAMCD = MYALGDUR
 Set to Number of Days for Arthralgia if PARAMCD = ARTHRDUR
 Set to Number of Days for Nausea if PARAMCD = NAUSEDUR
 Set to Number of Days for Chills if PARAMCD = CHILLSDUR
 Set to Number of Days for Fever if PARAMCD = FEVERDUR
 Set to Number of Days for Rash by Health Provider if PARAMCD = HPRASDUR
 Set to Number of Days for Lymphadenopathy by Health Provider if PARAMCD = HPLYMDUR
 Set to Number of Days for Any Solicited AR if PARAMCD = ANYDUR
 Set to Number of Days for Local Solicited AR if PARAMCD = LOCDUR

Set to Number of Days for Systemic Solicited AR if PARAMCD = SYSDUR
Set to Rash Occurrence between Day 1 and Day 7 if PARAMCD = RASHOCYN
Set to Lymphadenopathy Occurrence between Day 1 and Day 7 if PARAMCD = LYMOCCYN
Set to Worst Analysis Toxicity Grade for Rash between Day 1 and Day 7 if PARAMCD = WRASH
Set to Worst Analysis Toxicity Grade for Underarm Gland Swelling or Tenderness between Day 1 and Day 7 if PARAMCD = WLYMPH
Set to Worst Analysis Toxicity Grade for Pain between Day 1 and Day 7 if PARAMCD = WPAIN
Set to Worst Analysis Toxicity Grade for Erythema between Day 1 and Day 7 if PARAMCD = WERYTH
Set to Worst Analysis Toxicity Grade for Swelling between Day 1 and Day 7 if PARAMCD = WSWELL
Set to Worst Analysis Toxicity Grade for Headache between Day 1 and Day 7 if PARAMCD = WHEAD
Set to Worst Analysis Toxicity Grade for Fatigue between Day 1 and Day 7 if PARAMCD = WFATIGUE
Set to Worst Analysis Toxicity Grade for Myalgia between Day 1 and Day 7 if PARAMCD = WMYALGIA
Set to Worst Analysis Toxicity Grade for Arthralgia between Day 1 and Day 7 if PARAMCD = WARTHRA
Set to Worst Analysis Toxicity Grade for Nausea between Day 1 and Day 7 if PARAMCD = WNAUSEA
Set to Worst Analysis Toxicity Grade for Chills between Day 1 and Day 7 if PARAMCD = WCHILLS
Set to Worst Analysis Toxicity Grade for Fever between Day 1 and Day 7 if PARAMCD = WFEVER
Set to Worst Analysis Toxicity Grade for Any Solicited AR between Day 1 and Day 7 if PARAMCD = WSAR
Set to Worst Analysis Toxicity Grade for Any Solicited Local AR between Day 1 and Day 7 if PARAMCD = WSLAR
Set to Worst Analysis Toxicity Grade for Any Solicited Systemic AR between Day 1 and Day 7 if PARAMCD = WSSAR