

# MAY2013-01-01 - Enhanced Person Data Dictionary

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## Document Summary

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## MAY2013-01-01 - Enhanced Person: Data Dictionary

### Section 1: Identifiers

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Variable	Label	Description	Format Text
<b>DCNTR_ID</b>	Data Center ID	Data Center ID	Char

## Section 2: Demographics

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Variable	Label	Description	Format Text
<b>age</b>	Age	Age	Numeric
<b>ethnicity</b>	Ethnicity	Ethnicity	0="Not Hispanic Or Latino" 1="Hispanic Or Latino" 9="Unknown"
<b>gender</b>	Gender	Gender	0="Male" 1="Female"
<b>race</b>	Race	Race	1="White" 2="Black Or African American" 3="Asian" 9="Unknown: Patient Unsure"
<b>race_2nd</b>	Race	Race	.M="Missing" 4="American Indian or Alaska Native"
<b>unblinding_arm</b>	Arm	Arm	.M="Missing" 0="Placebo" 1="MUC1"

## Section 3: Analysis

Variable	Label	Description	Format Text
<b>analysis_abdomen</b>	Abdomen Status	Abdomen Status	.F="No Record For This Visit" 0="No" 1="Yes"
<b>analysis_ad_recurr</b>	Adenoma Recurrence (Week 156)	Adenoma Recurrence (Week 156)	.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"
<b>analysis_aden_recurr_dif</b>	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)	.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"
<b>analysis_adenoma_sum_bsl</b>	Sum Of Adenomas (Baseline)	Sum Of Adenomas (Baseline)	Numeric .F="No Record For This Visit"
<b>analysis_adenoma_sum_int</b>	Sum Of Adenomas (Week 156)	Sum Of Adenomas (Week 156)	Numeric .F="No Record For This Visit" .M="Missing"
<b>analysis_adv_ad_recurr</b>	Advanced Adenoma Recurrence (Week 156)	Advanced Adenoma Recurrence (Week 156)	.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"
<b>analysis_adv_adenoma_bsl</b>	Total Number Advanced Adenomas (Baseline)	Total Number Advanced Adenomas (Baseline)	Numeric .F="No Record For This Visit"
<b>analysis_adv_adenoma_crit</b>	Criteria Of Qualifying Baseline Advanced Adenoma	Criteria Of Qualifying Baseline Advanced Adenoma	Numeric .F="No Record For This Visit"
<b>analysis_adv_adenoma_int</b>	Total Number Advanced Adenomas (Week 156)	Total Number Advanced Adenomas (Week 156)	Numeric .F="No Record For This Visit" .M="Missing"
<b>analysis_adv_adenoma_tot_bsl</b>	Total Number Advanced Adenomas (Baseline)	Total Number Advanced Adenomas (Baseline)	Numeric .F="No Record For This Visit"
<b>analysis_adv_adenoma_tot_int</b>	Total Number Advanced Adenomas (Week 156)	Total Number Advanced Adenomas (Week 156)	Numeric .F="No Record For This Visit" .M="Missing"
<b>analysis_age</b>	Age	Age	Numeric .F="No Record For This Visit"
<b>analysis_allergy</b>	Does The Participant Have Any Allergies?	Does The Participant Have Any Allergies?	.F="No Record For This Visit" 0="No" 1="Yes"
<b>analysis_appearance</b>	Appearance Status	Appearance Status	.F="No Record For This Visit" 0="No" 1="Yes"
<b>analysis_aspirin</b>	Aspirin Use	Aspirin Use	.F="No Record For This Visit" 0="No" 1="Yes"

Variable	Label	Description	Format Text
<b>analysis_avg_polyp_bsl</b>	Average Size Of All Polyps As Measured By A Pathologist (Baseline)	Average Size Of All Polyps As Measured By A Pathologist (Baseline)	Numeric .F="No Record For This Visit" .M="Missing"
<b>analysis_avg_polyp_int</b>	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 .F="No Record For This Visit" .M="Missing"
<b>analysis_bmi</b>	Body Mass Index (BMI)	Body Mass Index (BMI)	Numeric .F="No Record For This Visit"
<b>analysis_bwlprep_bsl</b>	Was The Overall Bowel Preparation Adequate, Good, Or Excellent? (Baseline)	Was The Overall Bowel Preparation Adequate, Good, Or Excellent? (Baseline)	.F="No Record For This Visit" 0="No" 1="Yes" 2="Not Reported"
<b>analysis_bwlprep_int</b>	Was The Overall Bowel Preparation Adequate, Good, Or Excellent? (Week 156)	Was The Overall Bowel Preparation Adequate, Good, Or Excellent? (Week 156)	.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes" 2="Not Reported"
<b>analysis_cardiovascular</b>	Cardiovascular Status	Cardiovascular Status	.F="No Record For This Visit" 0="No" 1="Yes" 2="Not Assessed"
<b>analysis_cat_dysp_bsl</b>	Polyp Presence Of Dysplasia (Week 156)	Polyp Presence Of Dysplasia (Baseline)	.F="No Record For This Visit" 1="No dysplasia" 2="Indefinite for dysplasia" 3="Low grade dysplasia" 5="Not available"
<b>analysis_cat_dysp_int</b>	Polyp Presence Of Dysplasia (Week 156)	Polyp Presence Of Dysplasia (Week 156)	.F="No Record For This Visit" .M="Missing" 2="Indefinite for dysplasia" 3="Low grade dysplasia" 5="Not available"
<b>analysis_cat_histot_p_bsl</b>	Polyp Histopathologic Type (Baseline)	Polyp Histopathologic Type (Baseline)	.F="No Record For This Visit" 1="Hyperplastic polyps" 2="Hamartomatous" 3="Inflammatory polyps" 4="Tubular adenoma" 5="Tubulovillous adenoma"
<b>analysis_cat_histot_p_int</b>	Polyp Histopathologic Type (Week 156)	Polyp Histopathologic Type (Week 156)	.F="No Record For This Visit" .M="Missing" 1="Hyperplastic polyps" 4="Tubular adenoma" 5="Tubulovillous adenoma" 8="Serrated adenoma"
<b>analysis_cat_large_bsl</b>	Polyp Size At Colonoscopy >= 1 cm (Baseline)	Polyp Size At Colonoscopy >= 1 cm (Baseline)	.F="No Record For This Visit" 0="No" 1="Yes"
<b>analysis_cat_large_int</b>	Polyp Size At Colonoscopy >= 1 cm (Week 156)	Polyp Size At Colonoscopy >= 1 cm (Week 156)	.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"

Variable	Label	Description	Format Text
<b>analysis_cat_loc_bsl</b>	Polyp Location (Baseline)	Polyp Location (Baseline)	.F="No Record For This Visit" 1="Cecum" 2="Ascending colon" 3="Hepatic flexure" 4="Transverse colon" 5="Splenic flexure"
<b>analysis_cat_loc_int</b>	Polyp Location (Week 156)	Polyp Location (Week 156)	.F="No Record For This Visit" .M="Missing" 1="Cecum" 2="Ascending colon" 3="Hepatic flexure" 4="Transverse colon" 5="Splenic flexure"
<b>analysis_cd15s</b>	CD15S (Baseline)	CD15S (Baseline)	Numeric .F="No Record For This Visit" .M="Missing"
<b>analysis_cd4_cd25</b>	CD4 + CD25 (Baseline)	CD4 + CD25 (Baseline)	Numeric .F="No Record For This Visit" .M="Missing"
<b>analysis_cecum_vis_bsl</b>	Was The Cecum Visualized? (Baseline)	Was The Cecum Visualized? (Baseline)	.F="No Record For This Visit" 1="Yes" 2="Not Reported"
<b>analysis_cecum_vis_int</b>	Was The Cecum Visualized? (Week 156)	Was The Cecum Visualized? (Week 156)	.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"
<b>analysis_cerv_lymph</b>	Cervical Lymph Nodes Status	Cervical Lymph Nodes Status	.F="No Record For This Visit" 1="Yes" 2="Not Assessed"
<b>analysis_col_bsl</b>	Colonoscopy Performed (Baseline)	Colonoscopy Performed (Baseline)	.F="No Record For This Visit" 1="Yes"
<b>analysis_col_int</b>	Colonoscopy Performed (Week 156)	Colonoscopy Performed (Week 156)	.F="No Record For This Visit" .M="Missing" 1="Yes"
<b>analysis_col_result_bsl</b>	Results Of Colonoscopy (Baseline)	Results Of Colonoscopy (Baseline)	.F="No Record For This Visit" 1="Normal" 2="Abnormal, specify"
<b>analysis_col_result_int</b>	Results Of Colonoscopy (Week 156)	Results Of Colonoscopy (Week 156)	.F="No Record For This Visit" .M="Missing" 1="Normal" 2="Abnormal, specify" 3="Other, specify"
<b>analysis_dose_dt</b>	Date Agent Administered (Week 0)	Date Agent Administered (Week 0)	SAS Date .F="No Record For This Visit"
<b>analysis_dx_responder</b>	Disease Responder	Disease Responder	.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"
<b>analysis_e_mdsc</b>	E-MDSC (Baseline)	E-MDSC (Baseline)	Numeric .F="No Record For This Visit" .M="Missing"
<b>analysis_foxp3</b>	FOXP3 (Baseline)	FOXP3 (Baseline)	Numeric .F="No Record For This Visit" .M="Missing"



Variable	Label	Description	Format Text
<b>analysis_heent</b>	H/E/E/N/T Status	H/E/E/N/T Status	.F="No Record For This Visit" 0="No" 1="Yes"
<b>analysis_height</b>	Height (cm)	Height (cm)	Numeric .F="No Record For This Visit"
<b>analysis_igg_bsl</b>	Baseline IGG Level	Baseline IGG Level	Numeric .F="No Record For This Visit" .M="Missing"
<b>analysis_igg_med_bsl</b>	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 .F="No Record For This Visit" .M="Missing"
<b>analysis_ing_lymph</b>	Inguinal Lymph Nodes Status	Inguinal Lymph Nodes Status	.F="No Record For This Visit" .M="Missing" 1="Yes" 2="Not Assessed"
<b>analysis_inject_colo_time</b>	Time From Week 0 Injection To Follow-Up Colonoscopy (Days)	Time From Week 0 Injection To Follow-Up Colonoscopy (Days)	Numeric .F="No Record For This Visit" .M="Missing"
<b>analysis_itch</b>	Itching At Injection Site	Itching At Injection Site	.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"
<b>analysis_itch_start_dt</b>	Date Symptom Appeared	Date Symptom Appeared	SAS Date .F="No Record For This Visit" .M="Missing"
<b>analysis_itch_stop_dt</b>	Date Itching Stopped	Date Itching Stopped	SAS Date .F="No Record For This Visit" .M="Missing"
<b>analysis_ig_aden_recurr</b>	>5 mm Adenoma Recurrence (Week 156)	>5 mm Adenoma Recurrence (Week 156)	.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"
<b>analysis_ig_aden_recurr_dif</b>	>=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)	.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"
<b>analysis_m_mdsc</b>	M-MDSC (Baseline)	M-MDSC (Baseline)	Numeric .F="No Record For This Visit" .M="Missing"
<b>analysis_mult_aden_bsl</b>	Multiple Adenomas (Baseline)	Multiple Adenomas (Baseline)	.F="No Record For This Visit" 0="No" 1="Yes"
<b>analysis_mult_aden_int</b>	Multiple Recurrent Adenomas (Week 156)	Multiple Recurrent Adenomas (Week 156)	.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"
<b>analysis_mult_adv_aden_bsl</b>	Multiple Advanced Adenomas (Baseline)	Multiple Advanced Adenomas (Baseline)	.F="No Record For This Visit" 0="No" 1="Yes"

Variable	Label	Description	Format Text
<b>analysis_mult_adv_aden_int</b>	Multiple Advanced Adenomas (Baseline)	Multiple Advanced Adenomas (Week 156)	.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"
<b>analysis_musculoskeletal</b>	Musculoskeletal Status	Musculoskeletal Status	.F="No Record For This Visit" 0="No" 1="Yes"
<b>analysis_nsaid</b>	NSAID Use	NSAID Use	.F="No Record For This Visit" 0="No" 1="Yes"
<b>analysis_num_adenoma</b>	Number Of Advanced Adenomas	Number Of Advanced Adenomas	Numeric .F="No Record For This Visit"
<b>analysis_num_adenoma_polyp_bsl</b>	Number Of Adenoma Polyps (Baseline)	Number Of Adenoma Polyps (Baseline)	Numeric .F="No Record For This Visit"
<b>analysis_num_adenoma_polyp_int</b>	Number Of Adenoma Polyps (Baseline)	Number Of Adenoma Polyps (Baseline)	Numeric .F="No Record For This Visit" .M="Missing"
<b>analysis_num_adv_aden_bsl</b>	Number Of Advanced Adenomas (Baseline)	Number Of Advanced Adenomas (Baseline)	Numeric .F="No Record For This Visit"
<b>analysis_num_adv_aden_int</b>	Number Of Advanced Adenomas (Baseline)	Number Of Advanced Adenomas (Baseline)	Numeric .F="No Record For This Visit" .M="Missing"
<b>analysis_num_cecum_polyp_bsl</b>	Number Of Polyps In Cecum (Baseline)	Number Of Polyps In Cecum (Baseline)	Numeric .F="No Record For This Visit" .M="Missing"
<b>analysis_num_cecum_polyp_int</b>	Number Of Polyps In Cecum (Baseline)	Number Of Polyps In Cecum (Baseline)	Numeric .F="No Record For This Visit" .M="Missing"
<b>analysis_num_desc_c_polyp_bsl</b>	Number Of Polyps In Descending Colon (Baseline)	Number Of Polyps In Descending Colon (Baseline)	Numeric .F="No Record For This Visit" .M="Missing"
<b>analysis_num_desc_c_polyp_int</b>	Number Of Polyps In Descending Colon (Baseline)	Number Of Polyps In Descending Colon (Baseline)	Numeric .F="No Record For This Visit" .M="Missing"
<b>analysis_num_dimu_polyp_bsl</b>	Number Of Diminutive Polyps (<mm) (Baseline)	Number Of Diminutive Polyps (<mm) (Baseline)	Numeric .F="No Record For This Visit"
<b>analysis_num_dimu_polyp_int</b>	Number Of Diminutive Polyps (<mm) (Baseline)	Number Of Diminutive Polyps (<mm) (Baseline)	Numeric .F="No Record For This Visit" .M="Missing"
<b>analysis_num_hemart_polyp_bsl</b>	Number Of Hemartomatous Polyps (Baseline)	Number Of Hemartomatous Polyps (Baseline)	Numeric .F="No Record For This Visit"
<b>analysis_num_hemart_polyp_int</b>	Number Of Hemartomatous Polyps (Baseline)	Number Of Hemartomatous Polyps (Baseline)	Numeric .F="No Record For This Visit" .M="Missing"
<b>analysis_num_hepatic_f_polyp_bsl</b>	Number Of Polyps In Hepatic Flexure (Baseline)	Number Of Polyps In Hepatic Flexure (Baseline)	Numeric .F="No Record For This Visit" .M="Missing"
<b>analysis_num_hepatic_f_polyp_int</b>	Number Of Polyps In Hepatic Flexure (Baseline)	Number Of Polyps In Hepatic Flexure (Baseline)	Numeric .F="No Record For This Visit" .M="Missing"

Variable	Label	Description	Format Text
<b>analysis_num_high_dysp_polyp_bsl</b>	Number Of Polyps With High Grade Dysplasia (Baseline)	Number Of Polyps With High Grade Dysplasia (Baseline)	Numeric .F="No Record For This Visit"
<b>analysis_num_high_dysp_polyp_int</b>	Number Of Polyps With High Grade Dysplasia (Baseline)	Number Of Polyps With High Grade Dysplasia (Baseline)	Numeric .F="No Record For This Visit" .M="Missing"
<b>analysis_num_hyper_polyp_bsl</b>	Number Of Hyperplastic Polyps (Baseline)	Number Of Hyperplastic Polyps (Baseline)	Numeric .F="No Record For This Visit"
<b>analysis_num_hyper_polyp_int</b>	Number Of Hyperplastic Polyps (Baseline)	Number Of Hyperplastic Polyps (Baseline)	Numeric .F="No Record For This Visit" .M="Missing"
<b>analysis_num_indefinite_polyp_bsl</b>	Number Of Polyps Indefinite For Dysplasia (Baseline)	Number Of Polyps Indefinite For Dysplasia (Baseline)	Numeric .F="No Record For This Visit"
<b>analysis_num_indefinite_polyp_int</b>	Number Of Polyps Indefinite For Dysplasia (Baseline)	Number Of Polyps Indefinite For Dysplasia (Baseline)	Numeric .F="No Record For This Visit" .M="Missing"
<b>analysis_num_inflammatory_polyp_bsl</b>	Number Of Inflammatory Polyps (Baseline)	Number Of Inflammatory Polyps (Baseline)	Numeric .F="No Record For This Visit"
<b>analysis_num_inflammatory_polyp_int</b>	Number Of Inflammatory Polyps (Baseline)	Number Of Inflammatory Polyps (Baseline)	Numeric .F="No Record For This Visit" .M="Missing"
<b>analysis_num_juvenile_polyp_bsl</b>	Number Of Juvenile Polyps	Number Of Juvenile Polyps	Numeric .F="No Record For This Visit"
<b>analysis_num_juvenile_polyp_int</b>	Number Of Juvenile Polyps	Number Of Juvenile Polyps	Numeric .F="No Record For This Visit" .M="Missing"
<b>analysis_num_large_polyp_bsl</b>	Number Of Large Polyps (>9mm) (Baseline)	Number Of Large Polyps (>9mm) (Baseline)	Numeric .F="No Record For This Visit"
<b>analysis_num_large_polyp_int</b>	Number Of Large Polyps (>9mm) (Baseline)	Number Of Large Polyps (>9mm) (Baseline)	Numeric .F="No Record For This Visit" .M="Missing"
<b>analysis_num_low_dysp_polyp_bsl</b>	Number Of Polyps With Low Grade Dysplasia (Baseline)	Number Of Polyps With Low Grade Dysplasia (Baseline)	Numeric .F="No Record For This Visit"
<b>analysis_num_low_dysp_polyp_int</b>	Number Of Polyps With Low Grade Dysplasia (Baseline)	Number Of Polyps With Low Grade Dysplasia (Baseline)	Numeric .F="No Record For This Visit" .M="Missing"
<b>analysis_num_medium_polyp_bsl</b>	Number Of Medium Polyps (5-9mm) (Baseline)	Number Of Medium Polyps (5-9mm) (Baseline)	Numeric .F="No Record For This Visit"
<b>analysis_num_medium_polyp_int</b>	Number Of Medium Polyps (5-9mm) (Baseline)	Number Of Medium Polyps (5-9mm) (Baseline)	Numeric .F="No Record For This Visit" .M="Missing"
<b>analysis_num_not_applicable_adenoma_bsl</b>	Number Of Not Applicable Adenomas (Baseline)	Number Of Not Applicable Adenomas (Baseline)	Numeric .F="No Record For This Visit"
<b>analysis_num_not_applicable_adenoma_int</b>	Number Of Not Applicable Adenomas (Baseline)	Number Of Not Applicable Adenomas (Baseline)	Numeric .F="No Record For This Visit" .M="Missing"
<b>analysis_num_not_applicable_grade_bsl</b>	Number Of Polyps With Grade Of Dysplasia Not Available (Baseline)	Number Of Polyps With Grade Of Dysplasia Not Available (Baseline)	Numeric .F="No Record For This Visit"

Variable	Label	Description	Format Text
<b>analysis_num_nagrade_polyp_int</b>	Number Of Polyps With Grade Of Dysplasia Not Available (Baseline)	Number Of Polyps With Grade Of Dysplasia Not Available (Baseline)	Numeric .F="No Record For This Visit" .M="Missing"
<b>analysis_num_nod_ysp_polyp_bsl</b>	Number Of Polyps With No Dysplasia (Baseline)	Number Of Polyps With No Dysplasia (Baseline)	Numeric .F="No Record For This Visit"
<b>analysis_num_nod_ysp_polyp_int</b>	Number Of Polyps With No Dysplasia (Baseline)	Number Of Polyps With No Dysplasia (Baseline)	Numeric .F="No Record For This Visit" .M="Missing"
<b>analysis_num_noloc_polyp_bsl</b>	Number Of Polyps In Unspecified Location (Baseline)	Number Of Polyps In Unspecified Location (Baseline)	Numeric .F="No Record For This Visit" .M="Missing"
<b>analysis_num_noloc_polyp_int</b>	Number Of Polyps In Unspecified Location (Baseline)	Number Of Polyps In Unspecified Location (Baseline)	Numeric .F="No Record For This Visit" .M="Missing"
<b>analysis_num_nonadv_ad_bsl</b>	Total Number Non-Advanced Adenomas (Baseline)	Total Number Non-Advanced Adenomas (Baseline)	Numeric .F="No Record For This Visit"
<b>analysis_num_nonadv_ad_int</b>	Total Number Non-Advanced Adenomas (Week 156)	Total Number Non-Advanced Adenomas (Week 156)	Numeric .F="No Record For This Visit" .M="Missing"
<b>analysis_num_nonadv_aden_bsl</b>	Number Of Non-Advanced Adenomas (Baseline)	Number Of Non-Advanced Adenomas (Baseline)	Numeric .F="No Record For This Visit"
<b>analysis_num_nonadv_aden_int</b>	Number Of Non-Advanced Adenomas (Baseline)	Number Of Non-Advanced Adenomas (Baseline)	Numeric .F="No Record For This Visit" .M="Missing"
<b>analysis_num_nonspec_config_bsl</b>	Number Of Non-Specified Configurations (Baseline)	Number Of Non-Specified Configurations (Baseline)	Numeric .F="No Record For This Visit"
<b>analysis_num_nonspec_config_int</b>	Number Of Non-Specified Configurations (Baseline)	Number Of Non-Specified Configurations (Baseline)	Numeric .F="No Record For This Visit" .M="Missing"
<b>analysis_num_not_spec_polyp_bsl</b>	Number Of Not Specified Polyps (Baseline)	Number Of Not Specified Polyps (Baseline)	Numeric .F="No Record For This Visit"
<b>analysis_num_not_spec_polyp_int</b>	Number Of Not Specified Polyps (Baseline)	Number Of Not Specified Polyps (Baseline)	Numeric .F="No Record For This Visit" .M="Missing"
<b>analysis_num_pendiculated_bsl</b>	Number Of Pendiculated Configurations (Baseline)	Number Of Pendiculated Configurations (Baseline)	Numeric .F="No Record For This Visit"
<b>analysis_num_pendiculated_int</b>	Number Of Pendiculated Configurations (Baseline)	Number Of Pendiculated Configurations (Baseline)	Numeric .F="No Record For This Visit" .M="Missing"
<b>analysis_num_poly_p_ascending_bsl</b>	Number Of Polyps In Ascending Colon (Baseline)	Number Of Polyps In Ascending Colon (Baseline)	Numeric .F="No Record For This Visit" .M="Missing"
<b>analysis_num_poly_p_ascending_int</b>	Number Of Polyps In Ascending Colon (Baseline)	Number Of Polyps In Ascending Colon (Baseline)	Numeric .F="No Record For This Visit" .M="Missing"
<b>analysis_num_rectosig_polyp_bsl</b>	Number Of Polyps In Rectosigmoid Junction (Baseline)	Number Of Polyps In Rectosigmoid Junction (Baseline)	Numeric .F="No Record For This Visit" .M="Missing"
<b>analysis_num_rectosig_polyp_int</b>	Number Of Polyps In Rectosigmoid Junction (Baseline)	Number Of Polyps In Rectosigmoid Junction (Baseline)	Numeric .F="No Record For This Visit" .M="Missing"

Variable	Label	Description	Format Text
<b>analysis_num_rectum_polyps_bsl</b>	Number Of Polyps In Rectum (Baseline)	Number Of Polyps In Rectum (Baseline)	Numeric .F="No Record For This Visit" .M="Missing"
<b>analysis_num_rectum_polyps_int</b>	Number Of Polyps In Rectum (Baseline)	Number Of Polyps In Rectum (Baseline)	Numeric .F="No Record For This Visit" .M="Missing"
<b>analysis_num_removed_polyps_bsl</b>	Number Of Polyps Removed Piecemeal (Baseline)	Number Of Polyps Removed Piecemeal (Baseline)	Numeric .F="No Record For This Visit"
<b>analysis_num_removed_polyps_int</b>	Number Of Polyps Removed Piecemeal (Baseline)	Number Of Polyps Removed Piecemeal (Baseline)	Numeric .F="No Record For This Visit" .M="Missing"
<b>analysis_num_serrated_polyps_bsl</b>	Number Of Serrated Polyps (Baseline)	Number Of Serrated Polyps (Baseline)	Numeric .F="No Record For This Visit"
<b>analysis_num_serrated_polyps_int</b>	Number Of Serrated Polyps (Baseline)	Number Of Serrated Polyps (Baseline)	Numeric .F="No Record For This Visit" .M="Missing"
<b>analysis_num_sessile_config_bsl</b>	Number Of Sessile Configurations (Baseline)	Number Of Sessile Configurations (Baseline)	Numeric .F="No Record For This Visit"
<b>analysis_num_sessile_config_int</b>	Number Of Sessile Configurations (Baseline)	Number Of Sessile Configurations (Baseline)	Numeric .F="No Record For This Visit" .M="Missing"
<b>analysis_num_sigmoid_polyps_bsl</b>	Number Of Polyps In Sigmoid Colon (Baseline)	Number Of Polyps In Sigmoid Colon (Baseline)	Numeric .F="No Record For This Visit" .M="Missing"
<b>analysis_num_sigmoid_polyps_int</b>	Number Of Polyps In Sigmoid Colon (Baseline)	Number Of Polyps In Sigmoid Colon (Baseline)	Numeric .F="No Record For This Visit" .M="Missing"
<b>analysis_num_splenic_polyp_bsl</b>	Number Of Polyps In Splenic Flexure (Baseline)	Number Of Polyps In Splenic Flexure (Baseline)	Numeric .F="No Record For This Visit" .M="Missing"
<b>analysis_num_splenic_polyp_int</b>	Number Of Polyps In Splenic Flexure (Baseline)	Number Of Polyps In Splenic Flexure (Baseline)	Numeric .F="No Record For This Visit" .M="Missing"
<b>analysis_num_transcending_colon_polyp_bsl</b>	Number Of Polyps In Transcending Colon (Baseline)	Number Of Polyps In Transcending Colon (Baseline)	Numeric .F="No Record For This Visit" .M="Missing"
<b>analysis_num_transcending_colon_polyp_int</b>	Number Of Polyps In Transcending Colon (Baseline)	Number Of Polyps In Transcending Colon (Baseline)	Numeric .F="No Record For This Visit" .M="Missing"
<b>analysis_num_tubular_polyp_bsl</b>	Number Of Tubular Polyps (Baseline)	Number Of Tubular Polyps (Baseline)	Numeric .F="No Record For This Visit"
<b>analysis_num_tubular_polyp_int</b>	Number Of Tubular Polyps (Baseline)	Number Of Tubular Polyps (Baseline)	Numeric .F="No Record For This Visit" .M="Missing"
<b>analysis_num_tubulovillous_polyp_bsl</b>	Number Of Tubulovillous Polyps (Baseline)	Number Of Tubulovillous Polyps (Baseline)	Numeric .F="No Record For This Visit"
<b>analysis_num_tubulovillous_polyp_int</b>	Number Of Tubulovillous Polyps (Baseline)	Number Of Tubulovillous Polyps (Baseline)	Numeric .F="No Record For This Visit" .M="Missing"
<b>analysis_num_villous_polyp_bsl</b>	Number Of Villous Polyps (Baseline)	Number Of Villous Polyps (Baseline)	Numeric .F="No Record For This Visit"

Variable	Label	Description	Format Text
<b>analysis_num_villous_polyp_int</b>	Number Of Villous Polyps (Baseline)	Number Of Villous Polyps (Baseline)	Numeric .F="No Record For This Visit" .M="Missing"
<b>analysis_oth_spec_bsl</b>	If Abnormal Or Other, Specify (Baseline)	If Abnormal Or Other, Specify (Baseline)	Char
<b>analysis_oth_spec_int</b>	If Abnormal Or Other, Specify (Week 156)	If Abnormal Or Other, Specify (Week 156)	Char
<b>analysis_pain</b>	Pain At Injection Site Without	Pain At Injection Site Without	.F="No Record For This Visit" 1="None" 2="A little, but it didn't interfere with normal activity" 3="Some, required OTC medications for more than 24 hours or limited normal activity" 4="A lot, required prescription medications, interfered with normal activity"
<b>analysis_pain_start_dt</b>	Date Symptom Appeared	Date Symptom Appeared	SAS Date .F="No Record For This Visit" .M="Missing"
<b>analysis_pain_stop_dt</b>	Date Pain Disappeared	Date Pain Disappeared	SAS Date .F="No Record For This Visit" .M="Missing"
<b>analysis_phys_exam</b>	Overall Physical Exam Performed	Overall Physical Exam Performed	.F="No Record For This Visit" 1="Yes"
<b>analysis_phys_exam_perf_sc</b>	Performance Status (ECOG)	Performance Status (ECOG)	Numeric .F="No Record For This Visit"
<b>analysis_pmn_mdsc_c</b>	PMN-MDSC (Baseline)	PMN-MDSC (Baseline)	Numeric .F="No Record For This Visit" .M="Missing"
<b>analysis_polyp_exc_bsl</b>	Were All Polyps Excised? (Baseline)	Were All Polyps Excised? (Baseline)	.F="No Record For This Visit" 0="No" 1="Yes" 2="Not Reported"
<b>analysis_polyp_exc_int</b>	Were All Polyps Excised? (Week 156)	Were All Polyps Excised? (Week 156)	.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes" 2="Not Reported"
<b>analysis_proc_dt_bsl</b>	Procedure Date (Baseline)	Procedure Date (Baseline)	SAS Date .F="No Record For This Visit"
<b>analysis_proc_dt_int</b>	Procedure Date (Week 156)	Procedure Date (Week 156)	SAS Date .F="No Record For This Visit" .M="Missing"
<b>analysis_recurr_aden_same</b>	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?	.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"
<b>analysis_red</b>	Redness At Injection Site	Redness At Injection Site	.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"
<b>analysis_red_size</b>	Measurement Of Redness	Measurement Of Redness	Numeric .F="No Record For This Visit" .M="Missing"

Variable	Label	Description	Format Text
<b>analysis_red_start_dt</b>	Date Redness Appeared	Date Redness Appeared	SAS Date .F="No Record For This Visit" .M="Missing"
<b>analysis_red_stop_dt</b>	Date Redness Disappeared	Date Redness Disappeared	SAS Date .F="No Record For This Visit" .M="Missing"
<b>analysis_respiratory</b>	Respiratory Status	Respiratory Status	.F="No Record For This Visit" 0="No" 1="Yes" 2="Not Assessed"
<b>analysis_skin</b>	Skin Status	Skin Status	.F="No Record For This Visit" 0="No" 1="Yes"
<b>analysis_swell_size</b>	Swelling Measurement (cm)	Swelling Measurement (cm)	Numeric .F="No Record For This Visit" .M="Missing"
<b>analysis_swell_start_dt</b>	Date Symptom Appeared	Date Symptom Appeared	SAS Date .F="No Record For This Visit" .M="Missing"
<b>analysis_swell_stop_dt</b>	Date Swelling Disappeared	Date Swelling Disappeared	SAS Date .F="No Record For This Visit" .M="Missing"
<b>analysis_swelling</b>	Swelling/Induration	Swelling/Induration	.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"
<b>analysis_tender</b>	Tenderness At Injection Site With Touch	Tenderness At Injection Site With Touch	.F="No Record For This Visit" 1="None" 2="A little, but it didn't interfere with normal activity" 3="Some, required OTC medications for more than 24 hours or limited normal activity" 4="A lot, required prescription medications, interfered with normal activity"
<b>analysis_tender_start_dt</b>	Date Symptom Appeared	Date Symptom Appeared	SAS Date .F="No Record For This Visit" .M="Missing"
<b>analysis_tender_stop_dt</b>	Date Tenderness Disappeared	Date Tenderness Disappeared	SAS Date .F="No Record For This Visit" .M="Missing"
<b>analysis_thyroid</b>	Thyroid Status	Thyroid Status	.F="No Record For This Visit" 1="Yes"
<b>analysis_total_mdsc</b>	Total MDSC (Baseline)	Total MDSC (Baseline)	Numeric .F="No Record For This Visit" .M="Missing"
<b>analysis_total_mdsc_bsl</b>	Total MDSC Level (Baseline)	Total MDSC Level (Baseline)	.F="No Record For This Visit" .M="Missing" 1="Normal" 2="Elevated"
<b>analysis_warm_start_dt</b>	Date Symptom Appeared	Date Symptom Appeared	SAS Date .F="No Record For This Visit" .M="Missing"

Variable	Label	Description	Format Text
<b>analysis_warm_stop_dt</b>	Date Warmth Disappeared	Date Warmth Disappeared	SAS Date .F="No Record For This Visit" .M="Missing"
<b>analysis_warmth</b>	Skin Warmth At Injection Site	Skin Warmth At Injection Site	.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"
<b>analysis_weight</b>	Weight (kg)	Weight (kg)	Numeric .F="No Record For This Visit"
<b>analysis_wk126_igg</b>	Week 156 IGG Level	Week 156 IGG Level	Numeric .F="No Record For This Visit" .M="Missing"
<b>analysis_wk126_igg_dt</b>	Date Blood Specimen Collected (Week 156)	Date Blood Specimen Collected (Week 156)	SAS Date .F="No Record For This Visit" .M="Missing"
<b>analysis_wk126_igg_time</b>	Time From Week 0 Injection To Week 156 Blood Collection (Days)	Time From Week 0 Injection To Week 156 Blood Collection (Days)	Numeric .F="No Record For This Visit" .M="Missing"
<b>analysis_wk12_55_igg_2</b>	Week 12 And Week 55 IGG Response (Ratio >=2)	Week 12 And Week 55 IGG Response (Ratio >=2)	.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"
<b>analysis_wk12_igg</b>	Week 12 IGG Level	Week 12 IGG Level	Numeric .F="No Record For This Visit" .M="Missing"
<b>analysis_wk12_igg_1-2</b>	Week 12 IGG Response (Ratio >= 2)	Week 12 IGG Response (Ratio >= 2)	.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"
<b>analysis_wk12_igg_1_5</b>	Week 12 IGG Ratio >= 1.5	Week 12 IGG Ratio >= 1.5	.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"
<b>analysis_wk12_igg_rat</b>	Week 12 IGG Ratio	Week 12 IGG Ratio	.F="No Record For This Visit" .M="Missing" 1="<1" 2="1 - <1.5" 3="1.5 - <2" 4=">=2"
<b>analysis_wk12_responder</b>	Type Of Week 12 Responder	Type Of Week 12 Responder	.F="No Record For This Visit" .M="Missing" 1="<1" 2="1 - <1.5" 3="1.5 - <2"
<b>analysis_wk12_to_bsl_igg_diff</b>	Absolute Change In IGG Levels From Baseline To Week 12	Absolute Change In IGG Levels From Baseline To Week 12	Numeric .F="No Record For This Visit" .M="Missing"
<b>analysis_wk12_to_bsl_igg_ratio</b>	Week 12 To Baseline IGG Ratio	Week 12 To Baseline IGG Ratio	Numeric .F="No Record For This Visit" .M="Missing"
<b>analysis_wk52_igg</b>	Week 52 IGG Level	Week 52 IGG Level	Numeric .F="No Record For This Visit" .M="Missing"



Variable	Label	Description	Format Text
<b>analysis_wk52_igg_1-2</b>	Week 52 IGG Response (Ratio >= 2)	Week 52 IGG Response (Ratio >= 2)	.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"
<b>analysis_wk52_igg_1_5</b>	Week 52 IGG Ratio >= 1.5	Week 52 IGG Ratio >= 1.5	.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"
<b>analysis_wk52_igg_rat</b>	Week 52 IGG Ratio	Week 52 IGG Ratio	.F="No Record For This Visit" .M="Missing" 1="<1" 2="1 - <1.5" 3="1.5 - <2" 4=">=2"
<b>analysis_wk52_to_bsl_igg_diff</b>	Absolute Change In IGG Levels From Baseline To Week 52	Absolute Change In IGG Levels From Baseline To Week 52	Numeric .F="No Record For This Visit" .M="Missing"
<b>analysis_wk52_to_bsl_igg_ratio</b>	Week 52 To Baseline IGG Ratio	Week 52 To Baseline IGG Ratio	Numeric .F="No Record For This Visit" .M="Missing"
<b>analysis_wk55_igg</b>	Week 55 IGG Level	Week 55 IGG Level	Numeric .F="No Record For This Visit" .M="Missing"
<b>analysis_wk55_igg_1-2</b>	Week 55 IGG Response (Ratio >= 2)	Week 55 IGG Response (Ratio >= 2)	.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"
<b>analysis_wk55_igg_1_5</b>	Week 55 IGG Ratio >= 1.5	Week 55 IGG Ratio >= 1.5	.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"
<b>analysis_wk55_igg_rat</b>	Week 55 IGG Ratio	Week 55 IGG Ratio	.F="No Record For This Visit" .M="Missing" 1="<1" 2="1 - <1.5" 3="1.5 - <2" 4=">=2"
<b>analysis_wk55_to_wk52_igg_ratio</b>	Week 55 To Week 52 IGG Ratio	Week 55 To Week 52 IGG Ratio	Numeric .F="No Record For This Visit" .M="Missing"

## Section 4: Checklist Pre-Registration

Variable	Label	Description	Format Text
<b>chklist_1_age_in_range</b>	Age 40-70 At Registration/Randomization	Age 40-70 years of age at time of registration/randomization.	1="Yes"
<b>chklist_1_allergic_to_agent</b>	History Of Allergic Reactions To Compounds Similar To Agent	History of allergic reactions attributed to compounds of similar chemical or biologic composition to the study agent.	0="No"
<b>chklist_1_auth_for_use</b>	Authorization For Use And Disclosure Of Protected Health Information	Authorization for use and disclosure of protected health information (USA institutions only) signed and dated. If not a USA institution (select NA)	1="Yes" 2="Not Available"
<b>chklist_1_auth_research</b>	Authorized Contact For Research	Participant has given permission to his/her doctor (or someone from the Cancer Prevention Network) to contact them in the future to ask them to take part in more research.	0="No" 1="Yes"
<b>chklist_1_auth_sample</b>	Authorized Sample	Participant has given permission to collect and store blood and/or tissue for future use in research to learn about, prevent, treat, or cure cancer.	0="No" 1="Yes"
<b>chklist_1_auth_sample_oth</b>	Authorized Sample: Other	Participant has given permission to collect and store blood and/or tissue for future use in research about other health problems (for example: Barrett's esophagus, causes of diabetes mellitus, Alzheimer's disease, and heart disease).	0="No" 1="Yes"
<b>chklist_1_auth_sample_out</b>	Authorized Sample Out	Participant has given permission to send blood and/or tissue sample(s) to researchers at an outside institution.	0="No" 1="Yes"

Variable	Label	Description	Format Text
<b>chklist_1_auto_immune_disease</b>	History Of Auto-Immune Disease	History of auto-immune disease such as, but not restricted to, inflammatory bowel disease, systemic lupus erythematosus, rheumatoid arthritis, ankylosing spondylitis, scleroderma, multiple sclerosis, Hashimoto's thyroiditis, or Grave's disease.	0="No"
<b>chklist_1_auto_reg_part</b>	Registration Office Personnel Will Automatically Register Participants	Registration Office personnel will automatically register participants separately to the translational components of the study (see Section 13.0).	1="Yes"
<b>chklist_1_breastfeeding</b>	Breastfeeding Women	Breastfeeding women, because there is an unknown but potential risk for adverse events in nursing infants secondary to treatment of the mother with the study agents.	0="No"
<b>chklist_1_bsl_prior_rand</b>	Baseline Evaluations <= 28 Days Prior To Registration	Baseline (screening) evaluations must be completed less than or equal to 28 days prior to registration (See Section 7.1).	1="Yes"
<b>chklist_1_colorectal_adenoma</b>	History Of Colorectal Adenomas	History of at least one of the following conditions in the previous 12 months: Colorectal adenoma(s) greater than or equal to 1 cm in maximal diameter Colorectal adenoma(s) with villous or tubulovillous histology Colorectal adenoma(s) with high grade (severe) dysplasia	1="Yes"
<b>chklist_1_consent_dt</b>	Consent Date	Date informed consent signed (mm/dd/yyyy)	SAS Date
<b>chklist_1_ctep_arm</b>	CTEP Arm Assigned	TAC/TAD Code:	0="TAC-0"
<b>chklist_1_eligible</b>	Participant Eligible For Study?	Is the patient eligible for inclusion on this study?	1="Yes"
<b>chklist_1_evidence_adenomas</b>	Presumptive Evidence That Adenomas Were Removed	Presumptive evidence that all adenomatous lesions, including qualifying advanced adenoma have been completely removed.	1="Yes"
<b>chklist_1_heritable_cancer_hist</b>	History Of Heritable Cancer Syndrome	History of heritable cancer syndrome (FAP, HNPCC)	0="No"
<b>chklist_1_hipaa_dt</b>	Date Of Authorization For HIPAA	If a USA institution - Date of authorization (mm/dd/yyyy)	SAS Date .M="Missing"

Variable	Label	Description	Format Text
<b>chklist_1_hist_crc</b>	History Of Colorectal Cancer	History of any colorectal cancer	0="No"
<b>chklist_1_icf_signed</b>	Consent Form Signed And Dated	Is the patient eligible for inclusion on this study?	1="Yes"
<b>chklist_1_immunomodulators</b>	Current Or Planned Use Of Immunomodulators	Current or planned use of immunomodulators including: infliximab, 6-MP (mercaptopurine), methotrexate, cyclosporine, or other immunomodulatory drugs.	0="No"
<b>chklist_1_immunosuppressed</b>	Acquired Immunosuppressive Diseases	Acquired immunosuppressive diseases such as active HIV infection or congenital diseases of immunity	0="No"
<b>chklist_1_not_pregnant</b>	Not Pregnant Or Nursing	Not pregnant or nursing. Note: A negative (serum or urine) pregnancy test must be documented less than or equal to 7 days prior to registration/randomization for women of childbearing potential. If not a woman of childbearing potential or male (select NA)	1="Yes" 2="Not Available"
<b>chklist_1_oth_malignancy</b>	History Of Other Malignancy Within 5 Years	History of other malignancy less than or equal to 5 years prior to the Registration/Randomization evaluation, with the exception of basal cell or squamous cell skin cancer.	0="No"
<b>chklist_1_pregnant</b>	Pregnant Women	Pregnant women, because the teratogenic or abortifacient effects of the study agents remain incompletely defined.	0="No"
<b>chklist_1_sign_icf</b>	Ability To Understand And Willing To Sign Informed Consent	Ability to understand and the willingness to sign a written informed consent document.	1="Yes"

Variable	Label	Description	Format Text
<b>chklist_1_steatohepatitis</b>	Diagnosis Of Non-Alcoholic Steatohepatitis	Diagnosis of nonalcoholic steatohepatitis (NASH) and a NAFLD (nonalcoholic fatty liver disease) activity score (NAS) >= 5. NOTES and EXCEPTIONS: NAS is based on findings from a liver biopsy. Participants with NAS of <= 2 are eligible for enrollment. Participants with NAS of 3-4 must be discussed with the Principal Investigator and DCP before enrollment to consider other risk factors (i.e., obesity, alcohol intake). Participants with a prior diagnosis of NASH and no available NAS must be discussed with	.M="Missing" 0="No"
<b>chklist_1_study_agent_avail</b>	Study Agent Is Available And Authorized To The Registering Site	Study agent is available and Drug Shipment Authorization has been granted to the registering site.	1="Yes"
<b>chklist_1_uncont_ill</b>	Presence Of Acute Or Chronic Infection Or Uncontrolled Illness	Presence of an active acute or chronic infection or uncontrolled illness including, but not limited to, unstable congestive heart failure, unstable angina pectoris, cardiac arrhythmia, or psychiatric illness/social situations that would limit compliance with study requirements	0="No"
<b>chklist_1_willing_blood_samples</b>	Willingness To Provide Blood Samples For Toxicity	Willingness to provide blood samples for toxicity monitoring and research purposes.	1="Yes"
<b>chklist_1_willing_contraception</b>	Willingness To Employ Adequate Contraception Through Week 53	Willingness to employ adequate contraception through Week 53 of the study. Note: The effects of the MUC1 vaccine on the developing human fetus at the dose specified in this study are unknown. For this reason, women of child-bearing potential and men must agree to use adequate contraception (hormonal, barrier method of birth control,; abstinence) prior to study entry and for the period of active vaccination (through Week 53). Should a woman become pregnant or suspect she is pregnant while participating in	1="Yes"

Variable	Label	Description	Format Text
<b>chklist_1_willing_tests_procs</b>	Willingness To Undergo Screening Tests And Procedures	Willingness to undergo screening tests and procedures.	1="Yes"

## Section 5: Demographic And Registration Data Pre-Registration

Variable	Label	Description	Format Text
<b>casecrse_1_accrual_mem</b>	Accrual Member	Accrual Member	Numeric
<b>casecrse_1_alliance_prot</b>	Alliance Protocol	Alliance Protocol	0="No"
<b>casecrse_1_case</b>	Case Number	Case Number	Numeric
<b>casecrse_1_country</b>	Country Code	Country Code	1="US" 2="PR"
<b>casecrse_1_ctep_id</b>	CTEP ID	CTEP ID	"MA034"="MA034" "MN026"="MN026" "MO029"="MO029" "PA015"="PA015" "PA121"="PA121" "PR008"="PR008"
<b>casecrse_1_cur_dc</b>	Current Date Center	Current Date Center	2806="CPN"
<b>casecrse_1_cur_grp</b>	Current Group	Current Group	2806="CPN"
<b>casecrse_1_cur_loc</b>	Current Location	Current Location	1="MC Rochester" 2="U of Pitt" 3="Thomas Jefferson" 4="Mass General Hosp CC" 5="VA Kansas Cty" 6="Univ PR - treating site"
<b>casecrse_1_cur_member</b>	Current Member	Current Member	1="Mayo" 2="U of Pitt" 3="Univ PR" 4="Mass General Hosp CC" 5="JeffersonHsp" 6="KS City VA"
<b>casecrse_1_cur_org</b>	Current Organization Number	Current Organization Number	1="Mayo" 2="U of Pitt" 3="Univ PR" 4="Mass General Hosp CC" 5="JeffersonHsp" 6="KS City VA"
<b>casecrse_1_cur_rel_type</b>	Current Organization Relationship Type	Current Organization Relationship Type	1="Component" 2="Affiliate"
<b>casecrse_1_data_center</b>	Data Center	Data Center	"CPN"="CPN"
<b>casecrse_1_dka_source</b>	Date Known Alive Source	Date Known Alive Source	1="Ingres"

Variable	Label	Description	Format Text
casecrse_1_dka_var	Date Known Alive Source Variable	Date Known Alive Source Variable	.M="Missing" 1="assessdt" 2="chem_dt" 3="col_dt1" 4="dose1_dt" 5="exam_dt" 6="hem_dt" 7="injectdt" 8="oper_dt" 9="proc_dt"
casecrse_1_dt_dead	Death Date	Death Date	SAS Date .M="Missing"
casecrse_1_dt_last_alive	Date Last Known Alive	Date Last Known Alive	SAS Date
casecrse_1_dt_off	Date Off	Date Off	SAS Date .M="Missing"
casecrse_1_dt_on	Date On	Date On	SAS Date
casecrse_1_dt_on_arm	Date On Current Arm	Date On Current Arm	SAS Date
casecrse_1_end_tx_dt	End Active Treatment	End Active Treatment	SAS Date .M="Missing"
casecrse_1_end_tx_reason	Reason End Treatment	Reason End Treatment	.M="Missing" 1="Study Complete" 2="Participant Withdrawal" 3="Physician Decision" 4="Ineligible (includes screen failures)" 5="Other, Specify"
casecrse_1_esp	Extended Participant Project	Extended Participant Project	0="No"
casecrse_1_ex_ref_id	External Reference Number	External Reference Number	Char
casecrse_1_fu_dt	Follow-Up Date	Follow-Up Date	SAS Date
casecrse_1_fu_stat	Follow-Up Status	Follow-Up Status	1="Alive"
casecrse_1_fu_study	Follow-Up Study	Follow-Up Study	Numeric .M="Missing"
casecrse_1_ineligible	Ineligible	Ineligible	.M="Missing" 1="Yes"
casecrse_1_mayo_id	Mayo ID	Mayo ID	Numeric .M="Missing"
casecrse_1_mayo_protocol	Mayo Protocol	Mayo Protocol	1="Yes"
casecrse_1_ncc_protocol	NCCTG Protocol	NCCTG Protocol	0="No"
casecrse_1_pay_method	Payment Method	Payment Method	1="Medicare/Medicaid" 2="Medicare" 3="Medicare/Private Insurance" 4="Military/VA Sponsored (NOS)" 5="Private Insurance" 6="Veterans Sponsored" 7="Other"
casecrse_1_pre_reg	Pre-Registration Study	Pre-Registration Study	1="Yes"



Variable	Label	Description	Format Text
<b>casecrse_1_prot_num</b>	Data Center Assigned Protocol Number	Data Center Assigned Protocol Number	.M="Missing" 1="MAY2013-01-01" 2="MC138AE"
<b>casecrse_1_protocol</b>	Data Center Assigned Protocol Number	Data Center Assigned Protocol Number	Char
<b>casecrse_1_study_num</b>	Ingres Study Number	Ingres Study Number	Numeric
<b>casecrse_1_subject_num</b>	Subject Number	Subject Number	Numeric

## Section 6: Screen Fail

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Variable	Label	Description	Format Text
<b>scr_fail_comp_dt</b>	Completion Date	Date aware of preregistration screening failure: (mm/dd/yyyy)	SAS Date .F="No Record For This Visit"
<b>scr_fail_oth_spec</b>	Reason For Screen Failure, Other Specify	Specify other (40 available characters.)	Char
<b>scr_fail_reason</b>	Reason For Screen Failure	Primary reason screening failed: (enter one) 3=Did not meet eligibility criteria 1=Investigator decision 2=Participant decision 4=Other reason, specify	.F="No Record For This Visit" 1="Investigator decision" 2="Participant decision" 3="Did not meet eligibility criteria" 4="Other reason, specify"

## Section 7: Blood Hematology Pre-Registration

Variable	Label	Description	Format Text
<b>intvlab_1_anc_csig</b>	Clinically Significant: Neutrophils	Clinically Significant: ANC	.M="Missing" 0="No"
<b>intvlab_1_anc_oor</b>	Out Of Range: Neutrophils	Out of Range: ANC	.M="Missing" 0="No" 1="Yes"
<b>intvlab_1_anc_val</b>	ANC Lab Value (# Blood 10 <sup>9</sup> /L)	Neutrophils (ANC), #, Blood 10 <sup>9</sup> /L (enter numeric value only) Decimal use available with entry, if needed	Numeric .M="Missing"
<b>intvlab_1_basos_csig</b>	Clinically Significant: Basophils	Clinically Significant: Basophils	.M="Missing" 0="No"
<b>intvlab_1_basos_oor</b>	Out Of Range: Basophils	Out of Range: Basophils	.M="Missing" 0="No" 1="Yes"
<b>intvlab_1_basos_val</b>	Basophils Lab Value (# Blood 10 <sup>9</sup> /L)	Basophils, #, Blood 10 <sup>9</sup> /L (Enter numeric value only) Decimal use available with entry, if needed	Numeric .M="Missing"
<b>intvlab_1_eosinos_csig</b>	Clinically Significant: Eosinophils	Clinically Significant: Eosinophils	.M="Missing" 0="No"
<b>intvlab_1_eosinos_oor</b>	Out Of Range: Eosinophils	Out of Range: Eosinophils	.M="Missing" 0="No" 1="Yes"
<b>intvlab_1_eosinos_val</b>	Eosinophils Lab Value (# Blood 10 <sup>9</sup> /L)	Eosinophils, #, Blood 10 <sup>9</sup> /L (Enter numeric value only) Decimal use available with entry, if needed	Numeric .M="Missing"
<b>intvlab_1_hema_dt</b>	Hematology Date	Sample collection date: (mm/dd/yyyy)	SAS Date .M="Missing"
<b>intvlab_1_hemato_csig</b>	Clinically Significant: Hematocrit	Clinically Significant: Hematocrit	.M="Missing" 0="No" 1="Yes"
<b>intvlab_1_hemato_oor</b>	Out Of Range: Hematocrit	Out of Range: Hematocrit	.M="Missing" 0="No" 1="Yes"
<b>intvlab_1_hemato_val</b>	Hematocrit Lab Value (%)	Hematocrit % (Enter numeric value only) Decimal use available with entry, if needed	Numeric .M="Missing"
<b>intvlab_1_hgb_csig</b>	Clinically Significant: Hemoglobin	Clinically Significant: HGB	.M="Missing" 0="No" 1="Yes"
<b>intvlab_1_hgb_oor</b>	Out Of Range: Hemoglobin	Out of Range: HGB	.M="Missing" 0="No" 1="Yes"

Variable	Label	Description	Format Text
<b>intvlab_1_hgb_val</b>	Hemoglobin Lab Value (g/dL)	Hemoglobin, Blood g/dL (Enter numeric value only) Decimal use available with entry, if needed	Numeric .M="Missing"
<b>intvlab_1_lymph_csig</b>	Clinically Significant: Lymphocytes	Clinically Significant: Lymphocytes	.M="Missing" 0="No"
<b>intvlab_1_lymph_oor</b>	Out Of Range: Lymphocytes	Out of Range: Lymphocytes	.M="Missing" 0="No" 1="Yes"
<b>intvlab_1_lymph_val</b>	Lymphocytes Lab Value (# Blood 10 <sup>9</sup> /L)	Lymphocytes, #, Blood 10 <sup>9</sup> /L (Enter numeric value only) Decimal use available with entry, if needed	Numeric .M="Missing"
<b>intvlab_1_monos_csig</b>	Clinically Significant: Monocytes	Clinically Significant: Monocytes	.M="Missing" 0="No"
<b>intvlab_1_monos_oor</b>	Out Of Range: Monocytes	Out of Range: Monocytes	.M="Missing" 0="No" 1="Yes"
<b>intvlab_1_monos_val</b>	Monocytes Lab Value (# Blood 10 <sup>9</sup> /L)	Monocytes, #, Blood 10 <sup>9</sup> /L (Enter numeric value only) Decimal use available with entry, if needed	Numeric .M="Missing"
<b>intvlab_1_plt_csig</b>	Clinically Significant: Platelets	Clinically Significant: Platelets	.M="Missing" 0="No" 1="Yes"
<b>intvlab_1_plt_oor</b>	Out Of Range: Platelets	Out of Range: Platelets	.M="Missing" 0="No" 1="Yes"
<b>intvlab_1_plt_val</b>	Platelets Lab Value (# Blood 10 <sup>9</sup> /L)	Platelets, Blood 10 <sup>9</sup> /L (Enter numeric value only) DO NOT use decimal or comma with entry	Numeric .M="Missing"
<b>intvlab_1_rbc_csig</b>	Clinically Significant: Red Blood Cells	Clinically Significant: RBC	.M="Missing" 0="No" 1="Yes" 2="Unknown"
<b>intvlab_1_rbc_oor</b>	Out Of Range: Red Blood Cells	Out of Range: RBC	.M="Missing" 0="No" 1="Yes"
<b>intvlab_1_rbc_val</b>	Red Blood Cells Lab Value (# Blood 10 <sup>12</sup> /L)	Red Blood Cells (RBC), #, Blood 10 <sup>12</sup> /L (Enter numeric value only) Decimal use available with entry, if needed	Numeric .M="Missing"
<b>intvlab_1_wbc_csig</b>	Clinically Significant: White Blood Cells	Clinically Significant: WBC	.M="Missing" 0="No"
<b>intvlab_1_wbc_oor</b>	Out Of Range: White Blood Cells	Out of Range: WBC	.M="Missing" 0="No" 1="Yes"

Variable	Label	Description	Format Text
<b>intvlab_1_wbc_val</b>	White Blood Cells Lab Value (# Blood 10 <sup>9</sup> /L)	White Blood Cells (WBC), #, Blood 10 <sup>9</sup> /L (Enter numeric value only) Decimal use available with entry, if needed	Numeric .M="Missing"

## Section 8: Concomitant Medication

Variable	Label	Description	Format Text
<b>conmed_cont_1_1-15</b>	Concomitant Medication Continuing? 15	Continuing 1=Yes 2=No	.M="Missing" 0="No" 1="Yes"
<b>conmed_cont_2_1-15</b>	Concomitant Medication Continuing? 15	Continuing 1=Yes 2=No	.M="Missing" 0="No" 1="Yes"
<b>conmed_cont_3_1-15</b>	Concomitant Medication Continuing? 15	Continuing 1=Yes 2=No	.M="Missing" 0="No" 1="Yes"
<b>conmed_cont_4_1-15</b>	Concomitant Medication Continuing? 15	Continuing 1=Yes 2=No	.M="Missing" 0="No" 1="Yes"
<b>conmed_cont_5_1-15</b>	Concomitant Medication Continuing? 15	Continuing 1=Yes 2=No	.M="Missing" 0="No" 1="Yes"
<b>conmed_cont_6_1-15</b>	Concomitant Medication Continuing? 15	Continuing 1=Yes 2=No	.M="Missing" 0="No" 1="Yes"
<b>conmed_cont_7_1-15</b>	Concomitant Medication Continuing? 15	Continuing 1=Yes 2=No	.M="Missing" 0="No"
<b>conmed_cont_8_1-15</b>	Concomitant Medication Continuing? 15	Continuing 1=Yes 2=No	.M="Missing" 0="No"
<b>conmed_dose_1_1-15</b>	Concomitant Medication Dose 15	Dose (Enter numeric value only.)	Numeric .M="Missing"
<b>conmed_dose_2_1-15</b>	Concomitant Medication Dose 15	Dose (Enter numeric value only.)	Numeric .M="Missing"
<b>conmed_dose_3_1-15</b>	Concomitant Medication Dose 15	Dose (Enter numeric value only.)	Numeric .M="Missing"
<b>conmed_dose_4_1-15</b>	Concomitant Medication Dose 15	Dose (Enter numeric value only.)	Numeric .M="Missing"
<b>conmed_dose_5_1-15</b>	Concomitant Medication Dose 15	Dose (Enter numeric value only.)	Numeric .M="Missing"
<b>conmed_dose_6_1-15</b>	Concomitant Medication Dose 15	Dose (Enter numeric value only.)	Numeric .M="Missing"
<b>conmed_dose_7_1-15</b>	Concomitant Medication Dose 15	Dose (Enter numeric value only.)	Numeric .M="Missing"
<b>conmed_dose_8_1-15</b>	Concomitant Medication Dose 15	Dose (Enter numeric value only.)	Numeric .M="Missing"
<b>conmed_has_conmed</b>	Has Concomitant Medication	Is the participant taking any concomitant medications? 1=Yes If Yes, enter all medications (including prescription, over-the-counter, alternative medications, vitamins and supplements) 2=No	0="No" 1="Yes"

Variable	Label	Description	Format Text
<b>conmed_medication_1_1-15</b>	Concomitant Medication Name 15	Concomitant agent name (1) (40 available characters.)	Char
<b>conmed_medication_2_1-15</b>	Concomitant Medication Name 15	Concomitant agent name (1) (40 available characters.)	Char
<b>conmed_medication_3_1-15</b>	Concomitant Medication Name 15	Concomitant agent name (1) (40 available characters.)	Char
<b>conmed_medication_4_1-15</b>	Concomitant Medication Name 15	Concomitant agent name (1) (40 available characters.)	Char
<b>conmed_medication_5_1-15</b>	Concomitant Medication Name 15	Concomitant agent name (1) (40 available characters.)	Char
<b>conmed_medication_6_1-15</b>	Concomitant Medication Name 15	Concomitant agent name (1) (40 available characters.)	Char
<b>conmed_medication_7_1-15</b>	Concomitant Medication Name 15	Concomitant agent name (1) (40 available characters.)	Char
<b>conmed_medication_8_1-15</b>	Concomitant Medication Name 15	Concomitant agent name (1) (40 available characters.)	Char
<b>conmed_reason_1_1-15</b>	Concomitant Medication Reason 15	Indication (200 available characters)	Char
<b>conmed_reason_2_1-15</b>	Concomitant Medication Reason 15	Indication (200 available characters)	Char
<b>conmed_reason_3_1-15</b>	Concomitant Medication Reason 15	Indication (200 available characters)	Char
<b>conmed_reason_4_1-15</b>	Concomitant Medication Reason 15	Indication (200 available characters)	Char
<b>conmed_reason_5_1-15</b>	Concomitant Medication Reason 15	Indication (200 available characters)	Char
<b>conmed_reason_6_1-15</b>	Concomitant Medication Reason 15	Indication (200 available characters)	Char
<b>conmed_reason_7_1-15</b>	Concomitant Medication Reason 15	Indication (200 available characters)	Char
<b>conmed_reason_8_1-15</b>	Concomitant Medication Reason 15	Indication (200 available characters)	Char
<b>conmed_schedule_1_1-15</b>	Concomitant Medication Schedule 15	Frequency (24 available characters.)	Char
<b>conmed_schedule_2_1-15</b>	Concomitant Medication Schedule 15	Frequency (24 available characters.)	Char
<b>conmed_schedule_3_1-15</b>	Concomitant Medication Schedule 15	Frequency (24 available characters.)	Char
<b>conmed_schedule_4_1-15</b>	Concomitant Medication Schedule 15	Frequency (24 available characters.)	Char
<b>conmed_schedule_5_1-15</b>	Concomitant Medication Schedule 15	Frequency (24 available characters.)	Char
<b>conmed_schedule_6_1-15</b>	Concomitant Medication Schedule 15	Frequency (24 available characters.)	Char
<b>conmed_schedule_7_1-15</b>	Concomitant Medication Schedule 15	Frequency (24 available characters.)	Char
<b>conmed_schedule_8_1-15</b>	Concomitant Medication Schedule 15	Frequency (24 available characters.)	Char

Variable	Label	Description	Format Text
<b>conmed_start_dt_1_1-15</b>	Concomitant Medication Start Date 15	Start Date (mm/dd/yyyy)	SAS Date .M="Missing"
<b>conmed_start_dt_2_1-15</b>	Concomitant Medication Start Date 15	Start Date (mm/dd/yyyy)	SAS Date .M="Missing"
<b>conmed_start_dt_3_1-15</b>	Concomitant Medication Start Date 15	Start Date (mm/dd/yyyy)	SAS Date .M="Missing"
<b>conmed_start_dt_4_1-15</b>	Concomitant Medication Start Date 15	Start Date (mm/dd/yyyy)	SAS Date .M="Missing"
<b>conmed_start_dt_5_1-15</b>	Concomitant Medication Start Date 15	Start Date (mm/dd/yyyy)	SAS Date .M="Missing"
<b>conmed_start_dt_6_1-15</b>	Concomitant Medication Start Date 15	Start Date (mm/dd/yyyy)	SAS Date .M="Missing"
<b>conmed_start_dt_7_1-15</b>	Concomitant Medication Start Date 15	Start Date (mm/dd/yyyy)	SAS Date .M="Missing"
<b>conmed_start_dt_8_1-15</b>	Concomitant Medication Start Date 15	Start Date (mm/dd/yyyy)	SAS Date .M="Missing"
<b>conmed_stop_dt_1_1-15</b>	Concomitant Medication Stop Date 15	Stop Date (mm/dd/yyyy)	SAS Date .M="Missing"
<b>conmed_stop_dt_2_1-15</b>	Concomitant Medication Stop Date 15	Stop Date (mm/dd/yyyy)	SAS Date .M="Missing"
<b>conmed_stop_dt_3_1-15</b>	Concomitant Medication Stop Date 15	Stop Date (mm/dd/yyyy)	SAS Date .M="Missing"
<b>conmed_stop_dt_4_1-15</b>	Concomitant Medication Stop Date 15	Stop Date (mm/dd/yyyy)	SAS Date .M="Missing"
<b>conmed_stop_dt_5_1-15</b>	Concomitant Medication Stop Date 15	Stop Date (mm/dd/yyyy)	SAS Date .M="Missing"
<b>conmed_stop_dt_6_1-15</b>	Concomitant Medication Stop Date 15	Stop Date (mm/dd/yyyy)	SAS Date .M="Missing"
<b>conmed_stop_dt_7_1-15</b>	Concomitant Medication Stop Date 15	Stop Date (mm/dd/yyyy)	SAS Date .M="Missing"
<b>conmed_stop_dt_8_1-15</b>	Concomitant Medication Stop Date 15	Stop Date (mm/dd/yyyy)	SAS Date .M="Missing"
<b>conmed_units_1_1-15</b>	Concomitant Medication Units 15	Units of measure (15 available characters)	Char
<b>conmed_units_2_1-15</b>	Concomitant Medication Units 15	Units of measure (15 available characters)	Char
<b>conmed_units_3_1-15</b>	Concomitant Medication Units 15	Units of measure (15 available characters)	Char
<b>conmed_units_4_1-15</b>	Concomitant Medication Units 15	Units of measure (15 available characters)	Char
<b>conmed_units_5_1-15</b>	Concomitant Medication Units 15	Units of measure (15 available characters)	Char
<b>conmed_units_6_1-15</b>	Concomitant Medication Units 15	Units of measure (15 available characters)	Char
<b>conmed_units_7_1-15</b>	Concomitant Medication Units 15	Units of measure (15 available characters)	Char
<b>conmed_units_8_1-15</b>	Concomitant Medication Units 15	Units of measure (15 available characters)	Char



## Section 9: Physical Exam Pre-Registration

Variable	Label	Description	Format Text
<b>phys_1_abdomen_com</b>	Comments: Abdomen	Comments: Abdomen	Char
<b>phys_1_abdomen_stat</b>	Status: Abdomen	Abdomen 1=Normal 2=Abnormal 3=Not Assessed	1="Normal" 2="Abnormal"
<b>phys_1_allergy</b>	Does Participant Have Any Allergies?	Does the participant have any allergies? 1=Yes 2=No	0="No" 1="Yes"
<b>phys_1_allergy_spec</b>	Allergies: Other Specify	If Yes, specify (allergies): (200 available characters)	Char
<b>phys_1_appear_com</b>	Comments: Appearance	Comments: Appearance	Char
<b>phys_1_appear_stat</b>	Status: Appearance	Appearance 1=Normal 2=Abnormal 3=Not Assessed	1="Normal" 2="Abnormal"
<b>phys_1_cardio_com</b>	Comments: Cardiovascular	Comments: Cardiovascular	Char
<b>phys_1_cardio_stat</b>	Status: Cardiovascular	Cardiovascular 1=Normal 2=Abnormal 3=Not Assessed	1="Normal" 2="Abnormal" 3="Not Assessed"
<b>phys_1_cerv_lymph_com</b>	Comments: Cervical Lymph Nodes	Comments: Cervical Lymph Nodes	Char
<b>phys_1_cerv_lymph_stat</b>	Status: Cervical Lymph Nodes	Cervical Lymph Nodes 1=Normal 2=Abnormal 3=Not Assessed	1="Normal" 3="Not Assessed"
<b>phys_1_diastolic</b>	Diastolic Blood Pressure	Diastolic: ___ ___ ___ (mm Hg)	Numeric
<b>phys_1_exam_dt</b>	Physical Exam Date	Evaluation Date: (mm/dd/yyyy)	SAS Date
<b>phys_1_heent_com</b>	Comments: H/E/E/N/T	Comments: H/E/E/N/T	Char
<b>phys_1_heent_stat</b>	Status: H/E/E/N/T	H/E/E/N/T 1=Normal 2=Abnormal 3=Not Assessed	1="Normal" 3="Not Assessed"
<b>phys_1_height</b>	Height (cm)	Height (cm) ___ ___ ___.___ The range for height is 135 to 210. If study participants height is notwithin this range and has been verified to be correct, Click on the validated button. If "Not Obtained" select the "Not Done" radio button.	Numeric
<b>phys_1_ing_lymph_com</b>	Comments: Inguinal Lymph Nodes	Comments: Inguinal Lymph Nodes	Char
<b>phys_1_ing_lymph_stat</b>	Status: Inguinal Lymph Nodes	Inguinal Lymph Nodes 1=Normal 2=Abnormal 3=Not Assessed	.M="Missing" 1="Normal" 3="Not Assessed"

Variable	Label	Description	Format Text
<b>phys_1_musculo_com</b>	Comments: Musculoskeletal	Comments: Musculoskeletal	Char
<b>phys_1_musculo_stat</b>	Status: Musculoskeletal	Musculoskeletal 1=Normal 2=Abnormal 3=Not Assessed	1="Normal" 2="Abnormal"
<b>phys_1_oth_site</b>	Other Site	Specify Other Body System/Site (40 available characters)	Char
<b>phys_1_oth_site_com</b>	Comments: Other Site	Comments: Other Body Site 1	Char
<b>phys_1_oth_site_stat</b>	Status: Other Site	Other Site 1 1=Normal 2=Abnormal 3=Not Assessed	.M="Missing" 3="Not Assessed"
<b>phys_1_performed</b>	Physical Exam Performed?	Overall Physical Exam Performed: (select one) 1=Yes 2=No	1="Yes"
<b>phys_1_pulse</b>	Pulse	Pulse: ___ ___	Numeric .M="Missing"
<b>phys_1_respiratory_com</b>	Comments: Respiratory	Comments: Respiratory	Char
<b>phys_1_respiratory_stat</b>	Status: Respiratory	Respiratory 1=Normal 2=Abnormal 3=Not Assessed	1="Normal" 2="Abnormal" 3="Not Assessed"
<b>phys_1_score</b>	Physical Exam Performance Score	Performance Status (ECOG) (Pre-Intervention only): (0, 1, 2, 3, 4)	Numeric
<b>phys_1_skin_com</b>	Comments: Skin	Comments: Skin	Char
<b>phys_1_skin_stat</b>	Status: Skin	Skin 1=Normal 2=Abnormal 3=Not Assessed	1="Normal" 3="Not Assessed"
<b>phys_1_systolic</b>	Systolic Blood Pressure	Blood Pressure: Systolic: ___ ___ (mm Hg)	Numeric
<b>phys_1_temperature</b>	Temperature (c)	Body temperature ___ ___ ___.___ ^0C	Numeric
<b>phys_1_thyroid_com</b>	Comments: Thyroid	Comments: Thyroid	Char
<b>phys_1_thyroid_stat</b>	Status: Thyroid	Thyroid 1=Normal 2=Abnormal 3=Not Assessed	1="Normal"
<b>phys_1_weight</b>	Weight (kg)	Weight (kg) ___ __. ___ The range for weight is 36.3 to 136.1. If study participants weight is not within this range and has been verified to be correct Click on the validated button.	Numeric

## Section 10: Pregnancy Test Pre-Registration

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Variable	Label	Description	Format Text
<b>preg_test_1_dt</b>	Pregnancy Test Date	Date Specimen Collected: (mm/dd/yyyy)	SAS Date .F="No Record For This Visit" .M="Missing"
<b>preg_test_1_result</b>	Pregnancy Test Result	Pregnancy Test Result: 2=Positive 3=Negative 1=Not obtained 4=Not applicable, not female of child-bearing potential	.F="No Record For This Visit" 2="Positive" 3="Negative"
<b>preg_test_1_spec_source</b>	Pregnancy Test Specimen Source	Pregnancy Test Type: 1=Urine 2=Serum	.F="No Record For This Visit" .M="Missing" 1="Urine" 2="Serum"

## Section 11: Colonoscopy Baseline

Variable	Label	Description	Format Text
<b>colon_bsl_adenoma_sum</b>	Sum Of Adenomas (Baseline)	Sum Of Adenomas (Baseline)	Numeric
<b>colon_bsl_adv_adenoma_crit</b>	Criteria Of Qualifying Baseline Advanced Adenoma	Criteria Of Qualifying Baseline Advanced Adenoma	.M="Missing" 1=">1cm, High Grade Dysplasia, and Villous or Tubulovillous" 3=">1cm, and Villous or Tubulovillous" 5=">1cm" 7="Villous or Tubulovillous"
<b>colon_bsl_bowel_prep_adequate</b>	Was The Overall Bowel Preparation Adequate, Good, Or Excellent? (Baseline)	Was The Overall Bowel Preparation Adequate, Good, Or Excellent? (Baseline)	0="No" 1="Yes" 2="Not Reported"
<b>colon_bsl_cecum_visualized</b>	Was The Cecum Visualized? (Baseline)	Was The Cecum Visualized? (Baseline)	1="Yes" 2="Not Reported"
<b>colon_bsl_mean_polyp_size</b>	Average Size Of All Polyps As Measured By A Pathologist (Baseline)	Average Size Of All Polyps As Measured By A Pathologist (Baseline)	Numeric .M="Missing"
<b>colon_bsl_mult_adenomas</b>	Multiple Adenomas (Baseline)	Multiple Adenomas (Baseline)	0="No" 1="Yes"
<b>colon_bsl_mult_adv_adenomas</b>	Multiple Advanced Adenomas (Baseline)	Multiple Advanced Adenomas (Baseline)	0="No" 1="Yes"
<b>colon_bsl_num_adenoma_polyp</b>	Number Of Adenoma Polyps (Baseline)	Number Of Adenoma Polyps (Baseline)	Numeric
<b>colon_bsl_num_adv_adenoma</b>	Total Number Advanced Adenomas (Baseline)	Total Number Advanced Adenomas (Baseline)	Numeric
<b>colon_bsl_num_adv_adenoma_cat</b>	Total Number Advanced Adenomas (Baseline)	Total Number Advanced Adenomas (Baseline)	Numeric
<b>colon_bsl_num_adv_adenoma_polyp</b>	Number Of Advanced Adenomas (Baseline)	Number Of Advanced Adenomas (Baseline)	Numeric
<b>colon_bsl_num_cecum_polyp</b>	Number Of Polyps In Cecum (Baseline)	Number Of Polyps In Cecum (Baseline)	Numeric .M="Missing"
<b>colon_bsl_num_descending_polyp</b>	Number Of Polyps In Descending Colon	Number Of Polyps In Descending Colon	Numeric .M="Missing"
<b>colon_bsl_num_diminutive_polyp</b>	Number Of Diminutive Polyps (<mm) (Baseline)	Number Of Diminutive Polyps (<mm) (Baseline)	Numeric .M="Missing"
<b>colon_bsl_num_hemartomatous_polyp</b>	Number Of Hemartomatous Polyps (Baseline)	Number Of Hemartomatous Polyps (Baseline)	Numeric
<b>colon_bsl_num_hepatic_flexure_polyp</b>	Number Of Polyps In Hepatic Flexure (Baseline)	Number Of Polyps In Hepatic Flexure (Baseline)	Numeric .M="Missing"
<b>colon_bsl_num_high_grade_dysplasia_polyp</b>	Number Of Polyps With High Grade Dysplasia (Baseline)	Number Of Polyps With High Grade Dysplasia (Baseline)	Numeric
<b>colon_bsl_num_hyperplastic_polyp</b>	Number Of Hyperplastic Polyps (Baseline)	Number Of Hyperplastic Polyps (Baseline)	Numeric

Variable	Label	Description	Format Text
<b>colon_bsl_num_indef_dysp_polyp</b>	Number Of Polyps Indefinite For Dysplasia (Baseline)	Number Of Polyps Indefinite For Dysplasia (Baseline)	Numeric
<b>colon_bsl_num_inflammatory_polyp</b>	Number Of Inflammatory Polyps (Baseline)	Number Of Inflammatory Polyps (Baseline)	Numeric
<b>colon_bsl_num_juvenile_polyp</b>	Number Of Juvenile Polyps	Number Of Juvenile Polyps	Numeric
<b>colon_bsl_num_large_polyp</b>	Number Of Large Polyps (>9mm) (Baseline)	Number Of Large Polyps (>9mm) (Baseline)	Numeric .M="Missing"
<b>colon_bsl_num_low_dysp_polyp</b>	Number Of Polyps With Low Grade Dysplasia (Baseline)	Number Of Polyps With Low Grade Dysplasia (Baseline)	Numeric
<b>colon_bsl_num_medium_polyp</b>	Number Of Medium Polyps (5-9mm) (Baseline)	Number Of Medium Polyps (5-9mm) (Baseline)	Numeric .M="Missing"
<b>colon_bsl_num_nadenoma_polyp</b>	Number Of Not Applicable Adenomas (Baseline)	Number Of Not Applicable Adenomas (Baseline)	Numeric
<b>colon_bsl_num_nagrade_polyp</b>	Number Of Polyps With Grade Of Dysplasia Not Available (Baseline)	Number Of Polyps With Grade Of Dysplasia Not Available (Baseline)	Numeric
<b>colon_bsl_num_nodysp_polyp</b>	Number Of Polyps With No Dysplasia (Baseline)	Number Of Polyps With No Dysplasia (Baseline)	Numeric
<b>colon_bsl_num_noloc_polyp</b>	Number Of Polyps In Unspecified Location (Baseline)	Number Of Polyps In Unspecified Location (Baseline)	Numeric .M="Missing"
<b>colon_bsl_num_nonadv_aden_polyp</b>	Number Of Non-Advanced Adenomas (Baseline)	Number Of Non-Advanced Adenomas (Baseline)	Numeric
<b>colon_bsl_num_nonadv_adenoma</b>	Total Number Non-Advanced Adenomas (Baseline)	Total Number Non-Advanced Adenomas (Baseline)	Numeric
<b>colon_bsl_num_nonspec_config</b>	Number Of Non-Specified Configurations (Baseline)	Number Of Non-Specified Configurations (Baseline)	Numeric
<b>colon_bsl_num_notspec_polyp</b>	Number Of Not Specified Polyps (Baseline)	Number Of Not Specified Polyps (Baseline)	Numeric
<b>colon_bsl_num_peniculated</b>	Number Of Pediculated Configurations (Baseline)	Number Of Pediculated Configurations (Baseline)	Numeric
<b>colon_bsl_num_polyp_ascending</b>	Number Of Polyps In Ascending Colon (Baseline)	Number Of Polyps In Ascending Colon (Baseline)	Numeric .M="Missing"
<b>colon_bsl_num_rectosig_polyp</b>	Number Of Polyps In Rectosigmoid Junction (Baseline)	Number Of Polyps In Rectosigmoid Junction (Baseline)	Numeric .M="Missing"
<b>colon_bsl_num_rectum_polyps</b>	Number Of Polyps In Rectum (Baseline)	Number Of Polyps In Rectum (Baseline)	Numeric .M="Missing"
<b>colon_bsl_num_removed_polyps</b>	Number Of Polyps Removed Piecemeal (Baseline)	Number Of Polyps Removed Piecemeal (Baseline)	Numeric
<b>colon_bsl_num_serrated_polyps</b>	Number Of Serrated Polyps (Baseline)	Number Of Serrated Polyps (Baseline)	Numeric
<b>colon_bsl_num_sessile_config</b>	Number Of Sessile Configurations (Baseline)	Number Of Sessile Configurations (Baseline)	Numeric

Variable	Label	Description	Format Text
<b>colon_bsl_num_sig_moid_polyps</b>	Number Of Polyps In Sigmoid Colon (Baseline)	Number Of Polyps In Sigmoid Colon (Baseline)	Numeric .M="Missing"
<b>colon_bsl_num_splenic_polyp</b>	Number Of Polyps In Splenic Flexure (Baseline)	Number Of Polyps In Splenic Flexure (Baseline)	Numeric .M="Missing"
<b>colon_bsl_num_trans_colon_polyp</b>	Number Of Polyps In Transcending Colon (Baseline)	Number Of Polyps In Transcending Colon (Baseline)	Numeric .M="Missing"
<b>colon_bsl_num_tubular_polyp</b>	Number Of Tubular Polyps (Baseline)	Number Of Tubular Polyps (Baseline)	Numeric
<b>colon_bsl_num_tubulo_polyp</b>	Number Of Tubulovillous Polyps (Baseline)	Number Of Tubulovillous Polyps (Baseline)	Numeric
<b>colon_bsl_num_villous_polyp</b>	Number Of Villous Polyps (Baseline)	Number Of Villous Polyps (Baseline)	Numeric
<b>colon_bsl_oth_spec</b>	If Abnormal Or Other, Specify (Baseline)	If Abnormal Or Other, Specify (Baseline)	Char
<b>colon_bsl_performed</b>	Colonoscopy Performed (Baseline)	Colonoscopy Performed (Baseline)	1="Yes"
<b>colon_bsl_polyp_hist_type</b>	Polyp Histopathologic Type (Baseline)	Polyp Histopathologic Type (Baseline)	1="Hyperplastic polyps" 2="Hamartomatous" 3="Inflammatory polyps" 4="Tubular adenoma" 5="Tubulovillous adenoma"
<b>colon_bsl_polyp_location</b>	Polyp Location (Baseline)	Polyp Location (Baseline)	1="Cecum" 2="Ascending colon" 3="Hepatic flexure" 4="Transverse colon" 5="Splenic flexure"
<b>colon_bsl_polyp_presence</b>	Polyp Presence Of Dysplasia (Baseline)	Polyp Presence Of Dysplasia (Baseline)	1="No dysplasia" 2="Indefinite for dysplasia" 3="Low grade dysplasia" 5="Not available"
<b>colon_bsl_polyp_size_1_cm</b>	Polyp Size At Colonoscopy >= 1 cm (Baseline)	Polyp Size At Colonoscopy >= 1 cm (Baseline)	0="No" 1="Yes"
<b>colon_bsl_polyps_excised</b>	Were All Polyps Excised? (Baseline)	Were All Polyps Excised? (Baseline)	0="No" 1="Yes" 2="Not Reported"
<b>colon_bsl_proc_dt</b>	Procedure Date (Baseline)	Procedure Date (Baseline)	SAS Date
<b>colon_bsl_results</b>	Results Of Colonoscopy (Baseline)	Results Of Colonoscopy (Baseline)	1="Normal" 2="Abnormal, specify"

## Section 12: Colonoscopy Pre-Registration

Variable	Label	Description	Format Text
<b>colon_1_adenoma_type1-14</b>	Type Of Adenoma	Type of adenoma: 1=Advanced* 2=Non-advanced 3=Not applicable *Advanced adenoma-One of the following characteristics must be present: (1) >=1 cm on colonoscopy report, (2) villous or tubulovillous, or (3) high grade (severe) dysplasia. Insert pathologist's conclusions, if any, into the comments section on the electronic CRF.	.M="Missing" 1="Advanced" 2="Non-Advanced" 3="Not Applicable"
<b>colon_1_any_polyps</b>	Any Polyps Found?	Were all polyps excised? 1=Yes 2=No 3=Not reported	0="No" 1="Yes" 2="Not Reported"
<b>colon_1_bwl_prep_adeq</b>	Was Bowel Prep Adequate?	Was the overall bowel preparation adequate, good, or excellent (i.e., 90% of the rectal mucosa was well visualized. Note: preparation characterized as fair or poor is not adequate)? 1=Yes 2=No 3=Not reported	0="No" 1="Yes" 2="Not Reported"
<b>colon_1_cecum_visualized</b>	Was The Cecum Visualized?	Was the cecum visualized (including identification of cecal landmarks, i.e. ileocecal valve, appendiceal orifice, or terminal ileum)? 1=Yes 2=No 3=Not reported	1="Yes" 2="Not Reported"
<b>colon_1_configuration1-14</b>	Configuration	Configuration: 1=Pendunculated 2=Sessile 3=Not specified	.M="Missing" 1="Pendunculated" 2="Sessile" 3="Not specified"
<b>colon_1_done</b>	Colonoscopy Done?	Colonoscopy performed: 1=Yes 2=No	1="Yes"
<b>colon_1_dysplasia1-14</b>	Presence Of Dysplasia	Presence of dysplasia: 1=No dysplasia 2=Indefinite for dysplasia 3=Low grade dysplasia 4=High grade dysplasia 5=Not available	.M="Missing" 1="No dysplasia" 3="Low grade dysplasia" 4="High grade dysplasia" 5="Not available"

Variable	Label	Description	Format Text
<b>colon_1_histopath_type1-14</b>	Histopathologic Type	Histopathologic type: 1=Hyperplastic polyps 2=Hamartomatous 3=Inflammatory polyps 4=Tubular adenoma 5=Tubulovillous adenoma 6=Adenoma 7=Villous adenoma 8=Serrated adenoma 9=Not specified 10=Juvenile 11=Other, specify	.M="Missing" 1="Hyperplastic polyps" 4="Tubular adenoma" 5="Tubulovillous adenoma" 6="Adenoma" 7="Villous adenoma" 8="Serrated adenoma" 9="Not specified" 11="Other, specify"
<b>colon_1_location1-14</b>	Location	Location: 1=Cecum 2=Ascending colon 3=Hepatic flexure 4=Transverse colon 5=Splenic flexure 6=Descending colon 7=Sigmoid colon 8=Rectosigmoid Junction 9=Rectum 10=Not specified	.M="Missing" 1="Cecum" 2="Ascending colon" 3="Hepatic flexure" 4="Transverse colon" 5="Splenic flexure" 6="Descending colon" 7="Sigmoid colon" 8="Rectosigmoid junction" 9="Rectum" 10="Not specified"
<b>colon_1_location_cm1-14</b>	Location If Identified By cm Only	If location only identified by cm: __ __. __	Numeric .M="Missing"
<b>colon_1_mult_polyps1-14</b>	Multiple Polyps Per Container	Were multiple polyps/fragments placed in one specimen container? 1=Yes 2=No	.M="Missing" 0="No" 1="Yes"
<b>colon_1_num_adv_adenoma</b>	Number Of Advanced Adenomas	Total number advanced adenomas*: *Advanced adenoma-One of the following characteristics must be present: (1) greater than or equal to 1cm on colonoscopy report, (2) villous or tubulovillous, or (3) high grade (severe) dysplasia. Insert pathologist's conclusions, if any, into the comments section on the electronic CRF.	Numeric .M="Missing"
<b>colon_1_num_non_adv_adenoma</b>	Number Of Non-Advanced Adenomas	Total number non-advanced adenomas:	Numeric .M="Missing"
<b>colon_1_num_polyps1-14</b>	Polyp Number	Polyp #	Numeric .M="Missing"
<b>colon_1_oth_spec</b>	Other Specify	Other, specify	Char
<b>colon_1_oth_spec1-14</b>	Colonoscopy: Other Specify	Histopathologic Type: Other, specify (200 available characters)	Char
<b>colon_1_proc_dt</b>	Procedure Date	Procedure Date: (mm/dd/yyyy)	SAS Date



Variable	Label	Description	Format Text
<b>colon_1_rec_polyp_loc1-14</b>	Recurrent Polyp In Same Location As Baseline	(Follow Up Only) Is this recurrent polyp in the same location as a polyp identified on the baseline colonoscopy? 1=Yes 2=No 3=Unknown 4=Not specified	.M="Missing" 0="No" 2="Unknown"
<b>colon_1_rem_polyp_piece1-14</b>	Polyp Removed Piecemeal	Polyp removed piecemeal? 1=Yes 2=No	.M="Missing" 0="No" 1="Yes"
<b>colon_1_result</b>	Result Of Colonoscopy	Results of Colonoscopy: (select one) 1=Normal 2=Abnormal, specify 3=Other, specify	1="Normal" 2="Abnormal, specify"
<b>colon_1_size1-14</b>	Size At Colonoscopy (cm)	Size at Colonoscopy: 1=Diminutive (less than 5 mm) 2=Medium (5-9 mm) 3=Large (greater than or equal to 1 cm)	.M="Missing" 1="Diminutive (< 5mm)" 2="Medium (5-9mm)" 3="Large (>= 1cm)"
<b>colon_1_size_path1-14</b>	Size As Measured By Pathologist (cm)	Size as measured by Endoscopist (cm)	Numeric .M="Missing"
<b>colon_1_source1-14</b>	Form That Information Came From	Form That Information Came From	.N="N/A" 1="Colonoscopy Report" 2="Continuation Colonoscopy Report"

## Section 13: ANA Results Pre-Registration

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Variable	Label	Description	Format Text
<b>ana_1_hematology_dt</b>	Blood Hematology Date	Sample collection date: (mm/dd/yyyy)	SAS Date .M="Missing"
<b>ana_1_ratio</b>	ANA Ratio Value	Antinuclear Antibody (ANA) IU _____ : _____ The colon sign MUST be used for entry (i.e., 1:160). The less than symbol may be used if needed (i.e., <1:80)	Char

## Section 14: Blood Specimen Collection Pre-Registration

Variable	Label	Description	Format Text
<b>blood_spec_1_collected</b>	Blood Specimen Collected?	Was the specimen collected? 1=Yes, 2=No	1="Yes"
<b>blood_spec_1_dt</b>	Blood Specimen Collection Date	Date Specimen Collected: (mm/dd/yyyy)	SAS Date
<b>blood_spec_1_other_spec</b>	Reason Specimens Not Collected	Other, specify (200 available characters)	Char
<b>blood_spec_1_reason_not</b>	Reason Specimens Not Collected	Reason: (200 available characters.)	Char
<b>blood_spec_1_visit</b>	Blood Specimen Collection Visit	Blood Specimen Collection Visit	0="Baseline" 99="Other, specify"

## Section 15: Blood Chemistry Pre-Registration

Variable	Label	Description	Format Text
<b>bld_chm_1_alk_phos</b>	Alkaline Phosphatase, Serum (IU/L)	Alanine Aminotransferase (ALT/SGPT), serum IU/L (Enter numeric value only) DO NOT use decimal with entry	Numeric .M="Missing"
<b>bld_chm_1_alk_phos_clin_sig</b>	Clinically Significant: Alkaline Phosphatase	Clinically Significant: ALT	.M="Missing" 0="No" 1="Yes"
<b>bld_chm_1_alk_phos_oor</b>	Out Of Range: Alkaline Phosphatase	Out of Range: ALT	.M="Missing" 0="No" 1="Yes"
<b>bld_chm_1_alt</b>	Alanine Aminotransferase (ALT/SGPT) Serum (IU/L)	Alanine Aminotransferase (ALT/SGPT), serum IU/L (Enter numeric value only) DO NOT use decimal with entry	Numeric .M="Missing"
<b>bld_chm_1_alt_2nd</b>	Alkaline Phosphatase, Serum (IU/L) (2nd)	Alanine Aminotransferase (ALT/SGPT), serum IU/L (Enter numeric value only) DO NOT use decimal with entry	Numeric .M="Missing"
<b>bld_chm_1_alt_clin_sig</b>	Clinically Significant: Alanine Aminotransferase	Clinically Significant: ALT	.M="Missing" 0="No" 1="Yes"
<b>bld_chm_1_alt_clin_sig_2nd</b>	Clinically Significant: Alanine Aminotransferase (2nd)	Clinically Significant: ALT	.M="Missing" 0="No"
<b>bld_chm_1_alt_oor</b>	Out Of Range: Alanine Aminotransferase	Out of Range: ALT	.M="Missing" 0="No" 1="Yes"
<b>bld_chm_1_alt_oor_2nd</b>	Out Of Range: Alanine Aminotransferase (2nd)	Out of Range: ALT	.M="Missing" 0="No"
<b>bld_chm_1_ast</b>	Aspartate Aminotransferase (AST/SGPT) Serum (IU/L)	Aspartate Aminotransferase (AST/SGOT), serum IU/L (Enter numeric value only) Decimal use available with entry, if needed	Numeric .M="Missing"
<b>bld_chm_1_ast_2nd</b>	Alanine Aminotransferase (ALT/SGPT) Serum (IU/L) (2nd)	Aspartate Aminotransferase (AST/SGOT), serum IU/L (Enter numeric value only) Decimal use available with entry, if needed	Numeric .M="Missing"
<b>bld_chm_1_ast_clin_sig</b>	Clinically Significant: Aspartate Aminotransferase	Clinically Significant: AST	.M="Missing" 0="No" 1="Yes"
<b>bld_chm_1_ast_clin_sig_2nd</b>	Clinically Significant: Aspartate Aminotransferase (2nd)	Clinically Significant: AST	.M="Missing" 0="No"

Variable	Label	Description	Format Text
<b>bld_chm_1_ast_oor</b>	Out Of Range: Aspartate Aminotransferase	Out of Range: AST	.M="Missing" 0="No" 1="Yes"
<b>bld_chm_1_ast_oor_2nd</b>	Out Of Range: Aspartate Aminotransferase (2nd)	Out of Range: AST	.M="Missing" 0="No"
<b>bld_chm_1_bicarb</b>	Bicarbonate Serum (mEq/L)	Bicarbonate, serum mEq/L (Enter numeric value only) Decimal use available with entry, if needed	Numeric .M="Missing"
<b>bld_chm_1_bicarb_clin_sig</b>	Clinically Significant: Bicarbonate	Clinically Significant: Bicarbonate	.M="Missing" 0="No" 1="Yes"
<b>bld_chm_1_bicarb_oor</b>	Out Of Range: Bicarbonate	Out of Range: Bicarbonate	.M="Missing" 0="No" 1="Yes"
<b>bld_chm_1_bun</b>	Blood Urea Nitrogen (BUN) Serum (mg/dL)	Blood Urea Nitrogen (BUN), serum mg/dL (Enter numeric value) Decimal use available with entry, if needed	Numeric .M="Missing"
<b>bld_chm_1_bun_clin_sig</b>	Clinically Significant: Blood Urea Nitrogen	Clinically Significant: BUN	.M="Missing" 0="No"
<b>bld_chm_1_bun_oor</b>	Out Of Range: Blood Urea Nitrogen	Out of Range: BUN	.M="Missing" 0="No" 1="Yes"
<b>bld_chm_1_creat</b>	Creatinine Serum (mg/dL)	Creatinine, serum mg/dL (Enter numeric value only) Decimal use available with entry, if needed	Numeric .M="Missing"
<b>bld_chm_1_creat_clin_sig</b>	Clinically Significant: Creatinine	Clinically Significant: Creatinine	.M="Missing" 0="No" 1="Yes"
<b>bld_chm_1_creat_oor</b>	Out Of Range: Creatinine	Out of Range: Creatinine	.M="Missing" 0="No" 1="Yes"
<b>bld_chm_1_dt</b>	Blood Chemistry Date	Sample collection date: (mm/dd/yyyy)	SAS Date .M="Missing"
<b>bld_chm_1_dt_2nd</b>	Blood Chemistry Date (2nd)	Sample collection date: (mm/dd/yyyy)	SAS Date .M="Missing"
<b>bld_chm_1_fasting</b>	Fasting?	Fasting: 1=Yes 2=No 3=Unknown	.M="Missing"
<b>bld_chm_1_glucose</b>	Glucose Serum (mg/dL)	Glucose, serum mg/dL (Enter numeric value only) DO NOT use decimal with entry	Numeric .M="Missing"
<b>bld_chm_1_glucose_clin_sig</b>	Clinically Significant: Glucose	Clinically Significant: Glucose	.M="Missing" 0="No" 1="Yes"
<b>bld_chm_1_glucose_oor</b>	Out Of Range: Glucose	Out of Range: Glucose	.M="Missing" 0="No" 1="Yes"

Variable	Label	Description	Format Text
<b>bld_chm_1_k</b>	Potassium Serum (mmol/L)	Potassium, serum mmol/L (Enter numeric value only) Decimal use available with entry, if needed	Numeric .M="Missing"
<b>bld_chm_1_scl</b>	Chloride Serum (mmol/L)	Chloride, serum mmol/L (Enter numeric value) DO NOT use decimal with entry	Numeric .M="Missing"
<b>bld_chm_1_scl_clin_sig</b>	Clinically Significant: Chloride	Clinically Significant: Chloride	.M="Missing" 0="No"
<b>bld_chm_1_scl_oor</b>	Out Of Range: Chloride	Out of Range: Chloride	.M="Missing" 0="No" 1="Yes"
<b>bld_chm_1_sna</b>	Sodium Serum (mmol/L)	Sodium, serum mmol/L (Enter numeric value only) Decimal use available with entry, if needed	Numeric .M="Missing"
<b>bld_chm_1_sna_clin_sig</b>	Clinically Significant: Sodium	Clinically Significant: Sodium	.M="Missing" 0="No"
<b>bld_chm_1_sna_oor</b>	Out Of Range: Sodium	Out of Range: Sodium	.M="Missing" 0="No" 1="Yes"
<b>bld_chm_1_tot_bili</b>	Bilirubin Total (mg/dL)	Bilirubin, Total mg/dL (Enter numeric value only) Decimal use available with entry, if needed	Numeric .M="Missing"
<b>bld_chm_1_tot_bili_clin_sig</b>	Clinically Significant: Bilirubin	Clinically Significant: Total Bilirubin	.M="Missing" 0="No"
<b>bld_chm_1_tot_bili_oor</b>	Out Of Range: Bilirubin	Out of Range: Total Bilirubin	.M="Missing" 0="No" 1="Yes"
<b>bld_chm_1_uric</b>	Uric Acid Serum (mg/dL)	Uric Acid, serum mg/dL (Enter numeric value only) Decimal use available with entry, if needed	Numeric .M="Missing"
<b>bld_chm_1_uric_clin_sig</b>	Clinically Significant: Uric Acid	Clinically Significant: Uric Acid	.M="Missing" 0="No" 1="Yes" 2="Unknown"
<b>bld_chm_1_uric_oor</b>	Out Of Range: Uric Acid	Out of Range: Uric Acid	.M="Missing" 0="No" 1="Yes"

## Section 16: Medical And Surgical History Pre-Registration

Variable	Label	Description	Format Text
<b>medsurg_1_all_normal</b>	All Normal?	Select if all body systems are normal; leave blank if one or more are abnormal.	.M="Missing"
<b>medsurg_1_comment1-24</b>	Medical And Surgical History Comment 24	Comments (Required, provide condition/diagnosis) (200 available characters)	Char
<b>medsurg_1_dxdt1-24</b>	Date Of Diagnosis 24	Date of Diagnosis/Surgery (mm/dd/yyyy)	SAS Date .M="Missing"
<b>medsurg_1_dxsp1-24</b>	Medical And Surgical History Procedure 24	Diagnosis/Surgical Procedure (100 available characters)	Char
<b>medsurg_1_hist1-24</b>	Medical And Surgical History 24	Body System/Site (1) (100 available characters)	Char
<b>medsurg_1_visit_dt</b>	Medical Surgery And History Visit Date	Evaluation Date: (mm/dd/yyyy)	SAS Date

## Section 17: Pathology Specimen Collection Pre-Registration

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Variable	Label	Description	Format Text
<b>path_1_access_num1-2</b>	Access Number	Accession number:	Char
<b>path_1_blocks_sub1-2</b>	Blocks Submitted	Number of blocks submitted:	Numeric .M="Missing"
<b>path_1_operation_dt1-2</b>	Operation Date	Procedure Date: (mm/dd/yyyy)	SAS Date .M="Missing"
<b>path_1_oth_spec1-2</b>	Reason Not Collected: Other Specify	Other, specify (40 available characters)	Char
<b>path_1_procedure_time1-2</b>	Procedure Time	Time of Procedure: (hh/mm) ____:____ (Enter time in hour hr hr and minutes min min without colon)	SAS Time .M="Missing"
<b>path_1_rsn_not_collected1-2</b>	Reason Not Collected	If No, reason: (200 available characters.)	Char
<b>path_1_sent_dt1-2</b>	Specimens Submitted Date	Specimen Submit Date: (mm/dd/yyyy)	SAS Date .M="Missing"
<b>path_1_slides_submitted1-2</b>	Slides Submitted	Number of slides submitted:	Numeric .M="Missing"
<b>path_1_spec_submitted1-2</b>	Number Of Specimens Submitted	Was specimen submitted? 1=Yes 2=No	.M="Missing" 0="No" 1="Yes"



## Section 18: End Active Treatment Pre-Registration

Variable	Label	Description	Format Text
<b>end_at_1_comment</b>	End Active Treatment Comments	Specify: (200 available characters.)	Char
<b>end_at_1_dt</b>	End Active Treatment Date	Off Study Date: (mm/dd/yyyy) (date of follow-up call, if the patient answers, otherwise the date of post study visit)	SAS Date .F="No Record For This Visit"
<b>end_at_1_last_dose_dt</b>	End Active Treatment Last Dose Date	Last date protocol therapy was given: (mm/dd/yyyy) (date of last treatment dose on this study or date decision made not to initiate protocol treatment)	SAS Date .F="No Record For This Visit" .M="Missing"
<b>end_at_1_reason</b>	End Active Treatment Reason	Off Study Reason: 29=Ineligible (includes screen failures) 17=Adverse Event 23=Death 18=Lost to Follow-up 8=Other, specify 22=Participant Withdrawal 27=Physician Decision 28=Protocol Violation 16=Study Complete	.F="No Record For This Visit" 1="Study Complete" 2="Participant Withdrawal" 3="Physician Decision" 4="Ineligible (includes screen failures)" 9="Other, specify"

## Section 19: Participant

Variable	Label	Description	Format Text
<b>participant_ana</b>	ANA Value	ANA Value	1="Yes"
<b>participant_ana_dt</b>	ANA Date	ANA Date	SAS Date .M="Missing"
<b>participant_blood_chem</b>	Blood Chemistry Done?	Blood Chemistry Done?	1="Yes"
<b>participant_chem_dt</b>	Blood Chemistry Date	Blood Chemistry Date	SAS Date .M="Missing"
<b>participant_col_dt</b>	Blood Collection Date	Blood Collection Date	SAS Date .M="Missing"
<b>participant_colonoscopy</b>	Colonoscopy Done?	Colonoscopy Done?	1="Yes"
<b>participant_comp_dt</b>	Completion Date	Completion Date	SAS Date .M="Missing"
<b>participant_consent</b>	Consented?	Consented?	1="Yes"
<b>participant_consent_dt</b>	Consent Date	Consent Date	SAS Date
<b>participant_country</b>	Country	Country	1="US" 2="PR"
<b>participant_eligible</b>	Eligible?	Eligible?	0="No" 1="Yes"
<b>participant_end_dt1-4</b>	End Active Treatment Date 4	End Active Treatment Date 4	SAS Date .M="Missing"
<b>participant_enroll_dt</b>	Enrollment Date	Enrollment Date	SAS Date
<b>participant_ethnicity</b>	Ethnicity	Ethnicity	0="Not Hispanic Or Latino" 1="Hispanic Or Latino" 9="Unknown"
<b>participant_exam_dt</b>	Physical Exam Date	Physical Exam Date	SAS Date
<b>participant_excluded</b>	Excluded From Study?	Excluded From Study?	.M="Missing" 2="Participant Withdrawal"
<b>participant_gender</b>	Gender	Gender	0="Male" 1="Female"
<b>participant_hematology</b>	Blood Hematology Done?	Blood Hematology Done?	1="Yes"
<b>participant_hematology_dt</b>	Blood Hematology Date	Blood Hematology Date	SAS Date .M="Missing"
<b>participant_off_dt</b>	Off Study Date	Off Study Date	SAS Date
<b>participant_operation_dt</b>	Operation Date	Operation Date	SAS Date .M="Missing"

Variable	Label	Description	Format Text
<b>participant_paymen t</b>	Payment	Payment	1="Medicare/Medicaid" 2="Medicare" 3="Medicare/Private Insurance" 4="Military/VA Sponsored (NOS)" 5="Private Insurance" 6="Veterans Sponsored" 7="Other"
<b>participant_pre_reg</b>	Pre-Registered?	Pre-Registered?	.M="Missing" 1="Yes"
<b>participant_pre_reg _bld_chem</b>	Pre-Registration Blood Chemistry Done?	Pre-Registration Blood Chemistry Done?	1="Yes"
<b>participant_pre_reg _elig</b>	Pre-Registration Eligible?	Pre-Registration Eligible?	1="Yes"
<b>participant_pre_reg _hematology</b>	Pre-Registration Hematology Done?	Pre-Registration Hematology Done?	1="Yes"
<b>participant_pre_reg _phys_exam</b>	Pre-Registration Physical Exam Done?	Pre-Registration Physical Exam Done?	1="Yes"
<b>participant_pre_reg _sx</b>	Pre-Registration SX Done?	Pre-Registration SX Done?	.M="Missing"
<b>participant_proc_dt</b>	Procedure Date	Procedure Date	SAS Date
<b>participant_rand_dt</b>	Randomization Date	Randomization Date	SAS Date .M="Missing"
<b>participant_reason_ off</b>	Reason Off Study	Reason Off Study	1="Study Complete" 2="Participant Withdrawal" 3="Physician Decision" 4="Ineligible" 5="Other, Specify" 6="Adverse Event" 7="Lost To Follow-Up"
<b>participant_reg_dt</b>	Registration Date?	Registration Date?	SAS Date .M="Missing"
<b>participant_reg_elig</b>	Registration Eligible?	Registration Eligible?	.M="Missing" 1="Yes"
<b>participant_register ed</b>	Registered?	Registered?	.M="Missing" 1="Yes"
<b>participant_rsn_off_ spec</b>	Reason Off Study: Other Specify	Reason Off Study: Other Specify	Char
<b>participant_screen_ dt</b>	Screen Fail Date	Screen Fail Date	SAS Date
<b>participant_screen_ elig</b>	Screen Eligible?	Screen Eligible?	.M="Missing" 0="No"
<b>participant_screen_ fail</b>	Screen Fail?	Screen Fail?	.M="Missing" 1="Yes"
<b>participant_screen_ form</b>	Screen Form	Screen Form	0="No" 1="Yes"
<b>participant_start_dt</b>	Start Study Date	Start Study Date	SAS Date .M="Missing"
<b>participant_tac_cod e</b>	TAC Code	TAC Code	0="TAC-0" 1="TAC1"

Variable	Label	Description	Format Text
<b>participant_test_dt</b>	Test Date	Test Date	SAS Date .M="Missing"

## Section 20: Protocol Data

Variable	Label	Description	Format Text
<b>protdata_agent_administered1-4</b>	Agent Administered (Week 53)	Was agent administered? (enter one) 1=Yes 2=No, specify	.F="No Record For This Visit" .M="Missing" 0="No, Specify" 1="Yes"
<b>protdata_agent_oth_spec1-4</b>	Agent Administration, Other Specify (Week 53)	Specify (60 available characters)	Char
<b>protdata_agent_start_dt1-4</b>	Agent Start Date (Week 53)	Date (mm/dd/yyyy)	SAS Date .F="No Record For This Visit" .M="Missing"
<b>protdata_agent_time_admin1-4</b>	Agent Administration Time (Week 53)	Time: (hh:mm) __ __ __ __ (Enter time in hour hr hr and minutes min min without colon)	SAS Time .F="No Record For This Visit" .M="Missing"
<b>protdata_bp_not_obt1-4</b>	Blood Pressure Not Obtained (Week 53)	Blood Pressure Select if Not obtained, otherwise leave blank.	.F="No Record For This Visit" .M="Missing" 2="Unknown"
<b>protdata_diastolic1-4</b>	Diastolic Blood Pressure (Week 53)	Diastolic (mmHg)	Numeric .F="No Record For This Visit" .M="Missing"
<b>protdata_pulse1-4</b>	Pulse (Week 53)	Pulse Rate ____ __ __	Numeric .F="No Record For This Visit" .M="Missing"
<b>protdata_pulse_not_obt1-4</b>	Pulse Not Obtained (Week 53)	Pulse Rate Select if Not obtained, otherwise leave blank.	.F="No Record For This Visit" .M="Missing" 2="Unknown"
<b>protdata_resp_not_obt1-4</b>	Respiration Rate Not Obtained (Week 53)	Respiration Rate Select if Not obtained, otherwise leave blank.	.F="No Record For This Visit" .M="Missing" 2="Unknown"
<b>protdata_resp_rate1-4</b>	Respiration Rate (Week 53)	Respiration Rate: ____ __ __	Numeric .F="No Record For This Visit" .M="Missing"
<b>protdata_systolic1-4</b>	Systolic Blood Pressure (Week 53)	Blood Pressure: Systolic (mmHg)	Numeric .F="No Record For This Visit" .M="Missing"
<b>protdata_temp_not_obt1-4</b>	Temperature Not Obtained (Week 53)	Temperature Select if Not obtained, otherwise leave blank.	.F="No Record For This Visit" .M="Missing" 2="Unknown"
<b>protdata_temperature1-4</b>	Temperature (C) (Week 53)	Temperature (^oC): ____ __ __ . ____ __ __	Numeric .F="No Record For This Visit" .M="Missing"
<b>protdata_total_dose1-4</b>	Total Dose Amount (Week 53)	Dose 0.3 cc	Numeric .F="No Record For This Visit" .M="Missing"
<b>protdata_vaccine_site1-4</b>	Site Of Vaccine Administration (Week 53)	Site 1=Left thigh 2=Right thigh	.F="No Record For This Visit" .M="Missing" 1="Left Thigh" 2="Right Thigh"

## Section 21: Unblinding

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Variable	Label	Description	Format Text
<b>unblinding_dose</b>	Active Agent Dose (cc)	Agent Dose (cc)	Numeric .F="No Record For This Visit"
<b>unblinding_dose_freq</b>	Agent Dose Frequency	Agent Frequency	.F="No Record For This Visit" 0="x 0 doses" 2="x 2 doses" 3="x 3 doses" 4="x 4 doses"

## Section 22: Checklist Registration

Variable	Label	Description	Format Text
<b>chklist_2_ana</b>	ANA <= 1:160	ANA less than or equal to 1:160.	.F="No Record For This Visit" 1="Yes"
<b>chklist_2_ana_val</b>	ANA Ratio	ANA ____ : ____ The colon sign MUST be used for entry (i.e., 1:160). The less than symbol may be used if needed (i.e., <1:80)	Char
<b>chklist_2_contact_pref</b>	Contact Preference	Preference for contact (select one) 1=fax number 2=email	.F="No Record For This Visit" 1="Fax Number" 2="Email"
<b>chklist_2_corticosteroids</b>	Any Use Of Oral Corticosteroids	Any use of oral corticosteroids less than or equal to 12 weeks prior to Registration/Randomization.	.F="No Record For This Visit" 0="No"
<b>chklist_2_cpn</b>	Intervention At CPN Institution Under CPN Clinician Supervision	Intervention on this protocol must commence at a CPN institution under the supervision of a CPN clinician.	.F="No Record For This Visit" 1="Yes"
<b>chklist_2_ctep_arm</b>	Arm Assigned CTEP	TAC/TAD Code:	.F="No Record For This Visit" 1="TAC1"
<b>chklist_2_earliest_lab_dt</b>	Earliest Lab Report Date	Earliest laboratory test date (mm/dd/yyyy) The earliest laboratory test date must be less than or equal to the latest laboratory test date.	SAS Date .F="No Record For This Visit"
<b>chklist_2_ecog_perf</b>	ECOG Performance Status <= 1	ECOG performance status less than or equal to 1 (Karnofsky greater than or equal to 70%; see Appendix A).	.F="No Record For This Visit" 1="Yes"
<b>chklist_2_eligible</b>	Participant Eligible For Study?	Is the patient eligible for inclusion on this study?	.F="No Record For This Visit" 1="Yes"
<b>chklist_2_hemoglobin</b>	Hemoglobin > 90% Of The Lower Limit Of Institutional Normal	Hemoglobin greater than 90% of the lower limit of institutional normal.	.F="No Record For This Visit" 1="Yes"
<b>chklist_2_inter_after_reg</b>	Intervention After Registration/Randomization And <= 14 Days After	Intervention cannot begin prior to Registration/Randomization and must begin less than or equal to 14 days after Registration/Randomization.	.F="No Record For This Visit" 1="Yes"
<b>chklist_2_latest_lab_dt</b>	Latest Lab Report Date	Latest laboratory test date (mm/dd/yyyy) The latest laboratory test date must be greater than or equal to the earliest laboratory test date.	SAS Date .F="No Record For This Visit"

Variable	Label	Description	Format Text
<b>chklist_2_normal_organ</b>	Normal Marrow And Organ Function <= 28 Days Prior To Registration	Normal marrow and organ function, obtained less than or equal to 28 days prior to Registration/Randomization, and defined as follows: NOTE: These dates pertain to the following labs only.	.F="No Record For This Visit" 1="Yes"
<b>chklist_2_num_adv_adenomas</b>	Number Of Advanced Adenomas	Number of advanced adenoma on qualifying colonoscopy 1=greater than or equal to 3 2=less than 3	.F="No Record For This Visit" 1="Greater >= 3" 2="< 3"
<b>chklist_2_oth_agent</b>	Receiving Any Other Investigational Agent <= 3 Months Prior To Registration	Receiving any other investigational agent less than or equal to 3 months prior to Registration/Randomization, except innocuous agents with no known interaction with the study agent (e.g., standard dose multivitamins or topical agents for limited skin conditions).	.F="No Record For This Visit" 0="No"
<b>chklist_2_other_bio markers</b>	Other Blood Chemistry Markers <= 1.5 x Upper Limit Of Institutional Normal	AST (SGOT), ALT (SGPT), alkaline phosphatase, total bilirubin, BUN, and creatinine less than or equal to 1.5 x upper limit of institutional normal.	.F="No Record For This Visit" 1="Yes"
<b>chklist_2_performance_score</b>	ECOG Performance Score	ECOG performance status = (0 or 1)	Numeric .F="No Record For This Visit"
<b>chklist_2_platelet_val</b>	Platelet Values	Platelets (10 <sup>9</sup> /L) =	Numeric .F="No Record For This Visit"
<b>chklist_2_platelets</b>	Platelets >= 100 B/L (10 <sup>9</sup> /L)	Platelets greater than or equal to 100 B/L (10 <sup>9</sup> /L).	.F="No Record For This Visit" 1="Yes"
<b>chklist_2_wbc</b>	White Blood Cell (WBC) >= 3.5 B/L (10 <sup>9</sup> /L)	WBC greater than 2.5 B/L (10 <sup>9</sup> /L).	.F="No Record For This Visit" 1="Yes"
<b>chklist_2_wbc_val</b>	White Blood Cell (WBC) Value	WBC	Numeric .F="No Record For This Visit"



## Section 23: Demographic And Registration Data Registration

Variable	Label	Description	Format Text
<b>casecrse_2_accrual_mem</b>	Accrual Member	Accrual Member	Numeric .F="No Record For This Visit"
<b>casecrse_2_alliance_prot</b>	Alliance Protocol	Alliance Protocol	Numeric .F="No Record For This Visit"
<b>casecrse_2_cancel_rep</b>	Participant Was Canceled From Study And Replaced	Participant Was Canceled From Study And Replaced	.F="No Record For This Visit" .M="Missing" 1="Yes"
<b>casecrse_2_case</b>	Case Number	Case Number	Numeric .F="No Record For This Visit"
<b>casecrse_2_clinic_clean</b>	Clinic Number Clean	Clinic Number Clean	Numeric .F="No Record For This Visit" .M="Missing"
<b>casecrse_2_ctep_id</b>	CTEP ID	CTEP ID	Char
<b>casecrse_2_cur_dc</b>	Current Date Center	Current Date Center	.F="No Record For This Visit" 2806="CPN"
<b>casecrse_2_cur_grp</b>	Current Group	Current Group	.F="No Record For This Visit" 2806="CPN"
<b>casecrse_2_cur_loc</b>	Current Location	Current Location	.F="No Record For This Visit" 1="MC Rochester" 2="U of Pitt" 3="Thomas Jefferson" 4="Mass General Hosp CC" 5="VA Kansas Cty" 6="Univ PR - treating site"
<b>casecrse_2_cur_member</b>	Current Member	Current Member	.F="No Record For This Visit" 1="Mayo" 2="U of Pitt" 3="Univ PR" 4="Mass General Hosp CC" 5="JeffersonHsp" 6="KS City VA"
<b>casecrse_2_cur_org</b>	Current Organization Number	Current Organization Number	.F="No Record For This Visit" 1="Mayo" 2="U of Pitt" 3="Univ PR" 4="Mass General Hosp CC" 5="JeffersonHsp" 6="KS City VA"
<b>casecrse_2_cur_rel_type</b>	Current Organization Relationship Type	Current Organization Relationship Type	.F="No Record For This Visit" 1="Component" 2="Affiliate"
<b>casecrse_2_data_center</b>	Data Center	Data Center	Char
<b>casecrse_2_dka_source</b>	Date Known Alive Source	Date Known Alive Source	.F="No Record For This Visit" 1="Ingres"

Variable	Label	Description	Format Text
<b>casecrse_2_dka_var</b>	Date Known Alive Source Variable	Date Known Alive Source Variable	.F="No Record For This Visit" .M="Missing" 2="chem_dt" 3="col_dt1" 4="dose1_dt" 5="exam_dt" 6="hem_dt" 7="injectdt" 8="oper_dt" 9="proc_dt"
<b>casecrse_2_dt_dea d</b>	Death Date	Death Date	SAS Date .F="No Record For This Visit" .M="Missing"
<b>casecrse_2_dt_last alive</b>	Date Last Known Alive	Date Last Known Alive	SAS Date .F="No Record For This Visit"
<b>casecrse_2_dt_off</b>	Date Off	Date Off	SAS Date .F="No Record For This Visit"
<b>casecrse_2_dt_on</b>	Date On	Date On	SAS Date .F="No Record For This Visit"
<b>casecrse_2_dt_on_ arm</b>	Date On Current Arm	Date On Current Arm	SAS Date .F="No Record For This Visit"
<b>casecrse_2_end_tx_ dt</b>	End Active Treatment	End Active Treatment	SAS Date .F="No Record For This Visit"
<b>casecrse_2_end_tx_ reason</b>	Reason End Treatment	Reason End Treatment	.F="No Record For This Visit" 1="Study Complete" 2="Participant Withdrawal" 5="Other, Specify" 6="Adverse Event" 7="Lost to Follow-Up"
<b>casecrse_2_epp</b>	Extended Participant Project	Extended Participant Project	.F="No Record For This Visit" 0="No"
<b>casecrse_2_ex_ref_ id</b>	External Reference Number	External Reference Number	Char
<b>casecrse_2_fu_dt</b>	Follow-Up Date	Follow-Up Date	SAS Date .F="No Record For This Visit"
<b>casecrse_2_fu_stat</b>	Follow-Up Status	Follow-Up Status	.F="No Record For This Visit" 1="Alive"
<b>casecrse_2_fu_stud y</b>	Follow-Up Study	Follow-Up Study	Numeric .F="No Record For This Visit" .M="Missing"
<b>casecrse_2_labels_ printed</b>	Randomization Labels Printed	Randomization Labels Printed	.F="No Record For This Visit" .M="Missing" 1="Printed"
<b>casecrse_2_mayo_ id</b>	Mayo ID	Mayo ID	Numeric .F="No Record For This Visit" .M="Missing"
<b>casecrse_2_mayo_p rotocol</b>	Mayo Protocol	Mayo Protocol	.F="No Record For This Visit" 1="Yes"
<b>casecrse_2_ncc_pr otocol</b>	NCCTG Protocol	NCCTG Protocol	.F="No Record For This Visit" 0="No"

Variable	Label	Description	Format Text
<b>casecrse_2_pay_method</b>	Payment Method	Payment Method	.F="No Record For This Visit" 1="Medicare/Medicaid" 2="Medicare" 3="Medicare/Private Insurance" 4="Military/VA Sponsored (NOS)" 5="Private Insurance" 6="Veterans Sponsored" 7="Other"
<b>casecrse_2_prot_num</b>	Data Center Assigned Protocol Number	Data Center Assigned Protocol Number	.F="No Record For This Visit" .M="Missing" 1="MAY2013-01-01"
<b>casecrse_2_protocol</b>	Data Center Assigned Protocol Number	Data Center Assigned Protocol Number	Char
<b>casecrse_2_status</b>	Status	Status	Numeric .F="No Record For This Visit"
<b>casecrse_2_study_num</b>	Ingres Study Number	Ingres Study Number	Numeric .F="No Record For This Visit"
<b>casecrse_2_subject_num</b>	Subject Number	Subject Number	Numeric .F="No Record For This Visit"
<b>casecrse_2_transfer_dt</b>	Transfer Date	Transfer Date	SAS Date .F="No Record For This Visit" .M="Missing"

## Section 24: Blood Hematology Registration

Variable	Label	Description	Format Text
intvlab_2_anc_csig1-4	Clinically Significant: Neutrophils (Week 55)	Clinically Significant: ANC	.F="No Record For This Visit" .M="Missing" .N="N/A" 0="No" 1="Yes"
intvlab_2_anc_oor1-4	Out Of Range: Neutrophils (Week 55)	Out of Range: ANC	.F="No Record For This Visit" .M="Missing" .N="N/A" 0="No" 1="Yes"
intvlab_2_anc_val1-4	ANC Lab Value (# Blood 10 <sup>9</sup> /L)	Neutrophils (ANC), #, Blood 10 <sup>9</sup> /L (enter numeric value only) Decimal use available with entry, if needed	Numeric .F="No Record For This Visit" .M="Missing" .N="N/A"
intvlab_2_basos_csig1-4	Clinically Significant: Basophils (Week 55)	Clinically Significant: Basophils	.F="No Record For This Visit" .M="Missing" .N="N/A" 0="No"
intvlab_2_basos_oor1-4	Out Of Range: Basophils (Week 55)	Out of Range: Basophils	.F="No Record For This Visit" .M="Missing" .N="N/A" 0="No" 1="Yes"
intvlab_2_basos_val1-4	Basophils Lab Value (# Blood 10 <sup>9</sup> /L) (Week 55)	Basophils, #, Blood 10 <sup>9</sup> /L (Enter numeric value only) Decimal use available with entry, if needed	Numeric .F="No Record For This Visit" .M="Missing" .N="N/A"
intvlab_2_eosinos_csig1-4	Clinically Significant: Eosinophils (Week 55)	Clinically Significant: Eosinophils	.F="No Record For This Visit" .M="Missing" .N="N/A" 0="No" 1="Yes"
intvlab_2_eosinos_oor1-4	Out Of Range: Eosinophils (Week 55)	Out of Range: Eosinophils	.F="No Record For This Visit" .M="Missing" .N="N/A" 0="No" 1="Yes"
intvlab_2_eosinos_val1-4	Eosinophils Lab Value (# Blood 10 <sup>9</sup> /L) (Week 55)	Eosinophils, #, Blood 10 <sup>9</sup> /L (Enter numeric value only) Decimal use available with entry, if needed	Numeric .F="No Record For This Visit" .M="Missing" .N="N/A"
intvlab_2_hema_dt1-4	Hematology Date (Week 55)	Sample collection date: (mm/dd/yyyy)	SAS Date .F="No Record For This Visit" .M="Missing" .N="N/A"
intvlab_2_hemato_csig1-4	Clinically Significant: Hematocrit (Week 55)	Clinically Significant: Hematocrit	.F="No Record For This Visit" .M="Missing" .N="N/A" 0="No" 1="Yes"

Variable	Label	Description	Format Text
<b>intvlab_2_hemato_or1-4</b>	Out Of Range: Hematocrit (Week 55)	Out of Range: Hematocrit	.F="No Record For This Visit" .M="Missing" .N="N/A" 0="No" 1="Yes"
<b>intvlab_2_hemato_val1-4</b>	Hematocrit Lab Value (%) (Week 55)	Hematocrit % (Enter numeric value only) Decimal use available with entry, if needed	Numeric .F="No Record For This Visit" .M="Missing" .N="N/A"
<b>intvlab_2_hgb_cs1-4</b>	Clinically Significant: Hemoglobin (Week 55)	Clinically Significant: HGB	.F="No Record For This Visit" .M="Missing" .N="N/A" 0="No" 1="Yes"
<b>intvlab_2_hgb_oor1-4</b>	Out Of Range: Hemoglobin (Week 55)	Out of Range: HGB	.F="No Record For This Visit" .M="Missing" .N="N/A" 0="No" 1="Yes"
<b>intvlab_2_hgb_val1-4</b>	Hemoglobin Lab Value (g/dL) (Week 55)	Hemoglobin, Blood g/dL (Enter numeric value only) Decimal use available with entry, if needed	Numeric .F="No Record For This Visit" .M="Missing" .N="N/A"
<b>intvlab_2_lymph_cs1-4</b>	Clinically Significant: Lymphocytes (Week 55)	Clinically Significant: Lymphocytes	.F="No Record For This Visit" .M="Missing" .N="N/A" 0="No" 1="Yes"
<b>intvlab_2_lymph_oor1-4</b>	Out Of Range: Lymphocytes (Week 55)	Out of Range: Lymphocytes	.F="No Record For This Visit" .M="Missing" .N="N/A" 0="No" 1="Yes"
<b>intvlab_2_lymph_val1-4</b>	Lymphocytes Lab Value (# Blood 10 <sup>9</sup> /L) (Week 55)	Lymphocytes, #, Blood 10 <sup>9</sup> /L (Enter numeric value only) Decimal use available with entry, if needed	Numeric .F="No Record For This Visit" .M="Missing" .N="N/A"
<b>intvlab_2_monos_cs1-4</b>	Clinically Significant: Monocytes (Week 55)	Clinically Significant: Monocytes	.F="No Record For This Visit" .M="Missing" .N="N/A" 0="No"
<b>intvlab_2_monos_oor1-4</b>	Out Of Range: Monocytes (Week 55)	Out of Range: Monocytes	.F="No Record For This Visit" .M="Missing" .N="N/A" 0="No" 1="Yes"
<b>intvlab_2_monos_val1-4</b>	Monocytes Lab Value (# Blood 10 <sup>9</sup> /L) (Week 55)	Monocytes, #, Blood 10 <sup>9</sup> /L (Enter numeric value only) Decimal use available with entry, if needed	Numeric .F="No Record For This Visit" .M="Missing" .N="N/A"
<b>intvlab_2_plt_cs1-4</b>	Clinically Significant: Platelets (Week 55)	Clinically Significant: Platelets	.F="No Record For This Visit" .M="Missing" .N="N/A" 0="No" 1="Yes"

Variable	Label	Description	Format Text
<b>intvlab_2_plt_oor1-4</b>	Out Of Range: Platelets (Week 55)	Out of Range: Platelets	.F="No Record For This Visit" .M="Missing" .N="N/A" 0="No" 1="Yes"
<b>intvlab_2_plt_val1-4</b>	Platelets Lab Value (# Blood 10 <sup>9</sup> /L) (Week 55)	Platelets, Blood 10 <sup>9</sup> /L (Enter numeric value only) DO NOT use decimal or comma with entry	Numeric .F="No Record For This Visit" .M="Missing" .N="N/A"
<b>intvlab_2_rbc_csig1-4</b>	Clinically Significant: Red Blood Cells (Week 55)	Clinically Significant: RBC	.F="No Record For This Visit" .M="Missing" .N="N/A" 0="No" 1="Yes"
<b>intvlab_2_rbc_oor1-4</b>	Out Of Range: Red Blood Cells (Week 55)	Out of Range: RBC	.F="No Record For This Visit" .M="Missing" .N="N/A" 0="No" 1="Yes"
<b>intvlab_2_rbc_val1-4</b>	Red Blood Cells Lab Value (# Blood 10 <sup>12</sup> /L)	Red Blood Cells (RBC), #, Blood 10 <sup>12</sup> /L (Enter numeric value only) Decimal use available with entry, if needed	Numeric .F="No Record For This Visit" .M="Missing" .N="N/A"
<b>intvlab_2_wbc_csig1-4</b>	Clinically Significant: White Blood Cells (Week 55)	Clinically Significant: WBC	.F="No Record For This Visit" .M="Missing" .N="N/A" 0="No" 1="Yes"
<b>intvlab_2_wbc_oor1-4</b>	Out Of Range: White Blood Cells (Week 55)	Out of Range: WBC	.F="No Record For This Visit" .M="Missing" .N="N/A" 0="No" 1="Yes"
<b>intvlab_2_wbc_val1-4</b>	White Blood Cells Lab Value (# Blood 10 <sup>9</sup> /L) (Week 55)	White Blood Cells (WBC), #, Blood 10 <sup>9</sup> /L (Enter numeric value only) Decimal use available with entry, if needed	Numeric .F="No Record For This Visit" .M="Missing" .N="N/A"

## Section 25: Physical Exam Registration

Variable	Label	Description	Format Text
<b>phys_2_abdomen_com1-2</b>	Comments: Abdomen	Comments: Abdomen	Char
<b>phys_2_abdomen_stat1-2</b>	Status: Abdomen	Abdomen 1=Normal 2=Abnormal 3=Not Assessed	.F="No Record For This Visit" .M="Missing" 1="Normal" 2="Abnormal"
<b>phys_2_allergy1-2</b>	Does Participant Have Any Allergies?	Does the participant have any allergies? 1=Yes 2=No	.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"
<b>phys_2_allergy_spec1-2</b>	Allergies: Other Specify	If Yes, specify (allergies): (200 available characters)	Char
<b>phys_2_appear_com1-2</b>	Comments: Appearance	Comments: Appearance	Char
<b>phys_2_appear_stat1-2</b>	Status: Appearance	Appearance 1=Normal 2=Abnormal 3=Not Assessed	.F="No Record For This Visit" .M="Missing" 1="Normal" 2="Abnormal"
<b>phys_2_cardio_com1-2</b>	Comments: Cardiovascular	Comments: Cardiovascular	Char
<b>phys_2_cardio_stat1-2</b>	Status: Cardiovascular	Cardiovascular 1=Normal 2=Abnormal 3=Not Assessed	.F="No Record For This Visit" .M="Missing" 1="Normal" 2="Abnormal" 3="Not Assessed"
<b>phys_2_cerv_lymph_com1-2</b>	Comments: Cervical Lymph Nodes	Comments: Cervical Lymph Nodes	Char
<b>phys_2_cerv_lymph_stat1-2</b>	Status: Cervical Lymph Nodes	Cervical Lymph Nodes 1=Normal 2=Abnormal 3=Not Assessed	.F="No Record For This Visit" .M="Missing" 1="Normal"
<b>phys_2_diastolic1-2</b>	Diastolic Blood Pressure	Diastolic: ___ ___ ___ (mm Hg)	Numeric .F="No Record For This Visit" .M="Missing"
<b>phys_2_exam_dt1-2</b>	Physical Exam Date	Evaluation Date: (mm/dd/yyyy)	SAS Date .F="No Record For This Visit" .M="Missing"
<b>phys_2_heent_com1-2</b>	Comments: H/E/E/N/T	Comments: H/E/E/N/T	Char
<b>phys_2_heent_stat1-2</b>	Status: H/E/E/N/T	H/E/E/N/T 1=Normal 2=Abnormal 3=Not Assessed	.F="No Record For This Visit" .M="Missing" 1="Normal" 2="Abnormal"

Variable	Label	Description	Format Text
<b>phys_2_height1-2</b>	Height (cm)	Height (cm) ____ ____ ____.____ The range for height is 135 to 210. If study participants height is not within this range and has been verified to be correct, Click on the validated button. If "Not Obtained" select the "Not Done" radio button.	Numeric .F="No Record For This Visit" .M="Missing"
<b>phys_2_ing_lymph_com1-2</b>	Comments: Inguinal Lymph Nodes	Comments: Inguinal Lymph Nodes	Char
<b>phys_2_ing_lymph_stat1-2</b>	Status: Inguinal Lymph Nodes	Inguinal Lymph Nodes 1=Normal 2=Abnormal 3=Not Assessed	.F="No Record For This Visit" .M="Missing" 1="Normal" 3="Not Assessed"
<b>phys_2_musculo_com1-2</b>	Comments: Musculoskeletal	Comments: Musculoskeletal	Char
<b>phys_2_musculo_stat1-2</b>	Status: Musculoskeletal	Musculoskeletal 1=Normal 2=Abnormal 3=Not Assessed	.F="No Record For This Visit" .M="Missing" 1="Normal" 2="Abnormal"
<b>phys_2_oth_site1-2</b>	Other Site	Specify Other Body System/Site (40 available characters)	Char
<b>phys_2_oth_site_com1-2</b>	Comments: Other Site	Comments: Other Body Site 1	Char
<b>phys_2_oth_site_stat1-2</b>	Status: Other Site	Other Site 1 1=Normal 2=Abnormal 3=Not Assessed	.F="No Record For This Visit" .M="Missing" 1="Normal" 3="Not Assessed"
<b>phys_2_performed1-2</b>	Physical Exam Performed?	Pulse: ____ ____	Numeric .F="No Record For This Visit" .M="Missing"
<b>phys_2_pulse1-2</b>	Pulse	Comments: Respiratory	Char .F="No Record For This Visit" .M="Missing"
<b>phys_2_respiratory_com1-2</b>	Comments: Respiratory	Respiratory 1=Normal 2=Abnormal 3=Not Assessed	Char
<b>phys_2_respiratory_stat1-2</b>	Status: Respiratory	Performance Status (ECOG) (Pre-Intervention only): (0, 1, 2, 3, 4)	.F="No Record For This Visit" .M="Missing" 1="Normal" 2="Abnormal" 3="Not Assessed"
<b>phys_2_skin_com1-2</b>	Comments: Skin	Comments: Skin	Char
<b>phys_2_skin_stat1-2</b>	Status: Skin	Skin 1=Normal 2=Abnormal 3=Not Assessed	.F="No Record For This Visit" .M="Missing" 1="Normal" 2="Abnormal"
<b>phys_2_systolic1-2</b>	Systolic Blood Pressure	Blood Pressure: Systolic: ____ ____ (mm Hg)	Numeric .F="No Record For This Visit" .M="Missing"



Variable	Label	Description	Format Text
<b>phys_2_temperature1-2</b>	Temperature (c)	Body temperature __ __ __ . __ __ ^0C	Numeric .F="No Record For This Visit" .M="Missing"
<b>phys_2_thyroid_comment1-2</b>	Comments: Thyroid	Comments: Thyroid	Char
<b>phys_2_thyroid_status1-2</b>	Status: Thyroid	Thyroid 1=Normal 2=Abnormal 3=Not Assessed	.F="No Record For This Visit" .M="Missing" 1="Normal" 3="Not Assessed"
<b>phys_2_weight1-2</b>	Weight (kg)	Weight (kg) __ __ . __ __ The range for weight is 36.3 to 136.1. If study participants weight is not within this range and has been verified to be correct Click on the validated button.	Numeric .F="No Record For This Visit" .M="Missing"

## Section 26: Pregnancy Test Registration

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Variable	Label	Description	Format Text
<b>preg_test_2_dt1-4</b>	Pregnancy Test Date (Week 53)	Date Specimen Collected: (mm/dd/yyyy)	SAS Date .F="No Record For This Visit" .M="Missing"
<b>preg_test_2_result1-4</b>	1 = "Not Obtained" 2 = "Positive" 3 = "Negative" 4 = "Not applicable, not female of child bearing potential"	Pregnancy Test Result: 2=Positive 3=Negative 1=Not obtained 4=Not applicable, not female of child-bearing potential	Numeric .F="No Record For This Visit"
<b>preg_test_2_spec_source1-4</b>	1 = "Urine" 2 = "Serum"	Pregnancy Test Type: 1=Urine 2=Serum	Numeric .F="No Record For This Visit" .M="Missing"

## Section 27: Colonoscopy Intervention

Variable	Label	Description	Format Text
<b>colon_int_adeno_rec</b>	Adenoma Recurrence (Week 156)	Adenoma Recurrence (Week 156)	.F="No Record For This Visit" 0="No" 1="Yes"
<b>colon_int_adeno_rec_dif</b>	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)	.F="No Record For This Visit" 0="No" 1="Yes"
<b>colon_int_adenoma_sum</b>	Sum Of Adenomas (Week 156)	Sum Of Adenomas (Week 156)	Numeric .F="No Record For This Visit"
<b>colon_int_adv_adeno_rec</b>	Advanced Adenoma Recurrence (Week 156)	Advanced Adenoma Recurrence (Week 156)	.F="No Record For This Visit" 0="No" 1="Yes"
<b>colon_int_bowel_prep_adequate</b>	Was The Overall Bowel Preparation Adequate, Good, Or Excellent? (Week 156)	Was The Overall Bowel Preparation Adequate, Good, Or Excellent? (Week 156)	.F="No Record For This Visit" 0="No" 1="Yes" 2="Not Reported"
<b>colon_int_cecum_visualized</b>	Was The Cecum Visualized? (Week 156)	Was The Cecum Visualized? (Week 156)	.F="No Record For This Visit" 0="No" 1="Yes"
<b>colon_int_fu_colo</b>	Time From Week 0 Injection To Follow-Up Colonoscopy (Days)	Time From Week 0 Injection To Follow-Up Colonoscopy (Days)	Numeric .F="No Record For This Visit"
<b>colon_int_lg_adeno_rec</b>	>5 Mm Adenoma Recurrence (Week 156)	>5 Mm Adenoma Recurrence (Week 156)	.F="No Record For This Visit" 0="No" 1="Yes"
<b>colon_int_lg_adeno_rec_dif</b>	>=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)	.F="No Record For This Visit" 0="No" 1="Yes"
<b>colon_int_mean_pathsize</b>	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 .F="No Record For This Visit" .M="Missing"
<b>colon_int_mult_adenomas</b>	Multiple Adenomas (Week 156)	Multiple Adenomas (Week 156)	.F="No Record For This Visit" 0="No" 1="Yes"
<b>colon_int_mult_adv_adenomas</b>	Multiple Advanced Adenomas (Week 156)	Multiple Advanced Adenomas (Week 156)	.F="No Record For This Visit" 0="No" 1="Yes"
<b>colon_int_num_adenoma_polyp</b>	Number Of Adenoma Polyps (Week 156)	Number Of Adenoma Polyps (Week 156)	Numeric .F="No Record For This Visit" .M="Missing"
<b>colon_int_num_adv_adenoma</b>	Total Number Advanced Adenomas (Week 156)	Total Number Advanced Adenomas (Week 156)	Numeric .F="No Record For This Visit"
<b>colon_int_num_adv_adenoma_cat</b>	Total Number Advanced Adenomas (Week 156)	Total Number Advanced Adenomas (Week 156)	Numeric .F="No Record For This Visit"

Variable	Label	Description	Format Text
<b>colon_int_num_adv_adenoma_polyp</b>	Number Of Advanced Adenomas (Week 156)	Number Of Advanced Adenomas (Week 156)	Numeric .F="No Record For This Visit" .M="Missing"
<b>colon_int_num_cecum_polyp</b>	Number Of Polyps In Cecum (Week 156)	Number Of Polyps In Cecum (Week 156)	Numeric .F="No Record For This Visit" .M="Missing"
<b>colon_int_num_desc_c_polyp</b>	Number Of Polyps In Descending Colon	Number Of Polyps In Descending Colon	Numeric .F="No Record For This Visit" .M="Missing"
<b>colon_int_num_diminutive_polyp</b>	Number Of Diminutive Polyps (<mm) (Week 156)	Number Of Diminutive Polyps (<mm) (Week 156)	Numeric .F="No Record For This Visit" .M="Missing"
<b>colon_int_num_hemart_polyp</b>	Number Of Hemartomatous Polyps (Week 156)	Number Of Hemartomatous Polyps (Week 156)	Numeric .F="No Record For This Visit" .M="Missing"
<b>colon_int_num_hepatic_f_polyp</b>	Number Of Polyps In Hepatic Flexure (Week 156)	Number Of Polyps In Hepatic Flexure (Week 156)	Numeric .F="No Record For This Visit" .M="Missing"
<b>colon_int_num_high_dysp_polyp</b>	Number Of Polyps With High Grade Dysplasia (Week 156)	Number Of Polyps With High Grade Dysplasia (Week 156)	Numeric .F="No Record For This Visit" .M="Missing"
<b>colon_int_num_hyperplastic_polyp</b>	Number Of Hyperplastic Polyps (Week 156)	Number Of Hyperplastic Polyps (Week 156)	Numeric .F="No Record For This Visit" .M="Missing"
<b>colon_int_num_indef_dysp_polyp</b>	Number Of Polyps Indefinite For Dysplasia (Week 156)	Number Of Polyps Indefinite For Dysplasia (Week 156)	Numeric .F="No Record For This Visit" .M="Missing"
<b>colon_int_num_inflammatory_polyp</b>	Number Of Inflammatory Polyps (Week 156)	Number Of Inflammatory Polyps (Week 156)	Numeric .F="No Record For This Visit" .M="Missing"
<b>colon_int_num_juvenile_polyp</b>	Number Of Juvenile Polyps	Number Of Juvenile Polyps	Numeric .F="No Record For This Visit" .M="Missing"
<b>colon_int_num_large_polyp</b>	Number Of Large Polyps (>9mm) (Week 156)	Number Of Large Polyps (>9mm) (Week 156)	Numeric .F="No Record For This Visit" .M="Missing"
<b>colon_int_num_low_dysp_polyp</b>	Number Of Polyps With Low Grade Dysplasia (Week 156)	Number Of Polyps With Low Grade Dysplasia (Week 156)	Numeric .F="No Record For This Visit" .M="Missing"
<b>colon_int_num_medium_polyp</b>	Number Of Medium Polyps (5-9mm) (Week 156)	Number Of Medium Polyps (5-9mm) (Week 156)	Numeric .F="No Record For This Visit" .M="Missing"
<b>colon_int_num_na_adenoma_polyp</b>	Number Of Not Applicable Adenomas (Week 156)	Number Of Not Applicable Adenomas (Week 156)	Numeric .F="No Record For This Visit" .M="Missing"
<b>colon_int_num_na_grade_polyp</b>	Number Of Polyps With Grade Of Dysplasia Not Available (Week 156)	Number Of Polyps With Grade Of Dysplasia Not Available (Week 156)	Numeric .F="No Record For This Visit" .M="Missing"
<b>colon_int_num_no_dysp_polyp</b>	Number Of Polyps With No Dysplasia (Week 156)	Number Of Polyps With No Dysplasia (Week 156)	Numeric .F="No Record For This Visit" .M="Missing"

Variable	Label	Description	Format Text
<b>colon_int_num_no_loc_polyp</b>	Number Of Polyps In Unspecified Location (Week 156)	Number Of Polyps In Unspecified Location (Week 156)	Numeric .F="No Record For This Visit" .M="Missing"
<b>colon_int_num_non_adv_aden_polyp</b>	Number Of Non-Advanced Adenomas (Week 156)	Number Of Non-Advanced Adenomas (Week 156)	Numeric .F="No Record For This Visit" .M="Missing"
<b>colon_int_num_non_adv_adenoma</b>	Total Number Non-Advanced Adenomas (Week 156)	Total Number Non-Advanced Adenomas (Week 156)	Numeric .F="No Record For This Visit"
<b>colon_int_num_non_spec_config</b>	Number Of Non-Specified Configurations (Week 156)	Number Of Non-Specified Configurations (Week 156)	Numeric .F="No Record For This Visit" .M="Missing"
<b>colon_int_num_not_spec_polyp</b>	Number Of Not Specified Polyps (Week 156)	Number Of Not Specified Polyps (Week 156)	Numeric .F="No Record For This Visit" .M="Missing"
<b>colon_int_num_pen_diculated</b>	Number Of Pendiculated Configurations (Week 156)	Number Of Pendiculated Configurations (Week 156)	Numeric .F="No Record For This Visit" .M="Missing"
<b>colon_int_num_poly_p_ascending</b>	Number Of Polyps In Ascending Colon (Week 156)	Number Of Polyps In Ascending Colon (Week 156)	Numeric .F="No Record For This Visit" .M="Missing"
<b>colon_int_num_rectosig_polyp</b>	Number Of Polyps In Rectosigmoid Junction (Week 156)	Number Of Polyps In Rectosigmoid Junction (Week 156)	Numeric .F="No Record For This Visit" .M="Missing"
<b>colon_int_num_rectum_polyps</b>	Number Of Polyps In Rectum (Week 156)	Number Of Polyps In Rectum (Week 156)	Numeric .F="No Record For This Visit" .M="Missing"
<b>colon_int_num_removed_polyps</b>	Number Of Polyps Removed Piecemeal (Week 156)	Number Of Polyps Removed Piecemeal (Week 156)	Numeric .F="No Record For This Visit" .M="Missing"
<b>colon_int_num_serrated_polyps</b>	Number Of Serrated Polyps (Week 156)	Number Of Serrated Polyps (Week 156)	Numeric .F="No Record For This Visit" .M="Missing"
<b>colon_int_num_sessile_config</b>	Number Of Sessile Configurations (Week 156)	Number Of Sessile Configurations (Week 156)	Numeric .F="No Record For This Visit" .M="Missing"
<b>colon_int_num_sigmoid_polyps</b>	Number Of Polyps In Sigmoid Colon (Week 156)	Number Of Polyps In Sigmoid Colon (Week 156)	Numeric .F="No Record For This Visit" .M="Missing"
<b>colon_int_num_splenic_polyp</b>	Number Of Polyps In Splenic Flexure (Week 156)	Number Of Polyps In Splenic Flexure (Week 156)	Numeric .F="No Record For This Visit" .M="Missing"
<b>colon_int_num_trans_colon_polyp</b>	Number Of Polyps In Transcending Colon (Week 156)	Number Of Polyps In Transcending Colon (Week 156)	Numeric .F="No Record For This Visit" .M="Missing"
<b>colon_int_num_tubular_polyp</b>	Number Of Tubular Polyps (Week 156)	Number Of Tubular Polyps (Week 156)	Numeric .F="No Record For This Visit" .M="Missing"
<b>colon_int_num_tubulo_polyp</b>	Number Of Tubulovillous Polyps (Week 156)	Number Of Tubulovillous Polyps (Week 156)	Numeric .F="No Record For This Visit" .M="Missing"

Variable	Label	Description	Format Text
<b>colon_int_num_villous_polyp</b>	Number Of Villous Polyps (Week 156)	Number Of Villous Polyps (Week 156)	Numeric .F="No Record For This Visit" .M="Missing"
<b>colon_int_oth_spec</b>	If Abnormal Or Other, Specify (Week 156)	If Abnormal Or Other, Specify (Week 156)	Char
<b>colon_int_performed</b>	Colonoscopy Performed (Week 156)	Colonoscopy Performed (Week 156)	.F="No Record For This Visit" 1="Yes"
<b>colon_int_polyp_hist_type</b>	Polyp Histopathologic Type (Week 156)	Polyp Histopathologic Type (Week 156)	.F="No Record For This Visit" .M="Missing" 1="Hyperplastic polyps" 4="Tubular adenoma" 5="Tubulovillous adenoma" 8="Serrated adenoma"
<b>colon_int_polyp_loc</b>	Polyp Location (Week 156)	Polyp Location (Week 156)	.F="No Record For This Visit" 1="Cecum" 2="Ascending colon" 3="Hepatic flexure" 4="Transverse colon" 5="Splenic flexure"
<b>colon_int_polyp_presence</b>	Polyp Presence Of Dysplasia (Week 156)	Polyp Presence Of Dysplasia (Week 156)	.F="No Record For This Visit" 2="Indefinite for dysplasia" 3="Low grade dysplasia" 5="Not available"
<b>colon_int_polyp_size_1_cm</b>	Polyp Size At Colonoscopy >= 1 cm (Week 156)	Polyp Size At Colonoscopy >= 1 cm (Week 156)	.F="No Record For This Visit" 0="No" 1="Yes"
<b>colon_int_polyps_excised</b>	Were All Polyps Excised? (Week 156)	Were All Polyps Excised? (Week 156)	.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes" 2="Not Reported"
<b>colon_int_proc_dt</b>	Procedure Date (Week 156)	Procedure Date (Week 156)	SAS Date .F="No Record For This Visit"
<b>colon_int_rec_adenoma_same</b>	Is This Recurrent Adenoma In The Same Location As An Advanced Adenoma Identified At Baseline (Week 156)	Is This Recurrent Adenoma In The Same Location As An Advanced Adenoma Identified At Baseline (Week 156)	.F="No Record For This Visit" 0="No" 1="Yes"
<b>colon_int_results</b>	Results Of Colonoscopy (Week 156)	Results Of Colonoscopy (Week 156)	.F="No Record For This Visit" .M="Missing" 1="Normal" 2="Abnormal, specify" 3="Other, specify"
<b>colon_int_visit_spec</b>	If Other Visit, Specify (Week 156)	If Other Visit, Specify (Week 156)	Char

## Section 28: Colonoscopy Registration

Variable	Label	Description	Format Text
<b>colon_2_adenoma_type1-14</b>	Type Of Adenoma	Type of adenoma: 1=Advanced* 2=Non-advanced 3=Not applicable *Advanced adenoma-One of the following characteristics must be present: (1) >=1 cm on colonoscopy report, (2) villous or tubulovillous, or (3) high grade (severe) dysplasia. Insert pathologist's conclusions, if any, into the comments section on the electronic CRF.	.F="No Record For This Visit" .M="Missing" 1="Advanced" 2="Non-Advanced" 3="Not Applicable"
<b>colon_2_any_polyps</b>	Were All Polyps Excised?	Were all polyps excised? 1=Yes 2=No 3=Not reported	.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes" 2="Not Reported"
<b>colon_2_bwl_prep_adeq</b>	Was Bowel Prep Adequate?	Was the overall bowel preparation adequate, good, or excellent (i.e., 90% of the rectal mucosa was well visualized. Note: preparation characterized as fair or poor is not adequate)? 1=Yes 2=No 3=Not reported	.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes" 2="Not Reported"
<b>colon_2_cecum_visualized</b>	Was The Cecum Visualized?	Was the cecum visualized (including identification of cecal landmarks, i.e. ileocecal valve, appendiceal orifice, or terminal ileum)? 1=Yes 2=No 3=Not reported	.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"
<b>colon_2_configuration1-14</b>	Configuration	Configuration: 1=Pendunculated 2=Sessile 3=Not specified	.F="No Record For This Visit" .M="Missing" 1="Pendunculated" 2="Sessile" 3="Not specified"
<b>colon_2_done</b>	Colonoscopy Done?	Colonoscopy performed: 1=Yes 2=No	.F="No Record For This Visit" 0="No" 1="Yes"
<b>colon_2_dysplasia1-14</b>	Presence Of Dysplasia	Presence of dysplasia: 1=No dysplasia 2=Indefinite for dysplasia 3=Low grade dysplasia 4=High grade dysplasia 5=Not available	.F="No Record For This Visit" .M="Missing" 1="No dysplasia" 3="Low grade dysplasia" 5="Not available"

Variable	Label	Description	Format Text
<b>colon_2_histopath_type1-14</b>	Histopathologic Type	Histopathologic type: 1=Hyperplastic polyps 2=Hamartomatous 3=Inflammatory polyps 4=Tubular adenoma 5=Tubulovillous adenoma 6=Adenoma 7=Villous adenoma 8=Serrated adenoma 9=Not specified 10=Juvenile 11=Other, specify	.F="No Record For This Visit" .M="Missing" 1="Hyperplastic polyps" 4="Tubular adenoma" 5="Tubulovillous adenoma" 8="Serrated adenoma" 9="Not specified" 11="Other, specify"
<b>colon_2_location1-14</b>	Location	Location: 1=Cecum 2=Ascending colon 3=Hepatic flexure 4=Transverse colon 5=Splenic flexure 6=Descending colon 7=Sigmoid colon 8=Rectosigmoid Junction 9=Rectum 10=Not specified	.F="No Record For This Visit" .M="Missing" 1="Cecum" 2="Ascending colon" 3="Hepatic flexure" 4="Transverse colon" 5="Splenic flexure" 6="Descending colon" 7="Sigmoid colon" 8="Rectosigmoid junction" 9="Rectum" 10="Not specified"
<b>colon_2_location_cm1-14</b>	Location If Identified By cm Only	If location only identified by cm: ___ . ___	Numeric .F="No Record For This Visit" .M="Missing"
<b>colon_2_mult_polyps1-14</b>	Multiple Polyps Per Container	Were multiple polyps/fragments placed in one specimen container? 1=Yes 2=No	.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"
<b>colon_2_num_adv_adenoma</b>	Number Of Advanced Adenomas	Total number advanced adenomas*: *Advanced adenoma-One of the following characteristics must be present: (1) greater than or equal to 1cm on colonoscopy report, (2) villous or tubulovillous, or (3) high grade (severe) dysplasia. Insert pathologist's conclusions, if any, into the comments section on the electronic CRF.	Numeric .F="No Record For This Visit" .M="Missing"
<b>colon_2_num_non_adv_adeno</b>	Number Of Non-Advanced Adenomas	Total number non-advanced adenomas:	Numeric .F="No Record For This Visit" .M="Missing"
<b>colon_2_num_polyps1-14</b>	Polyp Number	Polyp #	Numeric .F="No Record For This Visit" .M="Missing"
<b>colon_2_oth_spec</b>	Other Specify	Other, specify	Char
<b>colon_2_oth_spec1-14</b>	Colonoscopy: Other Specify	Histopathologic Type: Other, specify (200 available characters)	Char
<b>colon_2_proc_dt</b>	Procedure Date	Procedure Date: (mm/dd/yyyy)	SAS Date .F="No Record For This Visit" .M="Missing"



Variable	Label	Description	Format Text
<b>colon_2_rec_polyp_loc1-14</b>	Recurrent Polyp In Same Location As Baseline	(Follow Up Only) Is this recurrent polyp in the same location as a polyp identified on the baseline colonoscopy? 1=Yes 2=No 3=Unknown 4=Not specified	.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes" 2="Unknown" 3="Not Specified"
<b>colon_2_rem_polyp_piece1-14</b>	Polyp Removed Piecemeal	Polyp removed piecemeal? 1=Yes 2=No	.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"
<b>colon_2_result</b>	Result Of Colonoscopy	Results of Colonoscopy: (select one) 1=Normal 2=Abnormal, specify 3=Other, specify	.F="No Record For This Visit" .M="Missing" 1="Normal" 2="Abnormal, specify" 3="Other, specify"
<b>colon_2_size1-14</b>	Size At Colonoscopy (cm)	Size at Colonoscopy: 1=Diminutive (less than 5 mm) 2=Medium (5-9 mm) 3=Large (greater than or equal to 1 cm)	.F="No Record For This Visit" .M="Missing" 1="Diminutive (< 5mm)" 2="Medium (5-9mm)" 3="Large (>= 1cm)"
<b>colon_2_size_path1-14</b>	Size As Measured By Pathologist (cm)	Size as measured by Endoscopist (cm)	Numeric .F="No Record For This Visit" .M="Missing"
<b>colon_2_source1-14</b>	Form That Information Came From	Form That Information Came From	.F="No Record For This Visit" .N="N/A" 1="Colonoscopy Report" 2="Continuation Colonoscopy Report"

## Section 29: ANA Results Registration

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Variable	Label	Description	Format Text
<b>ana_2_hematology_dt1-2</b>	Blood Hematology Date	Sample collection date: (mm/dd/yyyy)	SAS Date .F="No Record For This Visit" .M="Missing" .N="N/A"
<b>ana_2_ratio1-2</b>	ANA Ratio Value	Antinuclear Antibody (ANA) IU _____ : _____ The colon sign MUST be used for entry (i.e., 1:160). The less than symbol may be used if needed (i.e., <1:80)	Char

## Section 30: Blood Specimen Collection Registration

Variable	Label	Description	Format Text
<b>blood_spec_2_collected1-7</b>	Blood Specimen Collected?	Was the specimen collected? 1=Yes, 2=No	.F="No Record For This Visit" .N="N/A" 0="No" 1="Yes"
<b>blood_spec_2_dt1-7</b>	Blood Specimen Collection Date	Date Specimen Collected: (mm/dd/yyyy)	SAS Date .F="No Record For This Visit" .M="Missing" .N="N/A"
<b>blood_spec_2_other_spec1-7</b>	Reason Specimens Not Collected	Other, specify (200 available characters)	Char
<b>blood_spec_2_reason_not1-7</b>	Reason Specimens Not Collected	Reason: (200 available characters.)	Char
<b>blood_spec_2_visit1-7</b>	Blood Specimen Collection Visit	Blood Specimen Collection Visit	.F="No Record For This Visit" .N="N/A" 0="Baseline" 2="Week 2" 3="Week 10" 4="Week 12" 5="Week 52" 7="Week 57" 8="Week 156 or early termination"

## Section 31: Blood Chemistry Registration

Variable	Label	Description	Format Text
<b>bld_chm_2_alk_phos1-5</b>	Alkaline Phosphatase, Serum (IU/L) (Week 55)	Alkaline Phosphatase, serum IU/L (Enter numeric value only) Decimal use available with entry, if needed	Numeric .F="No Record For This Visit" .M="Missing"
<b>bld_chm_2_alk_phos_2nd</b>	Alkaline Phosphatase, Serum (IU/L) (2nd)	Alkaline Phosphatase, serum IU/L (Enter numeric value only) Decimal use available with entry, if needed	Numeric .F="No Record For This Visit" .M="Missing"
<b>bld_chm_2_alk_phos_clin_sig1-5</b>	Clinically Significant: Alkaline Phosphatase (Week 55)	Clinically Significant: Alkaline Phosphatase	.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"
<b>bld_chm_2_alk_phos_clin_sig_2nd</b>	Clinically Significant: Alkaline Phosphatase (2nd)	Clinically Significant: Alkaline Phosphatase	.F="No Record For This Visit" .M="Missing" 0="No"
<b>bld_chm_2_alk_phos_oor1-5</b>	Out Of Range: Alkaline Phosphatase (Week 55)	Out of Range: Alkaline Phosphatase	.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"
<b>bld_chm_2_alk_phos_oor_2nd</b>	Out Of Range: Alkaline Phosphatase (2nd)	Out of Range: Alkaline Phosphatase	.F="No Record For This Visit" .M="Missing" 0="No"
<b>bld_chm_2_alt1-5</b>	Alanine Aminotransferase (ALT/SGPT) Serum (IU/L) (Week 55)	Alanine Aminotransferase (ALT/SGPT), serum IU/L (Enter numeric value only) DO NOT use decimal with entry	Numeric .F="No Record For This Visit" .M="Missing"
<b>bld_chm_2_alt_2nd</b>	Alanine Aminotransferase (ALT/SGPT) Serum (IU/L) (2nd)	Alanine Aminotransferase (ALT/SGPT), serum IU/L (Enter numeric value only) DO NOT use decimal with entry	Numeric .F="No Record For This Visit" .M="Missing"
<b>bld_chm_2_alt_clin_sig1-5</b>	Clinically Significant: Alanine Aminotransferase (Week 55)	Clinically Significant: ALT	.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"
<b>bld_chm_2_alt_clin_sig_2nd</b>	Clinically Significant: Alanine Aminotransferase (2nd)	Clinically Significant: ALT	.F="No Record For This Visit" .M="Missing" 0="No"
<b>bld_chm_2_alt_oor1-5</b>	Out Of Range: Alanine Aminotransferase (Week 55)	Out of Range: ALT	.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"
<b>bld_chm_2_alt_oor_2nd</b>	Out Of Range: Alanine Aminotransferase (2nd)	Out of Range: ALT	.F="No Record For This Visit" .M="Missing" 0="No"

Variable	Label	Description	Format Text
<b>bld_chm_2_ast1-5</b>	Aspartate Aminotransferase (AST/SGPT) Serum (IU/L) (Week 55)	Aspartate Aminotransferase (AST/SGOT), serum IU/L (Enter numeric value only) Decimal use available with entry, if needed	Numeric .F="No Record For This Visit" .M="Missing"
<b>bld_chm_2_ast_2nd</b>	Aspartate Aminotransferase (AST/SGPT) Serum (IU/L) (2nd)	Aspartate Aminotransferase (AST/SGOT), serum IU/L (Enter numeric value only) Decimal use available with entry, if needed	Numeric .F="No Record For This Visit" .M="Missing"
<b>bld_chm_2_ast_clin_sig1-5</b>	Clinically Significant: Aspartate Aminotransferase (Week 55)	Clinically Significant: AST	.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"
<b>bld_chm_2_ast_clin_sig_2nd</b>	Clinically Significant: Aspartate Aminotransferase (2nd)	Clinically Significant: AST	.F="No Record For This Visit" .M="Missing" 0="No"
<b>bld_chm_2_ast_oor 1-5</b>	Out Of Range: Aspartate Aminotransferase (Week 55)	Out of Range: AST	.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"
<b>bld_chm_2_ast_oor_2nd</b>	Out Of Range: Aspartate Aminotransferase (2nd)	Out of Range: AST	.F="No Record For This Visit" .M="Missing" 0="No"
<b>bld_chm_2_bicarb1-5</b>	Bicarbonate Serum (mEq/L) (Week 55)	Bicarbonate, serum mEq/L (Enter numeric value only) Decimal use available with entry, if needed	Numeric .F="No Record For This Visit" .M="Missing"
<b>bld_chm_2_bicarb_2nd</b>	Bicarbonate Serum (mEq/L) (2nd)	Bicarbonate, serum mEq/L (Enter numeric value only) Decimal use available with entry, if needed	Numeric .F="No Record For This Visit" .M="Missing"
<b>bld_chm_2_bicarb_clin_sig1-5</b>	Clinically Significant: Bicarbonate (Week 55)	Clinically Significant: Bicarbonate	.F="No Record For This Visit" .M="Missing" 0="No"
<b>bld_chm_2_bicarb_clin_sig_2nd</b>	Clinically Significant: Bicarbonate (2nd)	Clinically Significant: Bicarbonate	.F="No Record For This Visit" .M="Missing" 0="No"
<b>bld_chm_2_bicarb_oor1-5</b>	Out Of Range: Bicarbonate (Week 55)	Out of Range: Bicarbonate	.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"
<b>bld_chm_2_bicarb_oor_2nd</b>	Out Of Range: Bicarbonate (2nd)	Out of Range: Bicarbonate	.F="No Record For This Visit" .M="Missing" 0="No"
<b>bld_chm_2_bun1-5</b>	Blood Urea Nitrogen (BUN) Serum (mg/dL) (Week 55)	Blood Urea Nitrogen (BUN), serum mg/dL (Enter numeric value) Decimal use available with entry, if needed	Numeric .F="No Record For This Visit" .M="Missing"
<b>bld_chm_2_bun_2nd</b>	Blood Urea Nitrogen (BUN) Serum (mg/dL) (2nd)	Blood Urea Nitrogen (BUN), serum mg/dL (Enter numeric value) Decimal use available with entry, if needed	Numeric .F="No Record For This Visit" .M="Missing"

Variable	Label	Description	Format Text
<b>bld_chm_2_bun_clin_sig1-5</b>	Clinically Significant: Blood Urea Nitrogen (Week 55)	Clinically Significant: Total Bilirubin	.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"
<b>bld_chm_2_bun_clin_sig_2nd</b>	Clinically Significant: Blood Urea Nitrogen (2nd)	Clinically Significant: Total Bilirubin	.F="No Record For This Visit" .M="Missing" 0="No"
<b>bld_chm_2_bun_or1-5</b>	Out Of Range: Blood Urea Nitrogen (Week 55)	Out of Range: Total Bilirubin	.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"
<b>bld_chm_2_bun_or_2nd</b>	Out Of Range: Blood Urea Nitrogen (2nd)	Out of Range: Total Bilirubin	.F="No Record For This Visit" .M="Missing" 0="No"
<b>bld_chm_2_creat1-5</b>	Creatinine Serum (mg/dL) (Week 55)	Creatinine, serum mg/dL (Enter numeric value only) Decimal use available with entry, if needed	Numeric .F="No Record For This Visit" .M="Missing"
<b>bld_chm_2_creat_2nd</b>	Creatinine Serum (mg/dL) (2nd)	Creatinine, serum mg/dL (Enter numeric value only) Decimal use available with entry, if needed	Numeric .F="No Record For This Visit" .M="Missing"
<b>bld_chm_2_creat_clin_sig1-5</b>	Clinically Significant: Creatinine (Week 55)	Clinically Significant: Creatinine	.F="No Record For This Visit" .M="Missing" 0="No"
<b>bld_chm_2_creat_clin_sig_2nd</b>	Clinically Significant: Creatinine (2nd)	Clinically Significant: Creatinine	.F="No Record For This Visit" .M="Missing" 0="No"
<b>bld_chm_2_creat_or1-5</b>	Out Of Range: Creatinine (Week 55)	Out of Range: Creatinine	.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"
<b>bld_chm_2_creat_or_2nd</b>	Out Of Range: Creatinine (2nd)	Out of Range: Creatinine	.F="No Record For This Visit" .M="Missing" 0="No"
<b>bld_chm_2_dt1-5</b>	Blood Chemistry Date (Week 55)	Sample collection date: (mm/dd/yyyy)	SAS Date .F="No Record For This Visit" .M="Missing"
<b>bld_chm_2_dt_2nd</b>	Blood Chemistry Date (2nd)	Sample collection date: (mm/dd/yyyy)	SAS Date .F="No Record For This Visit" .M="Missing"
<b>bld_chm_2_fasting1-5</b>	Fasting? (Week 55)	Fasting: 1=Yes 2=No 3=Unknown	.F="No Record For This Visit" .M="Missing"
<b>bld_chm_2_fasting_2nd</b>	Fasting? (2nd)	Fasting: 1=Yes 2=No 3=Unknown	.F="No Record For This Visit" .M="Missing"
<b>bld_chm_2_glucose1-5</b>	Glucose Serum (mg/dL) (Week 55)	Glucose, serum mg/dL (Enter numeric value only) DO NOT use decimal with entry	Numeric .F="No Record For This Visit" .M="Missing"
<b>bld_chm_2_glucose_2nd</b>	Glucose Serum (mg/dL) (2nd)	Glucose, serum mg/dL (Enter numeric value only) DO NOT use decimal with entry	Numeric .F="No Record For This Visit" .M="Missing"

Variable	Label	Description	Format Text
<b>bld_chm_2_glucose_clin_sig1-5</b>	Clinically Significant: Glucose (Week 55)	Clinically Significant: Glucose	.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"
<b>bld_chm_2_glucose_clin_sig_2nd</b>	Clinically Significant: Glucose (2nd)	Clinically Significant: Glucose	.F="No Record For This Visit" .M="Missing" 0="No"
<b>bld_chm_2_glucose_oor1-5</b>	Out Of Range: Glucose (Week 55)	Out of Range: Glucose	.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"
<b>bld_chm_2_glucose_oor_2nd</b>	Out Of Range: Glucose (2nd)	Out of Range: Glucose	.F="No Record For This Visit" .M="Missing" 1="Yes"
<b>bld_chm_2_k1-5</b>	Potassium Serum (mmol/L) (Week 55)	Potassium, serum mmol/L (Enter numeric value only) Decimal use available with entry, if needed	Numeric .F="No Record For This Visit" .M="Missing"
<b>bld_chm_2_k_2nd</b>	Potassium Serum (mmol/L) (2nd)	Potassium, serum mmol/L (Enter numeric value only) Decimal use available with entry, if needed	Numeric .F="No Record For This Visit" .M="Missing"
<b>bld_chm_2_scl1-5</b>	Chloride Serum (mmol/L) (Week 55)	Chloride, serum mmol/L (Enter numeric value) DO NOT use decimal with entry	Numeric .F="No Record For This Visit" .M="Missing"
<b>bld_chm_2_scl_2nd</b>	Chloride Serum (mmol/L) (2nd)	Chloride, serum mmol/L (Enter numeric value) DO NOT use decimal with entry	Numeric .F="No Record For This Visit" .M="Missing"
<b>bld_chm_2_scl_clin_sig1-5</b>	Clinically Significant: Chloride (Week 55)	Clinically Significant: Chloride	.F="No Record For This Visit" .M="Missing" 0="No"
<b>bld_chm_2_scl_clin_sig_2nd</b>	Clinically Significant: Chloride (2nd)	Clinically Significant: Chloride	.F="No Record For This Visit" .M="Missing" 0="No"
<b>bld_chm_2_scl_oor1-5</b>	Out Of Range: Chloride (Week 55)	Out of Range: Chloride	.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"
<b>bld_chm_2_scl_oor_2nd</b>	Out Of Range: Chloride (2nd)	Out of Range: Chloride	.F="No Record For This Visit" .M="Missing" 0="No"
<b>bld_chm_2_sna1-5</b>	Sodium Serum (mmol/L) (Week 55)	Sodium, serum mmol/L (Enter numeric value only) Decimal use available with entry, if needed	Numeric .F="No Record For This Visit" .M="Missing"
<b>bld_chm_2_sna_2nd</b>	Sodium Serum (mmol/L) (2nd)	Sodium, serum mmol/L (Enter numeric value only) Decimal use available with entry, if needed	Numeric .F="No Record For This Visit" .M="Missing"
<b>bld_chm_2_sna_clin_sig1-5</b>	Clinically Significant: Sodium (Week 55)	Clinically Significant: Sodium	.F="No Record For This Visit" .M="Missing" 0="No"

Variable	Label	Description	Format Text
<b>bld_chm_2_sna_clin_sig_2nd</b>	Clinically Significant: Sodium (2nd)	Clinically Significant: Sodium	.F="No Record For This Visit" .M="Missing" 0="No"
<b>bld_chm_2_sna_oor1-5</b>	Out Of Range: Sodium (Week 55)	Out of Range: Sodium	.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"
<b>bld_chm_2_sna_oor_2nd</b>	Out Of Range: Sodium (2nd)	Out of Range: Sodium	.F="No Record For This Visit" .M="Missing" 0="No"
<b>bld_chm_2_tot_bili1-5</b>	Bilirubin Total (mg/dL) (Week 55)	Bilirubin, Total mg/dL (Enter numeric value only) Decimal use available with entry, if needed	Numeric .F="No Record For This Visit" .M="Missing"
<b>bld_chm_2_tot_bili_2nd</b>	Bilirubin Total (mg/dL) (2nd)	Bilirubin, Total mg/dL (Enter numeric value only) Decimal use available with entry, if needed	Numeric .F="No Record For This Visit" .M="Missing"
<b>bld_chm_2_tot_bili_clin_sig1-5</b>	Clinically Significant: Bilirubin (Week 55)	Clinically Significant: Total Bilirubin	.F="No Record For This Visit" .M="Missing" 0="No"
<b>bld_chm_2_tot_bili_clin_sig_2nd</b>	Clinically Significant: Bilirubin (2nd)	Clinically Significant: Total Bilirubin	.F="No Record For This Visit" .M="Missing" 0="No"
<b>bld_chm_2_tot_bili_oor1-5</b>	Out Of Range: Bilirubin (Week 55)	Out of Range: Total Bilirubin	.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"
<b>bld_chm_2_tot_bili_oor_2nd</b>	Out Of Range: Bilirubin (2nd)	Out of Range: Total Bilirubin	.F="No Record For This Visit" .M="Missing" 0="No"
<b>bld_chm_2_uric1-5</b>	Uric Acid Serum (mg/dL) (Week 55)	Uric Acid, serum mg/dL (Enter numeric value only) Decimal use available with entry, if needed	Numeric .F="No Record For This Visit" .M="Missing"
<b>bld_chm_2_uric_2nd</b>	Uric Acid Serum (mg/dL) (2nd)	Uric Acid, serum mg/dL (Enter numeric value only) Decimal use available with entry, if needed	Numeric .F="No Record For This Visit" .M="Missing"
<b>bld_chm_2_uric_clin_sig1-5</b>	Clinically Significant: Uric Acid (Week 55)	Clinically Significant: Uric Acid	.F="No Record For This Visit" .M="Missing" 0="No"
<b>bld_chm_2_uric_clin_sig_2nd</b>	Clinically Significant: Uric Acid (2nd)	Clinically Significant: Uric Acid	.F="No Record For This Visit" .M="Missing" 0="No"
<b>bld_chm_2_uric_oor1-5</b>	Out Of Range: Uric Acid (Week 55)	Out of Range: Uric Acid	.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"
<b>bld_chm_2_uric_oor_2nd</b>	Out Of Range: Uric Acid (2nd)	Out of Range: Uric Acid	.F="No Record For This Visit" .M="Missing" 0="No"



Variable	Label	Description	Format Text
<b>bld_chm_2_visit_num</b>	Visit Number With A Second Visit	Evaluation Visit Number	.F="No Record For This Visit" .M="Missing" 2="Week 2" 5="Week 52"

## Section 32: Medical And Surgical History Registration

Variable	Label	Description	Format Text
<b>medsurg_2_all_normal_1-2</b>	All Normal? (Week 156 Or Early Termination)	Select if all body systems are normal; leave blank if one or more are abnormal.	.F="No Record For This Visit" .M="Missing" 1="Yes"
<b>medsurg_2_comment1_1-2</b>	Medical And Surgical History Comment (Week 156 Or Early Termination)	Comments (Required, provide condition/diagnosis) (200 available characters)	Char
<b>medsurg_2_comment2_1-2</b>	Medical And Surgical History Comment (Week 156 Or Early Termination)	Comments (Required, provide condition/diagnosis) (200 available characters)	Char
<b>medsurg_2_comment3_1-2</b>	Medical And Surgical History Comment (Week 156 Or Early Termination)	Comments (Required, provide condition/diagnosis) (200 available characters)	Char
<b>medsurg_2_comment4_1-2</b>	Medical And Surgical History Comment (Week 156 Or Early Termination)	Comments (Required, provide condition/diagnosis) (200 available characters)	Char
<b>medsurg_2_comment5_1-2</b>	Medical And Surgical History Comment (Week 156 Or Early Termination)	Comments (Required, provide condition/diagnosis) (200 available characters)	Char
<b>medsurg_2_comment6_1-2</b>	Medical And Surgical History Comment (Week 156 Or Early Termination)	Comments (Required, provide condition/diagnosis) (200 available characters)	Char
<b>medsurg_2_comment7_1-2</b>	Medical And Surgical History Comment (Week 156 Or Early Termination)	Comments (Required, provide condition/diagnosis) (200 available characters)	Char
<b>medsurg_2_comment8_1-2</b>	Medical And Surgical History Comment (Week 156 Or Early Termination)	Comments (Required, provide condition/diagnosis) (200 available characters)	Char
<b>medsurg_2_dxdt1_1-2</b>	Date Of Diagnosis (Week 156 Or Early Termination)	Date of Diagnosis/Surgery (mm/dd/yyyy)	SAS Date .F="No Record For This Visit" .M="Missing"
<b>medsurg_2_dxdt2_1-2</b>	Date Of Diagnosis (Week 156 Or Early Termination)	Date of Diagnosis/Surgery (mm/dd/yyyy)	SAS Date .F="No Record For This Visit" .M="Missing"
<b>medsurg_2_dxdt3_1-2</b>	Date Of Diagnosis (Week 156 Or Early Termination)	Date of Diagnosis/Surgery (mm/dd/yyyy)	SAS Date .F="No Record For This Visit" .M="Missing"
<b>medsurg_2_dxdt4_1-2</b>	Date Of Diagnosis (Week 156 Or Early Termination)	Date of Diagnosis/Surgery (mm/dd/yyyy)	SAS Date .F="No Record For This Visit" .M="Missing"
<b>medsurg_2_dxdt5_1-2</b>	Date Of Diagnosis (Week 156 Or Early Termination)	Date of Diagnosis/Surgery (mm/dd/yyyy)	SAS Date .F="No Record For This Visit" .M="Missing"
<b>medsurg_2_dxdt6_1-2</b>	Date Of Diagnosis (Week 156 Or Early Termination)	Date of Diagnosis/Surgery (mm/dd/yyyy)	SAS Date .F="No Record For This Visit" .M="Missing"

Variable	Label	Description	Format Text
<b>medsurg_2_dxdt7_1-2</b>	Date Of Diagnosis (Week 156 Or Early Termination)	Date of Diagnosis/Surgery (mm/dd/yyyy)	SAS Date .F="No Record For This Visit" .M="Missing"
<b>medsurg_2_dxdt8_1-2</b>	Date Of Diagnosis (Week 156 Or Early Termination)	Date of Diagnosis/Surgery (mm/dd/yyyy)	SAS Date .F="No Record For This Visit" .M="Missing"
<b>medsurg_2_dxsp1_1-2</b>	Medical And Surgical History Procedure (Week 156 Or Early Termination)	Diagnosis/Surgical Procedure (100 available characters)	Char
<b>medsurg_2_dxsp2_1-2</b>	Medical And Surgical History Procedure (Week 156 Or Early Termination)	Diagnosis/Surgical Procedure (100 available characters)	Char
<b>medsurg_2_dxsp3_1-2</b>	Medical And Surgical History Procedure (Week 156 Or Early Termination)	Diagnosis/Surgical Procedure (100 available characters)	Char
<b>medsurg_2_dxsp4_1-2</b>	Medical And Surgical History Procedure (Week 156 Or Early Termination)	Diagnosis/Surgical Procedure (100 available characters)	Char
<b>medsurg_2_dxsp5_1-2</b>	Medical And Surgical History Procedure (Week 156 Or Early Termination)	Diagnosis/Surgical Procedure (100 available characters)	Char
<b>medsurg_2_dxsp6_1-2</b>	Medical And Surgical History Procedure (Week 156 Or Early Termination)	Diagnosis/Surgical Procedure (100 available characters)	Char
<b>medsurg_2_dxsp7_1-2</b>	Medical And Surgical History Procedure (Week 156 Or Early Termination)	Diagnosis/Surgical Procedure (100 available characters)	Char
<b>medsurg_2_dxsp8_1-2</b>	Medical And Surgical History Procedure (Week 156 Or Early Termination)	Diagnosis/Surgical Procedure (100 available characters)	Char
<b>medsurg_2_hist1_1-2</b>	Medical And Surgical History (Week 156 Or Early Termination)	Body System/Site (1) (100 available characters)	Char
<b>medsurg_2_hist2_1-2</b>	Medical And Surgical History (Week 156 Or Early Termination)	Body System/Site (1) (100 available characters)	Char
<b>medsurg_2_hist3_1-2</b>	Medical And Surgical History (Week 156 Or Early Termination)	Body System/Site (1) (100 available characters)	Char
<b>medsurg_2_hist4_1-2</b>	Medical And Surgical History (Week 156 Or Early Termination)	Body System/Site (1) (100 available characters)	Char
<b>medsurg_2_hist5_1-2</b>	Medical And Surgical History (Week 156 Or Early Termination)	Body System/Site (1) (100 available characters)	Char
<b>medsurg_2_hist6_1-2</b>	Medical And Surgical History (Week 156 Or Early Termination)	Body System/Site (1) (100 available characters)	Char
<b>medsurg_2_hist7_1-2</b>	Medical And Surgical History (Week 156 Or Early Termination)	Body System/Site (1) (100 available characters)	Char

Variable	Label	Description	Format Text
<b>medsurg_2_hist8_1-2</b>	Medical And Surgical History (Week 156 Or Early Termination)	Body System/Site (1) (100 available characters)	Char
<b>medsurg_2_visit_dt_1-2</b>	Medical Surgery And History Visit Date (Week 156 Or Early Termination)	Evaluation Date: (mm/dd/yyyy)	SAS Date .F="No Record For This Visit" .M="Missing"

## Section 33: Pathology Specimen Collection Registration

Variable	Label	Description	Format Text
<b>path_2_access_num1-2</b>	Access Number	Accession number:	Char
<b>path_2_blocks_sub1-2</b>	Blocks Submitted	Number of blocks submitted:	Numeric .F="No Record For This Visit" .M="Missing"
<b>path_2_operation_dt1-2</b>	Operation Date	Procedure Date: (mm/dd/yyyy)	SAS Date .F="No Record For This Visit" .M="Missing"
<b>path_2_oth_spec1-2</b>	Reason Not Collected: Other Specify	Other, specify (40 available characters)	Char
<b>path_2_procedure_time1-2</b>	Procedure Time	Time of Procedure: (hh/mm) __ __: __ __ (Enter time in hour hr hr and minutes min min without colon)	SAS Time .F="No Record For This Visit" .M="Missing"
<b>path_2_rsn_not_collected1-2</b>	Reason Not Collected	If No, reason: (200 available characters.)	Char
<b>path_2_sent_dt1-2</b>	Specimens Submitted Date	Specimen Submit Date: (mm/dd/yyyy)	SAS Date .F="No Record For This Visit" .M="Missing"
<b>path_2_slides_submitted1-2</b>	Slides Submitted	Number of slides submitted:	Numeric .F="No Record For This Visit" .M="Missing"
<b>path_2_spec_submitted1-2</b>	Number Of Specimens Submitted	Was specimen submitted? 1=Yes 2=No	.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"

## Section 34: End Active Treatment Registration

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Variable	Label	Description	Format Text
<b>end_at_2_comment</b>	End Active Treatment Comments	Specify: (200 available characters.)	Char
<b>end_at_2_dt</b>	End Active Treatment Date	Off Study Date: (mm/dd/yyyy) (date of follow-up call, if the patient answers, otherwise the date of post study visit)	SAS Date .F="No Record For This Visit"
<b>end_at_2_last_dose_dt</b>	End Active Treatment Last Dose Date	Last date protocol therapy was given: (mm/dd/yyyy) (date of last treatment dose on this study or date decision made not to initiate protocol treatment)	SAS Date .F="No Record For This Visit"
<b>end_at_2_reason</b>	End Active Treatment Reason	Off Study Reason: 29=Ineligible (includes screen failures) 17=Adverse Event 23=Death 18=Lost to Follow-up 8=Other, specify 22=Participant Withdrawal 27=Physician Decision 28=Protocol Violation 16=Study Complete	.F="No Record For This Visit" 1="Study Complete" 2="Participant Withdrawal" 5="Adverse Event" 6="Lost to Follow-up" 9="Other, specify"

## Section 35: Was It Worth It Questionnaire

Variable	Label	Description	Format Text
<b>qol_do_again</b>	If You Had Do It Over, Would You Participate Again?	If you had to do it over, would you participate in this research study again? 1=Y 2=N 3=U	.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes" 2="Unknown"
<b>qol_form_done</b>	Form Completed?	Was any/all data completed? 1=Yes 2=No	.F="No Record For This Visit" 0="No" 1="Yes"
<b>qol_life_change</b>	Overall Quality Of Life Change	Directions: Select one response: Overall, did your quality of life change by participating in this research study? 1=It improved 2=It stayed the same 3=It got worse	.F="No Record For This Visit" .M="Missing" 1="It improved" 2="It stayed the same"
<b>qol_one_thing_improve</b>	One Thing That Could Have Been Done to Improve Your Experience	If there was one thing that could have been done to improve your experience in this research study, what would it be? (200 available characters)	Numeric .F="No Record For This Visit" .M="Missing"
<b>qol_overall_exp</b>	Overall Experience	Overall, how was your experience of participating in this research study? 1=Better than I expected 2=The same as I expected 3=Worse than I expected	.F="No Record For This Visit" .M="Missing" 1="Better than I expected" 2="The same as I expected" 3="Worse than I expected"
<b>qol_talk_about_concerns</b>	Would You Like To Talk To Someone About Your Concerns?	Would you like to talk to someone about your concerns (select one response)? 1=Yes 2=No	Numeric .F="No Record For This Visit" .M="Missing"
<b>qol_was_it_worthwhile</b>	Was It Worthwhile To Participate?	Was it worthwhile for you to participate in this research study? 1=Y 2=N 3=U	.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes" 2="Unknown"
<b>qol_would_recommend</b>	Would You Recommend Participating In This Study To Others?	Would you recommend participating in this research study to others? 1=Y 2=N 3=U	.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes" 2="Unknown"

## Section 36: Tregs Analysis

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Variable	Label	Description	Format Text
<b>tregs_cd15s</b>	CD15S Value	CD15S Value	Numeric .F="No Record For This Visit" .M="Missing"
<b>tregs_cd4_cd25</b>	CD4 + CD25 Value	CD4 + CD25 Value	Numeric .F="No Record For This Visit" .M="Missing"
<b>tregs_foxp3</b>	FOXP3 Value	FOXP3 Value	Numeric .F="No Record For This Visit" .M="Missing"



## Section 37: Vaccine Report Card

Variable	Label	Description	Format Text
<b>vaccrpt_after_inj_dt1-4</b>	Date After Injection (Week 53)	Date of injection (mm/dd/yyyy)	SAS Date .F="No Record For This Visit" .M="Missing"
<b>vaccrpt_comments1-4</b>	CRA Comments (Week 53)	CRA comments. If not applicable leave blank. (200 available characters; if over 200 characters click on the Comment box to complete entry.)	Char
<b>vaccrpt_day_after_inj1-4</b>	Days After Injection (Week 53)	Day after injection: (select one)	Numeric .F="No Record For This Visit" .M="Missing"
<b>vaccrpt_itch1-4</b>	Itching At Injection Site (Week 53)	Itching at site (No, Yes)	.F="No Record For This Visit" .M="Missing" 0="No"
<b>vaccrpt_itch_start_dt1-4</b>	Date Itch Started (Week 53)	(If itching at site) , date symptom appeared (mm/dd/yyyy)	SAS Date .F="No Record For This Visit" .M="Missing"
<b>vaccrpt_itch_stop_dt1-4</b>	Date Itch Stopped (Week 53)	(If itching at site) , date symptom disappeared (mm/dd/yyyy)	SAS Date .F="No Record For This Visit" .M="Missing"
<b>vaccrpt_pain1-4</b>	Pain At Itching Site (Week 53)	Pain at the injection site without touching (select one)	.F="No Record For This Visit" .M="Missing" 1="None" 2="A little, but it didn't interfere with normal activity"
<b>vaccrpt_pain_start_dt1-4</b>	Date Pain Started (Week 53)	(If pain at the injection site without touching) , date symptom appeared (mm/dd/yyyy)	SAS Date .F="No Record For This Visit" .M="Missing"
<b>vaccrpt_pain_stop_dt1-4</b>	Date Pain Stopped (Week 53)	(If pain at the injection site without touching) , date symptom disappeared (mm/dd/yyyy)	SAS Date .F="No Record For This Visit" .M="Missing"
<b>vaccrpt_red1-4</b>	Redness At Injection Site (Week 53)	Redness at the injection site: (No, Yes)	.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"
<b>vaccrpt_red_size1-4</b>	Size Of Redness (cm) (Week 53)	(If yes) , measurement: ___ ___ (cm)	Numeric .F="No Record For This Visit" .M="Missing"
<b>vaccrpt_red_start_dt1-4</b>	Date Redness Started (Week 53)	(If redness at the injection site) , date symptom appeared (mm/dd/yyyy)	SAS Date .F="No Record For This Visit" .M="Missing"
<b>vaccrpt_red_stop_dt1-4</b>	Date Redness Stopped (Week 53)	(If redness at the injection site) , date symptom disappeared (mm/dd/yyyy)	SAS Date .F="No Record For This Visit" .M="Missing"

Variable	Label	Description	Format Text
<b>vaccrpt_swell1-4</b>	Swelling At Injection Site (Week 53)	Swelling/induration (No, Yes)	.F="No Record For This Visit" .M="Missing" 0="No" 1="Yes"
<b>vaccrpt_swell_size1-4</b>	Size Of Swelling (cm) (Week 53)	(If yes) , measurement: ___ ___ (cm)	Numeric .F="No Record For This Visit" .M="Missing"
<b>vaccrpt_swell_start_dt1-4</b>	Date Swelling Started (Week 53)	(If swelling/induration) , date symptom appeared (mm/dd/yyyy)	SAS Date .F="No Record For This Visit" .M="Missing"
<b>vaccrpt_swell_stop_dt1-4</b>	Date Swelling Stopped (Week 53)	(If swelling/induration) , date symptom disappeared (mm/dd/yyyy)	SAS Date .F="No Record For This Visit" .M="Missing"
<b>vaccrpt_tender1-4</b>	Tenderness At Injection Site (Week 53)	Tenderness (pain at the injection site with touch) (select one)	.F="No Record For This Visit" .M="Missing" 1="None" 2="A little, but it didn't interfere with normal activity"
<b>vaccrpt_tender_start_dt1-4</b>	Date Tenderness Started (Week 53)	(If tenderness/pain at the injection site with touch) , date symptom appeared (mm/dd/yyyy)	SAS Date .F="No Record For This Visit" .M="Missing"
<b>vaccrpt_tender_stop_dt1-4</b>	Date Tenderness Stopped (Week 53)	(If tenderness/pain at the injection site with touch) , date symptom disappeared (mm/dd/yyyy)	SAS Date .F="No Record For This Visit" .M="Missing"
<b>vaccrpt_warm1-4</b>	Skin Warmth At Injection Site (Week 53)	Skin warmth at site (No, Yes)	.F="No Record For This Visit" .M="Missing" 0="No"
<b>vaccrpt_warm_start_dt1-4</b>	Date Skin Warmth Started (Week 53)	(If skin warmth at site) , date symptom appeared (mm/dd/yyyy)	SAS Date .F="No Record For This Visit" .M="Missing"
<b>vaccrpt_warm_stop_dt1-4</b>	Date Skin Warmth Stopped (Week 53)	(If skin warmth at site) , date symptom disappeared (mm/dd/yyyy)	SAS Date .F="No Record For This Visit" .M="Missing"

## Section 38: MDSC Baseline Values

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Variable	Label	Description	Format Text
<b>mdsc_bsl_e</b>	e-MDSC (Myeloid Derived Suppressor Cells) Value	e-MDSC (Myeloid Derived Suppressor Cells) Value	Numeric .F="No Record For This Visit"
<b>mdsc_bsl_m</b>	M-MDSC (Myeloid Derived Suppressor Cells) Value	M-MDSC (Myeloid Derived Suppressor Cells) Value	Numeric .F="No Record For This Visit"
<b>mdsc_bsl_pmn</b>	PMN-MDSC (Myeloid Derived Suppressor Cells) Value	PMN-MDSC (Myeloid Derived Suppressor Cells) Value	Numeric .F="No Record For This Visit"
<b>mdsc_bsl_total</b>	Total-MDSC (Myeloid Derived Suppressor Cells) Value	Total-MDSC (Myeloid Derived Suppressor Cells) Value	Numeric .F="No Record For This Visit"

## Section 39: IGG Baseline And Week 12

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Variable	Label	Description	Format Text
<b>igg_1_bsl_values</b>	IGG Levels At Baseline	IGG Levels At Baseline	Numeric .F="No Record For This Visit"
<b>igg_1_wk_12_values</b>	IGG Levels At Week 12	IGG Levels At Week 12	Numeric .F="No Record For This Visit"

## Section 40: IGG Week 52 And 55

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Variable	Label	Description	Format Text
<b>igg_2_comments</b>	IGG Level Comments	IGG Level Comments	Char
<b>igg_2_wk_0_values</b>	IGG Levels At Week 0	IGG Levels At Week 0	Numeric .F="No Record For This Visit"
<b>igg_2_wk_12_response</b>	IGG Level Week 12 Response	IGG Level Week 12 Response	Char
<b>igg_2_wk_12_values</b>	IGG Levels At Week 12	IGG Levels At Week 12	Numeric .F="No Record For This Visit"
<b>igg_2_wk_52_values</b>	IGG Levels At Week 52	IGG Levels At Week 52	Numeric .F="No Record For This Visit" .M="Missing"
<b>igg_2_wk_55_values</b>	IGG Levels At Week 55	IGG Levels At Week 55	Numeric .F="No Record For This Visit" .M="Missing"

## Section 41: IGG Week 156

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Variable	Label	Description	Format Text
<b>igg_3_wk_0_values</b>	IGG Levels At Week 0	IGG Levels At Week 0	Numeric .F="No Record For This Visit"
<b>igg_3_wk_12_values</b>	IGG Levels At Week 12	IGG Levels At Week 12	Numeric .F="No Record For This Visit"
<b>igg_3_wk_156_values</b>	IGG Levels At Week 156	IGG Levels At Week 156	Numeric .F="No Record For This Visit" .M="Missing"
<b>igg_3_wk_52_values</b>	IGG Levels At Week 52	IGG Levels At Week 52	Numeric .F="No Record For This Visit" .M="Missing"
<b>igg_3_wk_55_values</b>	IGG Levels At Week 55	IGG Levels At Week 55	Numeric .F="No Record For This Visit" .M="Missing"