# MAY2013-01-01 - Analysis Data Dictionary

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# MAY2013-01-01 - Analysis: Data Dictionary
## Section 1: Identifiers

| Variable | Label | Description | Format Text |
|----------|-------|-------------|-------------|
| **DCNTR_ID** | Participant ID | Participant ID | Char |

# Section 2: Study-wide

| Variable | Label | Description | Format Text |
|---|---|---|---|
| **ARM** | Arm | Arm | "A"="MUC1"<br>"B"="Placebo" |

# Section 3: Analysis

| Variable | Label | Description | Format Text |
|---|---|---|---|
| **ADENOMA** | Number Of Advanced Adenomas | Number Of Advanced Adenomas | Numeric |
| **adenoman_bsl** | Sum Of Adenomas (Baseline) | Sum Of Adenomas (Baseline) | Numeric |
| **adenoman_int** | Sum Of Adenomas (Week 156) | Sum Of Adenomas (Week 156) | Numeric |
| **advadeno_bsl** | Total Number Advanced Adenomas (Baseline) | Total Number Advanced Adenomas (Baseline) | Numeric |
| **advadeno_int** | Total Number Advanced Adenomas (Week 156) | Total Number Advanced Adenomas (Week 156) | Numeric |
| **advcrit_bsl** | Criteria Of Qualifying Baseline Advanced Adenoma | Criteria Of Qualifying Baseline Advanced Adenoma | 1=">1cm, High Grade Dysplasia, and Villous or Tubulovillous"<br>3=">1cm, and Villous or Tubulovillous"<br>5=">1cm"<br>7="Villous or Tubulovillous" |
| **AGE** | Age | Age | Numeric |
| **ALLERGY** | Does The Participant Have Any Allergies? | Does The Participant Have Any Allergies? | Numeric |
| **aspirin** | Aspirin Use | Aspirin Use | 0="No"<br>1="Yes" |
| **bmi** | Body Mass Index (BMI) | Body Mass Index (BMI) | Numeric |
| **bsl_igg** | Baseline IGG Level | Baseline IGG Level | Numeric |
| **bsl_iggmed** | Week 12 Non-Responders: Is Baseline IGG Above Or Below The Median Baseline IGG? | Week 12 Non-Responders: Is Baseline IGG Above Or Below The Median Baseline IGG? | Numeric |
| **bwlprep_bsl** | Was The Overall Bowel Preparation Adequate, Good, Or Excellent? (Baseline) | Was The Overall Bowel Preparation Adequate, Good, Or Excellent? (Baseline) | 1="Yes"<br>2="No"<br>3="Not Reported" |
| **bwlprep_int** | Was The Overall Bowel Preparation Adequate, Good, Or Excellent? (Week 156) | Was The Overall Bowel Preparation Adequate, Good, Or Excellent? (Week 156) | 1="Yes"<br>2="No"<br>3="Not Reported" |
| **cat_adv_bsl** | Total number advanced adenomas (Baseline) | Total number advanced adenomas (Baseline) | Numeric |
| **cat_adv_int** | Total number advanced adenomas (Week 156) | Total number advanced adenomas (Week 156) | Numeric |
| **cat_dysp_bsl** | Polyp presence of dysplasia (Baseline) | Polyp presence of dysplasia (Baseline) | 1="No dysplasia"<br>2="Indefinite for dysplasia"<br>3="Low grade dysplasia"<br>5="Not available" |
| **cat_dysp_int** | Polyp presence of dysplasia (Week 156) | Polyp presence of dysplasia (Week 156) | 2="Indefinite for dysplasia"<br>3="Low grade dysplasia"<br>5="Not available" |

| Variable | Label | Description | Format Text |
|---|---|---|---|
| **cat_histotp_bsl** | Polyp histopathologic type (Baseline) | Polyp histopathologic type (Baseline) | 1="Hyperplastic polyps"<br>2="Hamartomatous"<br>3="Inflammatory polyps"<br>4="Tubular adenoma"<br>5="Tubulovillous adenoma" |
| **cat_histotp_int** | Polyp histopathologic type (Week 156) | Polyp histopathologic type (Week 156) | 1="Hyperplastic polyps"<br>4="Tubular adenoma"<br>5="Tubulovillous adenoma"<br>8="Serrated adenoma" |
| **cat_large_bsl** | Polyp size at colonoscopy >= 1 cm (Baseline) | Polyp size at colonoscopy >= 1 cm (Baseline) | 1="Yes"<br>2="No" |
| **cat_large_int** | Polyp size at colonoscopy >= 1 cm (Week 156) | Polyp size at colonoscopy >= 1 cm (Week 156) | 1="Yes"<br>2="No" |
| **cat_locatn_bsl** | Polyp location (Baseline) | Polyp location (Baseline) | 1="Cecum"<br>2="Ascending colon"<br>3="Hepatic flexure"<br>4="Transverse colon"<br>5="Splenic flexure" |
| **cat_locatn_int** | Polyp location (Week 156) | Polyp location (Week 156) | 1="Cecum"<br>2="Ascending colon"<br>3="Hepatic flexure"<br>4="Transverse colon"<br>5="Splenic flexure" |
| **CD15s** | CD15S (Baseline) | CD15S (Baseline) | Numeric |
| **cd4_cd25** | CD4+CD25+ (Baseline) | CD4+CD25+ (Baseline) | Numeric |
| **cecumvis_bsl** | Was The Cecum Visualized? (Baseline) | Was The Cecum Visualized? (Baseline) | 1="Yes"<br>3="Not Reported" |
| **cecumvis_int** | Was The Cecum Visualized? (Week 156) | Was The Cecum Visualized? (Week 156) | 1="Yes"<br>2="No" |
| **col_rslt_bsl** | Results Of Colonoscopy (Baseline) | Results Of Colonoscopy (Baseline) | 1="Normal"<br>2="Abnormal, specify" |
| **col_rslt_int** | Results Of Colonoscopy (Week 156) | Results Of Colonoscopy (Week 156) | 1="Normal"<br>2="Abnormal, specify"<br>3="Other, specify" |
| **colpscpy_bsl** | Colonoscopy Performed (Baseline) | Colonoscopy Performed (Baseline) | 1="Yes" |
| **colpscpy_int** | Colonoscopy Performed (Week 156) | Colonoscopy Performed (Week 156) | 1="Yes" |
| **CTEP_ID** | Site | Site | "MA034"="MA034"<br>"MN026"="MN026"<br>"MO029"="MO029"<br>"PA015"="PA015"<br>"PA121"="PA121"<br>"PR008"="PR008" |
| **dosew0_dt** | Date Agent Administered (Week 0) | Date Agent Administered (Week 0) | SAS Date |
| **dx_resp** | Disease Responder | Disease Responder | 0="No"<br>1="Yes" |
| **e_mdsc** | E-Mdsc (Baseline) | E-Mdsc (Baseline) | Numeric |
| **ETHNCTY1** | Ethnicity | Ethnicity | "1"="Hispanic or Latino"<br>"2"="Not Hispanic or Latino"<br>"9"="Unknown" |

| Variable | Label | Description | Format Text |
|---|---|---|---|
| **expsep3a_recur** | >5 mm Adenoma Recurrence (Week 156) | >5 mm Adenoma Recurrence (Week 156) | 0="No"<br>1="Yes" |
| **expsep3b_recur** | Adenoma Recurrence In Segment Of Bowel Different Than Previous Advanced Adenoma (Week 156) | Adenoma Recurrence In Segment Of Bowel Different Than Previous Advanced Adenoma (Week 156) | 0="No"<br>1="Yes" |
| **expsep3c_recur** | >=5 mm Adenoma Recurrence In Segment Of Bowel Different Than Previous Advanced Adenoma (Week 156) | >=5 mm Adenoma Recurrence In Segment Of Bowel Different Than Previous Advanced Adenoma (Week 156) | 0="No"<br>1="Yes" |
| **Foxp3** | FOXP3 (Baseline) | FOXP3 (Baseline) | Numeric |
| **fucolon_time** | Time From Week 0 Injection To Follow-Up Colonoscopy (Days) | Time From Week 0 Injection To Follow-Up Colonoscopy (Days) | Numeric |
| **GENDER** | Gender | Gender | 1="Male"<br>2="Female" |
| **HEIGHT** | Height | Height (cm) | Numeric |
| **ITCAPPDT** | Date Symptom Appeared | Date Symptom Appeared | SAS Date |
| **ITCH** | Itching At Injection Site | Itching At Injection Site | 1="Yes"<br>2="No" |
| **ITCHDT** | Date Itching Stopped | Date Itching Stopped | SAS Date |
| **m_mdsc** | M-MDSC (Baseline) | M-MDSC (Baseline) | Numeric |
| **mean_pathsize_bsl** | Average Size Of All Polyps As Measured By A Pathologist (Baseline) | Average Size Of All Polyps As Measured By A Pathologist (Baseline) | Numeric |
| **mean_pathsize_int** | Average Size Of All Polyps As Measured By A Pathologist (Week 156) | Average Size Of All Polyps As Measured By A Pathologist (Week 156) | Numeric |
| **multaden_bsl** | Multiple Adenomas (Baseline) | Multiple Adenomas (Baseline) | 0="No"<br>1="Yes" |
| **multaden_int** | Multiple Recurrent Adenomas (Week 156) | Multiple Recurrent Adenomas (Week 156) | 0="No"<br>1="Yes" |
| **multadva_bsl** | Multiple Advanced Adenomas (Baseline) | Multiple Advanced Adenomas (Baseline) | 0="No"<br>1="Yes" |
| **multadva_int** | Multiple Recurrent Advanced Adenomas (Week 156) | Multiple Recurrent Advanced Adenomas (Week 156) | 0="No"<br>1="Yes" |
| **naadenom_bsl** | Total Number Non-Advanced Adenomas (Baseline) | Total Number Non-Advanced Adenomas (Baseline) | Numeric |
| **naadenom_int** | Total Number Non-Advanced Adenomas (Week 156) | Total Number Non-Advanced Adenomas (Week 156) | Numeric |
| **nsaid** | NSAID Use | NSAID Use | 0="No"<br>1="Yes" |
| **num_acol_bsl** | Number Of Polyps In Ascending Colon (Baseline) | Number Of Polyps In Ascending Colon (Baseline) | Numeric |

| Variable | Label | Description | Format Text |
|---|---|---|---|
| num_acol_int | Number Of Polyps In Ascending Colon (Week 156) | Number Of Polyps In Ascending Colon (Week 156) | Numeric |
| num_aden_bsl | Number Of Adenoma Polyps (Baseline) | Number Of Adenoma Polyps (Baseline) | Numeric |
| num_aden_int | Number Of Adenoma Polyps (Week 156) | Number Of Adenoma Polyps (Week 156) | Numeric |
| num_adnns_bsl | Number Of Not Specified Polyps (Baseline) | Number Of Not Specified Polyps (Baseline) | Numeric |
| num_adnns_int | Number Of Not Specified Polyps (Week 156) | Number Of Not Specified Polyps (Week 156) | Numeric |
| num_adv_bsl | Number Of Advanced Adenomas (Baseline) | Number Of Advanced Adenomas (Baseline) | Numeric |
| num_adv_int | Number Of Advanced Adenomas (Week 156) | Number Of Advanced Adenomas (Week 156) | Numeric |
| num_advna_bsl | Number Of Not Applicable Adenomas (Baseline) | Number Of Not Applicable Adenomas (Baseline) | Numeric |
| num_advna_int | Number Of Not Applicable Adenomas (Week 156) | Number Of Not Applicable Adenomas (Week 156) | Numeric |
| num_cecum_bsl | Number Of Polyps In Cecum (Baseline) | Number Of Polyps In Cecum (Baseline) | Numeric |
| num_cecum_int | Number Of Polyps In Cecum (Week 156) | Number Of Polyps In Cecum (Week 156) | Numeric |
| num_dcol_bsl | Number Of Polyps In Descending Colon (Baseline) | Number Of Polyps In Descending Colon (Baseline) | Numeric |
| num_dcol_int | Number Of Polyps In Descending Colon (Week 156) | Number Of Polyps In Descending Colon (Week 156) | Numeric |
| num_dimun_bsl | Number Of Dimunitive Polyps (<5mm) (Baseline) | Number Of Dimunitive Polyps (<5mm) (Baseline) | Numeric |
| num_dimun_int | Number Of Dimunitive Polyps (<5mm) (Week 156) | Number Of Dimunitive Polyps (<5mm) (Week 156) | Numeric |
| num_hemart_bsl | Number Of Hemartomatous Polyps (Baseline) | Number Of Hemartomatous Polyps (Baseline) | Numeric |
| num_hemart_int | Number Of Hemartomatous Polyps (Week 156) | Number Of Hemartomatous Polyps (Week 156) | Numeric |
| num_hflex_bsl | Number Of Polyps In Hepatic Flexure (Baseline) | Number Of Polyps In Hepatic Flexure (Baseline) | Numeric |
| num_hflex_int | Number Of Polyps In Hepatic Flexure (Week 156) | Number Of Polyps In Hepatic Flexure (Week 156) | Numeric |
| num_high_bsl | Number Of Polyps With High Grade Dysplasia (Baseline) | Number Of Polyps With High Grade Dysplasia (Baseline) | Numeric |
| num_high_int | Number Of Polyps With High Grade Dysplasia (Week 156) | Number Of Polyps With High Grade Dysplasia (Week 156) | Numeric |

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| Variable | Label | Description | Format Text |
|---|---|---|---|
| num_hyper_bsl | Number Of Hyperplastic Polyps (Baseline) | Number Of Hyperplastic Polyps (Baseline) | Numeric |
| num_hyper_int | Number Of Hyperplastic Polyps (Week 156) | Number Of Hyperplastic Polyps (Week 156) | Numeric |
| num_indef_bsl | Number Of Polyps Indefinite For Dysplasia (Baseline) | Number Of Polyps Indefinite For Dysplasia (Baseline) | Numeric |
| num_indef_int | Number Of Polyps Indefinite For Dysplasia (Week 156) | Number Of Polyps Indefinite For Dysplasia (Week 156) | Numeric |
| num_inflam_bsl | Number Of Inflammatory Polyps (Baseline) | Number Of Inflammatory Polyps (Baseline) | Numeric |
| num_inflam_int | Number Of Inflammatory Polyps (Week 156) | Number Of Inflammatory Polyps (Week 156) | Numeric |
| num_juv_bsl | Number Of Juvenile Polyps | Number Of Juvenile Polyps | Numeric |
| num_juv_int | Number Of Juvenile Polyps | Number Of Juvenile Polyps | Numeric |
| num_large_bsl | Number Of Large Polyps (>9mm) (Baseline) | Number Of Large Polyps (>9mm) (Baseline) | Numeric |
| num_large_int | Number Of Large Polyps (>9mm) (Week 156) | Number Of Large Polyps (>9mm) (Week 156) | Numeric |
| num_low_bsl | Number Of Polyps With Low Grade Dysplasia (Baseline) | Number Of Polyps With Low Grade Dysplasia (Baseline) | Numeric |
| num_low_int | Number Of Polyps With Low Grade Dysplasia (Week 156) | Number Of Polyps With Low Grade Dysplasia (Week 156) | Numeric |
| num_med_bsl | Number Of Medium Polyps (5-9mm) (Baseline) | Number Of Medium Polyps (5-9mm) (Baseline) | Numeric |
| num_med_int | Number Of Medium Polyps (5-9mm) (Week 156) | Number Of Medium Polyps (5-9mm) (Week 156) | Numeric |
| num_na_bsl | Number Of Polyps With Grade Of Dysplasia Not Available (Baseline) | Number Of Polyps With Grade Of Dysplasia Not Available (Baseline) | Numeric |
| num_na_int | Number Of Polyps With Grade Of Dysplasia Not Available (Week 156) | Number Of Polyps With Grade Of Dysplasia Not Available (Week 156) | Numeric |
| num_nodysp_bsl | Number Of Polyps With No Dysplasia (Baseline) | Number Of Polyps With No Dysplasia (Baseline) | Numeric |
| num_nodysp_int | Number Of Polyps With No Dysplasia (Week 156) | Number Of Polyps With No Dysplasia (Week 156) | Numeric |
| num_nonadv_bsl | Number Of Non-Advanced Adenomas (Baseline) | Number Of Non-Advanced Adenomas (Baseline) | Numeric |
| num_nonadv_int | Number Of Non-Advanced Adenomas (Week 156) | Number Of Non-Advanced Adenomas (Week 156) | Numeric |
| num_notspec_bsl | Number Of Polyps In Unspecified Location (Baseline) | Number Of Polyps In Unspecified Location (Baseline) | Numeric |
| num_notspec_int | Number Of Polyps In Unspecified Location (Week 156) | Number Of Polyps In Unspecified Location (Week 156) | Numeric |

| Variable | Label | Description | Format Text |
|---|---|---|---|
| num_nspec_bsl | Number Of Non-Specified Configurations (Baseline) | Number Of Non-Specified Configurations (Baseline) | Numeric |
| num_nspec_int | Number Of Non-Specified Configurations (Week 156) | Number Of Non-Specified Configurations (Week 156) | Numeric |
| num_pend_bsl | Number Of Pendiculated Configurations (Baseline) | Number Of Pendiculated Configurations (Baseline) | Numeric |
| num_pend_int | Number Of Pendiculated Configurations (Week 156) | Number Of Pendiculated Configurations (Week 156) | Numeric |
| num_rect_bsl | Number Of Polyps In Rectum (Baseline) | Number Of Polyps In Rectum (Baseline) | Numeric |
| num_rect_int | Number Of Polyps In Rectum (Week 156) | Number Of Polyps In Rectum (Week 156) | Numeric |
| num_rjunct_bsl | Number Of Polyps In Rectosigmoid Junction (Baseline) | Number Of Polyps In Rectosigmoid Junction (Baseline) | Numeric |
| num_rjunct_int | Number Of Polyps In Rectosigmoid Junction (Week 156) | Number Of Polyps In Rectosigmoid Junction (Week 156) | Numeric |
| num_rmpiece_bsl | Number Of Polyps Removed Piecemeal (Baseline) | Number Of Polyps Removed Piecemeal (Baseline) | Numeric |
| num_rmpiece_int | Number Of Polyps Removed Piecemeal (Week 156) | Number Of Polyps Removed Piecemeal (Week 156) | Numeric |
| num_scol_bsl | Number Of Polyps In Sigmoid Colon (Baseline) | Number Of Polyps In Sigmoid Colon (Baseline) | Numeric |
| num_scol_int | Number Of Polyps In Sigmoid Colon (Week 156) | Number Of Polyps In Sigmoid Colon (Week 156) | Numeric |
| num_serrat_bsl | Number Of Serrated Polyps (Baseline) | Number Of Serrated Polyps (Baseline) | Numeric |
| num_serrat_int | Number Of Serrated Polyps (Week 156) | Number Of Serrated Polyps (Week 156) | Numeric |
| num_sess_bsl | Number Of Sessile Configurations (Baseline) | Number Of Sessile Configurations (Baseline) | Numeric |
| num_sess_int | Number Of Sessile Configurations (Week 156) | Number Of Sessile Configurations (Week 156) | Numeric |
| num_sflex_bsl | Number Of Polyps In Splenic Flexure (Baseline) | Number Of Polyps In Splenic Flexure (Baseline) | Numeric |
| num_sflex_int | Number Of Polyps In Splenic Flexure (Week 156) | Number Of Polyps In Splenic Flexure (Week 156) | Numeric |
| num_tcol_bsl | Number Of Polyps In Transcending Colon (Baseline) | Number Of Polyps In Transcending Colon (Baseline) | Numeric |
| num_tcol_int | Number Of Polyps In Transcending Colon (Week 156) | Number Of Polyps In Transcending Colon (Week 156) | Numeric |
| num_tubular_bsl | Number Of Tubular Polyps (Baseline) | Number Of Tubular Polyps (Baseline) | Numeric |

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| Variable | Label | Description | Format Text |
|---|---|---|---|
| **num_tubular_int** | Number Of Tubular Polyps (Week 156) | Number Of Tubular Polyps (Week 156) | Numeric |
| **num_tubulov_bsl** | Number Of Tubulovillous Polyps (Baseline) | Number Of Tubulovillous Polyps (Baseline) | Numeric |
| **num_tubulov_int** | Number Of Tubulovillous Polyps (Week 156) | Number Of Tubulovillous Polyps (Week 156) | Numeric |
| **num_villous_bsl** | Number Of Villous Polyps (Baseline) | Number Of Villous Polyps (Baseline) | Numeric |
| **num_villous_int** | Number Of Villous Polyps (Week 156) | Number Of Villous Polyps (Week 156) | Numeric |
| **oth_spec_bsl** | If Abnormal Or Other, Specify (Baseline) | If Abnormal Or Other, Specify (Baseline) | Char |
| **oth_spec_int** | If Abnormal Or Other, Specify (Week 156) | If Abnormal Or Other, Specify (Week 156) | Char |
| **PAIN** | Pain At Injection Site Without | Pain At Injection Site Without | 1="None"<br>2="A little, but it didn't interfere with normal activity"<br>3="Some, required OTC medications for more than 24 hours or limited normal activity"<br>4="A lot, requred prescription medications, interfered with normal activity" |
| **PAINDT** | Date Pain Disappeared | Date Pain Disappeared | SAS Date |
| **PHYSEXAM** | Overall Physical Exam Performed | Overall Physical Exam Performed | 1="Yes" |
| **PHYXAM1** | Appearance | Appearance | "1"="Yes"<br>"2"="No" |
| **PHYXAM10** | Inguinal Lymph Nodes | Inguinal Lymph Nodes | "1"="Yes"<br>"3"="Not Assessed" |
| **PHYXAM2** | Skin | Skin | "1"="Yes"<br>"2"="No" |
| **PHYXAM3** | H/E/E/N/T | H/E/E/N/T | "1"="Yes"<br>"2"="No" |
| **PHYXAM4** | Thyroid | Thyroid | "1"="Yes" |
| **PHYXAM5** | Cervical Lymph Nodes | Cervical Lymph Nodes | "1"="Yes"<br>"3"="Not Assessed" |
| **PHYXAM6** | Respiratory | Respiratory | "1"="Yes"<br>"2"="No"<br>"3"="Not Assessed" |
| **PHYXAM7** | Cardiovascular | Cardiovascular | "1"="Yes"<br>"2"="No"<br>"3"="Not Assessed" |
| **PHYXAM8** | Abdomen | Abdomen | "1"="Yes"<br>"2"="No" |
| **PHYXAM9** | Musculoskeletal | Musculoskeletal | "1"="Yes"<br>"2"="No" |
| **pmn_mdsc** | PMN-MDSC (Baseline) | PMN-MDSC (Baseline) | Numeric |
| **PNAPPDT** | Date Symptom Appeared | Date Symptom Appeared | SAS Date |
| **polyps_bsl** | Were All Polyps Excised? (Baseline) | Were All Polyps Excised? (Baseline) | 1="Yes"<br>2="No"<br>3="Not Reported" |

| Variable | Label | Description | Format Text |
|---|---|---|---|
| **polyps_int** | Were All Polyps Excised? (Week 156) | Were All Polyps Excised? (Week 156) | 1="Yes"<br>2="No"<br>3="Not Reported" |
| **proc_dt_bsl** | Procedure Date (Baseline) | Procedure Date (Baseline) | SAS Date |
| **proc_dt_int** | Procedure Date (Week 156) | Procedure Date (Week 156) | SAS Date |
| **PS** | Performance Status (ECOG) | Performance Status (ECOG) | Numeric |
| **race** | Race | Race | "01"="White"<br>"03"="Black or African American"<br>"05"="Asian"<br>"07"="More than one race"<br>"99"="Unknown: patient unsure" |
| **race_v2** | Race | Race | 1="White"<br>2="Not White"<br>3="Unknown" |
| **readenom** | Is This Recurrent Adenoma In The Same Location As A Previously Identified One? | Is This Recurrent Adenoma In The Same Location As A Previously Identified One? | 0="No"<br>1="Yes" |
| **REDAPPDT** | Date Redness Appeared | Date Redness Appeared | SAS Date |
| **REDDT** | Date Redness Disappeared | Date Redness Disappeared | SAS Date |
| **REDMEAS** | Measurement Of Redness | Measurement Of Redness (cm) | Numeric |
| **REDNESS** | Redness At Injection Site | Redness At Injection Site | 1="Yes"<br>2="No" |
| **sep3_aarecur** | Advanced Adenoma Recurrence (Week 156) | Advanced Adenoma Recurrence (Week 156) | 0="No"<br>1="Yes" |
| **sep3_recur** | Adenoma Recurrence (Week 156) | Adenoma Recurrence (Week 156) | 0="No"<br>1="Yes" |
| **SWEAPPDT** | Date Symptom Appeared | Date Symptom Appeared | SAS Date |
| **SWELL** | Swelling/Induration | Swelling/Induration | 1="Yes"<br>2="No" |
| **SWELLCM** | Swelling Measurement (cm) | Swelling Measurement (cm) | Numeric |
| **SWELLDT** | Date Swelling Disappeared | Date Swelling Disappeared | SAS Date |
| **TENAPPDT** | Date Symptom Appeared | Date Symptom Appeared | SAS Date |
| **TENDER** | Tenderness At Injection Site With Touch | Tenderness At Injection Site With Touch | 1="None"<br>2="A little, but it didn't interfere with normal activity"<br>3="Some, required OTC medications for more than 24 hours or limited normal activity"<br>4="A lot, requred prescription medications, interfered with normal activity" |
| **TENDERDT** | Date Tenderness Disappeared | Date Tenderness Disappeared | SAS Date |
| **total_mdsc** | Total Mdsc (Baseline) | Total Mdsc (Baseline) | Numeric |
| **total_mdsc_level** | Total Mdsc Level (Baseline) | Total Mdsc Level (Baseline) | 1="Normal"<br>2="Elevated" |
| **WARAPPDT** | Date Symptom Appeared | Date Symptom Appeared | SAS Date |

| Variable | Label | Description | Format Text |
|---|---|---|---|
| **WARMTH** | Skin Warmth At Injection Site | Skin Warmth At Injection Site | 1="Yes"<br>2="No" |
| **WARMTHDT** | Date Warmth Disappeared | Date Warmth Disappeared | SAS Date |
| **WEIGHT** | Weight | Weight (kg) | Numeric |
| **wk12_igg** | Week 12 IGG Level | Week 12 IGG Level | Numeric |
| **wk12_respcat** | Type of Week 12 Responder | Type of Week 12 Responder | 1="<1"<br>2="1 - <1.5"<br>3="1.5 - <2" |
| **wk12bsl_diff** | Absolute Change In IGG Levels From Baseline To Week 12 | Absolute Change In IGG Levels From Baseline To Week 12 | Numeric |
| **wk12bsl_rat1** | Week 12 IGG Ratio >= 1 | Week 12 IGG Ratio >= 1 | 0="No"<br>1="Yes" |
| **wk12bsl_rat1_5** | Week 12 IGG Ratio >= 1.5 | Week 12 IGG Ratio >= 1.5 | 0="No"<br>1="Yes" |
| **wk12bsl_ratcat** | Week 12 IGG Ratio | Week 12 IGG Ratio | 1="<1"<br>2="1 - <1.5"<br>3="1.5 - <2"<br>4=">=2" |
| **wk12bsl_ratio** | Week 12 To Baseline IGG Ratio | Week 12 To Baseline IGG Ratio | Numeric |
| **wk12bsl_resp** | Week 12 IGG Response (ratio >= 2) | Week 12 IGG Response (ratio >= 2) | 0="No"<br>1="Yes" |
| **wk12wk55_resp** | Week 12 And Week 55 IGG Response (ratio >=2) | Week 12 And Week 55 IGG Response (ratio >=2) | 0="No"<br>1="Yes" |
| **wk156_igg** | Week 156 IGG Level | Week 156 IGG Level | Numeric |
| **wk156bld_dt** | Date Blood Specimen Collected (Week 156) | Date Blood Specimen Collected (Week 156) | SAS Date |
| **wk156bld_time** | Time From Week 0 Injection To Week 156 Blood Collection (Days) | Time From Week 0 Injection To Week 156 Blood Collection (Days) | Numeric |
| **wk52_igg** | Week 52 IGG Level | Week 52 IGG Level | Numeric |
| **wk52bsl_diff** | Absolute Change In IGG Levels From Baseline To Week 52 | Absolute Change In IGG Levels From Baseline To Week 52 | Numeric |
| **wk52bsl_rat1** | Week 52 IGG Ratio >= 1 | Week 52 IGG Ratio >= 1 | 0="No"<br>1="Yes" |
| **wk52bsl_rat1_5** | Week 52 IGG Ratio >= 1.5 | Week 52 IGG Ratio >= 1.5 | 0="No"<br>1="Yes" |
| **wk52bsl_ratcat** | Week 52 IGG Ratio | Week 52 IGG Ratio | 1="<1"<br>2="1 - <1.5"<br>3="1.5 - <2"<br>4=">=2" |
| **wk52bsl_ratio** | Week 52 To Baseline IGG Ratio | Week 52 To Baseline IGG Ratio | Numeric |
| **wk52bsl_resp** | Week 52 IGG response (Ratio >= 2) | Week 52 IGG response (Ratio >= 2) | 0="No"<br>1="Yes" |
| **wk55_igg** | Week 55 IGG Level | Week 55 IGG Level | Numeric |

| Variable | Label | Description | Format Text |
|---|---|---|---|
| **wk55wk52_diff** | Absolute Change In IGG Levels From Week 52 To Week 55 | Absolute Change In IGG Levels From Week 52 To Week 55 | Numeric |
| **wk55wk52_rat1** | Week 55 IGG Ratio >= 1 | Week 55 IGG Ratio >= 1 | 0="No"<br>1="Yes" |
| **wk55wk52_rat1_5** | Week 55 IGG Ratio >= 1.5 | Week 55 IGG Ratio >= 1.5 | 0="No"<br>1="Yes" |
| **wk55wk52_ratcat** | Week 55 IGG Ratio | Week 55 IGG Ratio | 1="<1"<br>2="1 - <1.5"<br>3="1.5 - <2"<br>4=">=2" |
| **wk55wk52_ratio** | Week 55 To Week 52 IGG Ratio | Week 55 To Week 52 IGG Ratio | Numeric |
| **wk55wk52_resp** | Week 55 IGG Response (Ratio >= 2) | Week 55 IGG Response (Ratio >= 2) | 0="No"<br>1="Yes" |