MDA2013-02-02 - Interval 1 Questionnaire Data Dictionary

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Document Summary

Property	Value
Document Title	MDA2013-02-02 - Interval 1 Questionnaire: Data Dictionary
Date Created	05/20/2024
Sections	3
Entries	151
Document Filename	dictionary_intervalquestionnaire1.rtf

MDA2013-02-02 - Interval 1 Questionnaire: Data Dictionary
Section 1: Identifiers

Class	Variable	Label	Description	Format Text
01. Principal	**MRNO**	MRNO		Numeric

Section 2: Study Wide

Class	Variable	Label	Description	Format Text
01. Principal	**Accession**	Accession		Numeric
01. Principal	**Form**	Form		"Interval Questionnaire"="Interval Questionnaire"
01. Principal	**Institution**	Institution		"Baylor College of Medicine"="Baylor College of Medicine" "M. D. Anderson Cancer Center"="M. D. Anderson Cancer Center" "Mayo Clinic"="Mayo Clinic" "Northwestern University"="Northwestern University" "Saint Michael's Hospital Toronto"="Saint Michael's Hospital Toronto" "University of Colorado"="University of Colorado" "University of North Carolina at Chapel Hill"="University of North Carolina at Chapel Hill"
01. Principal	**Reg_Date**	Registration Date		SAS Date
01. Principal	**Trial**	Trial Name		"MDA2013-02-02"="MDA2013-02-02"

Section 3: Interval 1 Questionnaire

Class	Variable	Label	Description	Format Text
01. Principal	_3649_10890_8_Seizures	Seizures?		"None"="None"
01. Principal	_3649_10890_8_Seizures__Desc_	Seizures? (Description)		"None"="None"
01. Principal	_3649_10891_7_Trouble_Breathing	Trouble Breathing?		"None"="None" "Some"="Some"
01. Principal	_3649_10891_7_Trouble_Breathing_	Trouble Breathing? (Description)		"None"="None" "Some"="Some"
01. Principal	_3649_10892_6_Blood_on_stool	Blood On Stool?		"None"="None" "Some"="Some"
01. Principal	_3649_10892_6_Blood_on_stool__De	Blood On Stool? (Description)		"None"="None" "Some"="Some"
01. Principal	_3649_10893_5_Itching	Itching?		"Don't know"="Don't know" "None"="None" "Some"="Some"
01. Principal	_3649_10893_5_Itching__Desc_	Itching? (Description)		"Don't know"="Don't know" "None"="None" "Some"="Some"
01. Principal	_3649_10894_4_Loss_of_Appetite	Loss Of Appetite?		"None"="None"
01. Principal	_3649_10894_4_Loss_of_Appetite__	Loss Of Appetite? (Description)		"None"="None"
01. Principal	_3649_10895_3_Stomach_Cramps	Stomach Cramps?		"Don't know"="Don't know" "None"="None" "Severe"="Severe" "Some"="Some"
01. Principal	_3649_10895_3_Stomach_Cramps__De	Stomach Cramps? (Description)		"Don't know"="Don't know" "None"="None" "Severe"="Severe" "Some"="Some"
01. Principal	_3649_10896_2_Heartburn	Heartburn?		"None"="None" "Severe"="Severe" "Some"="Some"
01. Principal	_3649_10896_2_Heartburn__Desc_	Heartburn? (Description)		"None"="None" "Severe"="Severe" "Some"="Some"
01. Principal	_3649_10897_1_Nausea_or_vomiting	Nausea Or Vomiting?		"None"="None" "Severe"="Severe" "Some"="Some"
01. Principal	_3649_10898_Visit_Date	Visit Date		SAS Date

Class	Variable	Label	Description	Format Text
01. Principal	**_3649_14013_Co mpleted_by**	Completed By:		"Site designee (questionnaire as source)"="Site designee (questionnaire as source)" "Site designee (responses entered directly to eCRF, no paper sour"="Site designee (responses entered directly to eCRF, no paper sour"
01. Principal	**_3649_14013_Co mpleted_by__De sc_**	Completed By: (Description)		"Site designee (questionnaire as source)"="Site designee (questionnaire as source)" "Site designee (responses entered directly to eCRF, no paper source)"="Site designee (responses entered directly to eCRF, no paper source)"
01. Principal	**_3650_10899_m m_dd_yyyy**	Dr. Visit Date		Char
01. Principal	**_3650_10900_10_ Since_your_last_ s**	Since Your Last Study Questionnaire, Have You Been Hospitalized Overnight?		"No"="No" "Yes"="Yes"
01. Principal	**_3650_10901_9_ Seen_Dr_or_visit ed**	Since Your Last Study Questionnaire, Have You Seen A Doctor Or Other Medical Personnel For Any Reason Or Visited A Clinic For A Same-Day Procedure?		"No"="No" "Yes"="Yes"
01. Principal	**_3650_10902_9A _When_did_you_ visi**	When Did You Visit The Dr. Or Have The Same Day Procedure?		Char
01. Principal	**_3650_10903_9B _What_was_the_ purp**	What Was The Purpose Of This Visit?		Char
01. Principal	**_3650_10904_9C _What_was_the_ reas**	What Was The Reason Or Diagnosis?		Char
01. Principal	**_3650_10906_9E _Another_Dr_visi t_**	Do You Have Another Dr. Visit Or Same-Day Procedure For A Different Purpose, Reason Or Diagnosis, Or The Same Purpose, Reason Or Diagnosis On A Different Date To Report?		"No"="No" "Yes [please complete supplement pages as necessary]"="Yes [please complete supplement pages as necessary]"
01. Principal	**_3650_10907_10 D_Do_you_have_ anot**	Do You Have Another Hospitalization On A Different Date To Report?		"No"="No"
01. Principal	**_3650_10908_Ho spital_Clinic**	Hospital/Clinic		Char
01. Principal	**_3650_10909_m m_yyyy**	Hospital/Clinic Visit Date		Char

Class	Variable	Label	Description	Format Text
01. Principal	**_3650_10911_Year**	Year		Char
01. Principal	**_3650_10912_Reason_or_diagnosis**	Reason Or Diagnosis		Char
01. Principal	**_3651_10913_Angioplasty**	Diagnosis: Angioplasty		"False"="False"
01. Principal	**_3651_10914_Asthma**	Diagnosis: Asthma		"False"="False"
01. Principal	**_3651_10915_Atrial_Fibrillation**	Diagnosis: Atrial Fibrillation		"False"="False"
01. Principal	**_3651_10916_Back_Surgery**	Diagnosis: Back Surgery		"False"="False" "True"="True"
01. Principal	**_3651_10917_Bladder_Infection**	Diagnosis: Bladder Infection		"False"="False"
01. Principal	**_3651_10918_Cancer**	Diagnosis: Cancer		"False"="False"
01. Principal	**_3651_10919_Chest_pain**	Diagnosis: Chest Pain		"False"="False"
01. Principal	**_3651_10920_Chronic_Intestinal_M**	Diagnosis: Chronic Intestinal Malabsorption Syndrome		"False"="False"
01. Principal	**_3651_10921_Detached_Retina**	Diagnosis: Detached Retina		"False"="False"
01. Principal	**_3651_10922_Diverticulitis**	Diagnosis: Diverticulitis		"False"="False"
01. Principal	**_3651_10923_Familial_Colorectal_**	Diagnosis: Familial Colorectal Cancer Syndrome		"False"="False"
01. Principal	**_3651_10924_Flu_or_Influenza_lik**	Diagnosis: Flu Or Influenza-Like Illness		"False"="False"
01. Principal	**_3651_10925_Fracture**	Diagnosis: Fracture		"False"="False"
01. Principal	**_3651_10926_Gall_Bladder**	Diagnosis: Gall Bladder		"False"="False"
01. Principal	**_3651_10927_Heart_attack**	Diagnosis: Heart Attack		"False"="False"
01. Principal	**_3651_10928_Hepatitis_B_or_C**	Diagnosis: Hepatitis B Or C		"False"="False"
01. Principal	**_3651_10929_Hernia_repair**	Diagnosis: Hernia Repair		"False"="False" "True"="True"
01. Principal	**_3651_10930_Hip_replacement**	Diagnosis: Hip Replacement		"False"="False"
01. Principal	**_3651_10931_HIV**	Diagnosis: HIV		"False"="False"
01. Principal	**_3651_10932_Hysterectomy**	Diagnosis: Hysterectomy		"False"="False"

Class	Variable	Label	Description	Format Text
01. Principal	**_3651_10933_Inflammatory_Bowel_D**	Diagnosis: Inflammatory Bowel Disease		"False"="False"
01. Principal	**_3651_10934_Kidney_Disease**	Diagnosis: Kidney Disease		"False"="False"
01. Principal	**_3651_10935_Kidney_Stone**	Diagnosis: Kidney Stone		"False"="False"
01. Principal	**_3651_10936_Knee_Replacement**	Diagnosis: Knee Replacement		"False"="False"
01. Principal	**_3651_10937_Pneumonia**	Diagnosis: Pneumonia		"False"="False"
01. Principal	**_3651_10938_Pregnancy**	Diagnosis: Pregnancy		"False"="False"
01. Principal	**_3651_10939_Prostate_Enlargement**	Diagnosis: Prostate Enlargement		"False"="False"
01. Principal	**_3651_10940_Sleep_apnea**	Diagnosis: Sleep Apnea		"False"="False"
01. Principal	**_3651_10941_A_medical_condition_**	Diagnosis: A Medical Condition Requiring Treatment With Vitamin D		"False"="False"
01. Principal	**_3651_10942_Other**	Diagnosis: Other		Char
01. Principal	**_3651_10942_Other__Desc_**	Diagnosis: Other (Description)		Char
01. Principal	**_3651_10943_Other_please_specify**	Diagnosis: Other, Please Specify		Char
01. Principal	**_3651_10944_mm_dd_yyyy**	When Were You Admitted?		SAS Date
01. Principal	**_3651_10945_10A_When_were_you_ad**	When Were You Admitted?		Char
01. Principal	**_3651_10946_mm_yyyy**	When Were You Admitted?		Char
01. Principal	**_3651_10947_Year**	When Were You Admitted?		Char
01. Principal	**_3651_10948_10B_What_was_the_nam**	What Was The Name Of The Hospital?		"Methodist Hospital- TMC"="Methodist Hospital- TMC" "UT MD Anderson Cancer Center"="UT MD Anderson Cancer Center"
01. Principal	**_3651_10949_10B_What_was_the_nam**	What Was The Name Of The Hospital? (Description)		"False"="False"
01. Principal	**_3652_10950_Other_reason_specify**	What Was The Reason You Were Taking It? Other Reason (Specify):		Char

Class	Variable	Label	Description	Format Text
01. Principal	_3652_10951_11F_Reason_of_taking	What Was The Reason You Were Taking It? (Choose The Primary Reason)		"Cold/flu"="Cold/flu" "Headache"="Headache" "Other reason"="Other reason"
01. Principal	_3652_10952_Other_specify	What Was The Dose Per Pill Or Other Form? Other (Specify):		Char
01. Principal	_3652_10953_11E_What_was_the_dos	What Was The Dose Per Pill Or Other Form?		"81 mg (baby aspirin)"="81 mg (baby aspirin)" "Don't know"="Don't know"
01. Principal	_3652_10954_Specify	How Many Pills/Gums/Other Forms Per Day Did You Take On Average On The Days When You Were Taking It? Specify #:		Numeric
01. Principal	_3652_10955_11D_How_many_pills_p	How Many Pills/Gums/Other Forms Per Day Did You Take On Average On The Days When You Were Taking It?		Char
01. Principal	_3652_10956_specify	In What Form Did You Take This Aspirin Medication? (Specify):		Char
01. Principal	_3652_10957_11C_In_what_form_did	In What Form Did You Take This Aspirin Medication?		"Pill tablet"="Pill tablet"
01. Principal	_3652_10958_specify_days_per_wee	How Often On A Weekly Basis, Were You Taking It? (Specify #) Days Per Week:		Numeric
01. Principal	_3652_10959_11B_How_often_on_a_w	How Often On A Weekly Basis, Were You Taking It?		Char
01. Principal	_3652_10960_Aspirin_taken_specif	Aspirin Taken (Specify):		Char
01. Principal	_3652_10961_11A_What_Aspirin_med	What Aspirin Medication Did You Take? (Include Topicals, OTC And Precriptor)		Char
01. Principal	_3652_10962_11D_Taken_any_aspiri	Since Your Last Study Questionnaire, Have You Taken Aspirin Or Any Medications Containing Aspirin?		"No"="No" "Yes"="Yes"

Class	Variable	Label	Description	Format Text
01. Principal	**_3653_10963_12_ Taken_any_OTC_ med**	Since Your Last Study Questionnaire, Have You Taken Any Over-The-Counter Medications, Other Than The Vitamins And Minerals?		"No"="No" "Yes"="Yes"
01. Principal	**_3653_10964_12 A_What_over_th e_co**	What Over-The-Counter Medication Did You Take?		Char
01. Principal	**_3653_10965_Sp ecify_over_the_c ou**	Specify Over-The-Counter Medication		Char
01. Principal	**_3653_10966_12 B_Reason_of_tak ing**	What Was The Reason You Were Taking It? (Choose The Primary Reason)		Char
01. Principal	**_3653_10967_Oth er_reason**	What Was The Reason You Were Taking It? Other Reason:		Char
01. Principal	**_3653_10968_12 C_How_often_on _ave**	How Often, On Average, On A Weekly Basis, Were You Taking It?		Char
01. Principal	**_3653_10969_Sp ecify_days_per_ wee**	How Often, On Average, On A Weekly Basis, Were You Taking It? Days Per Week		Char
01. Principal	**_3653_10970_12 D_Do_you_have_ addi**	Do You Have Additional Over-The-Counter Medications To Report?		"No"="No" "Yes [please complete supplemental pages as necessary]"="Yes [please complete supplemental pages as necessary]"
01. Principal	**_3654_10971_13_ Taken_any_presc ri**	Since Your Last Study Questionnaire, Have You Taken Any New Prescription Medications?		"No"="No" "Yes"="Yes"
01. Principal	**_3654_10972_13 A_What_prescrip tio**	What Prescription Medication Did You Take?		Char
01. Principal	**_3654_10973_Sp ecify_prescriptio n**	Specify Prescription Medication		Char
01. Principal	**_3654_10974_13 B_Reason_of_tak ing**	What Was The Reason You Were Taking It? (Choose The Primary Reason)		Char
01. Principal	**_3654_10975_Oth er_reason**	What Was The Reason You Were Taking It? Other Reason		Char

Class	Variable	Label	Description	Format Text
01. Principal	_3654_10976_13 C_How_often_on _ave	How Often, On Average, On A Weekly Basis, Were You Taking It?		Char
01. Principal	_3654_10977_Sp ecify_number_da ys_	How Often, On Average, On A Weekly Basis, Were You Taking It? Days Per Week		Char
01. Principal	_3654_10978_13 D_Do_you_have_ addi	Do You Have Additional Types Of Prescription Medications To Report?		"No"="No" "Yes [please complete supplemental pages as necessary]"="Yes [please complete supplemental pages as necessary]"
01. Principal	_3655_10979_14_ Bottle	Study Bottle #?		Char
01. Principal	_3655_10980_14 A_Have_you_rec eive	Have You Received This Study Pill Bottle?		"False"="False" "True"="True"
01. Principal	_3655_10981_14 B_Was_this_bottl e_	Was This Bottle Damaged Or Was There Any Other Problem?		"False"="False"
01. Principal	_3655_10982_14 C_Usable	Study Pill Bottle Usable?		"False"="False" "True"="True"
01. Principal	_3655_10983_Sp ecify_start_date	Start Date:		SAS Date
01. Principal	_3655_10984_15_ No_of_study_pill s	Since Your Last Study Questionnaire, In A Normal Week Of Pill Taking, How Many Study Pills Per Week Did You Take?		"3 - 4 pills"="3 - 4 pills" "5 - 6 pills"="5 - 6 pills" "7 pills"="7 pills" "None - Off study pills"="None - Off study pills"
01. Principal	_3655_10985_16_ Any_period_of_a _w	Since Your Last Study Questionnaire, Was There Any Period Of A Week Or More When You Did Not Take Your Study Pills?		"No"="No" "Yes (go to 16A)"="Yes (go to 16A)"
01. Principal	_3655_10986_14 D_On_what_date _did	On What Date Did You Start Taking Pills From This Bottle?		Char
01. Principal	_3655_11472_16 A_For_how_man y_day	For How Many Days In Total Did You Not Take Your Pills?		Char
01. Principal	_3655_11473_Sp ecify_number_of _da	Specify Number Of Days:		Numeric
01. Principal	_3655_11474_Unr elated_illness	Reason For Stopping Study Agent: Unrelated Illness		"False"="False" "True"="True"
01. Principal	_3655_11475_If_ other_please_sp ec	If Other, Please Specify		Char

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Class	Variable	Label	Description	Format Text
01. Principal	_3655_11476_Vacation	Reason For Stopping Study Agent: Vacation		"False"="False" "True"="True"
01. Principal	_3655_11477_Perceived_symptom_or	Reason For Stopping Study Agent: Perceived Symptom Or Side Effect		"False"="False"
01. Principal	_3655_11478_Lost_Bottle	Reason For Stopping Study Agent: Lost Bottle		"False"="False"
01. Principal	_3655_11479_Other	Reason For Stopping Study Agent: Other		"False"="False" "True"="True"
01. Principal	_3655_11480_Refuse_to_answer	Reason For Stopping Study Agent: Refuse To Answer		"False"="False"
01. Principal	VAR100	Since Your Last Study Questionnaire, In A Normal Week Of Pill Taking, How Many Study Pills Per Week Did You Take?		"3 - 4 pills"="3 - 4 pills" "5 - 6 pills"="5 - 6 pills" "7 pills"="7 pills" "None - Off study pills"="None - Off study pills"
01. Principal	VAR102	Since Your Last Study Questionnaire, Was There Any Period Of A Week Or More When You Did Not Take Your Study Pills?		"No"="No" "Yes (go to 16A)"="Yes (go to 16A)"
01. Principal	VAR104	On What Date Did You Start Taking Pills From This Bottle?		Char
01. Principal	VAR106	For How Many Days In Total Did You Not Take Your Pills?		Char
01. Principal	VAR149	When Were You Admitted?		Char
01. Principal	VAR22	Nausea Or Vomiting?		"None"="None" "Severe"="Severe" "Some"="Some"
01. Principal	VAR28	Since Your Last Study Questionnaire, Have You Been Hospitalized Overnight?		"No"="No" "Yes"="Yes"
01. Principal	VAR30	Since Your Last Study Questionnaire, Have You Seen A Doctor Or Other Medical Personnel For Any Reason Or Visited A Clinic For A Same-Day Procedure?		"No"="No" "Yes"="Yes"
01. Principal	VAR32	When Did You Visit The Dr. Or Have The Same Day Procedure?		Char
01. Principal	VAR34	What Was The Purpose Of This Visit?		Char

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Class	Variable	Label	Description	Format Text
01. Principal	**VAR36**	What Was The Reason Or Diagnosis?		Char
01. Principal	**VAR38**	Var38		Char
01. Principal	**VAR40**	Do You Have Another Dr. Visit Or Same-Day Procedure For A Different Purpose, Reason Or Diagnosis, Or The Same Purpose, Reason Or Diagnosis On A Different Date To Report?		"No"="No" "Yes [please complete supplement pages as necessary]"="Yes [please complete supplement pages as necessary]"
01. Principal	**VAR42**	Do You Have Another Hospitalization On A Different Date To Report?		"No"="No"
01. Principal	**VAR50**	What Was The Reason You Were Taking It? (Choose The Primary Reason)		"Cold/flu"="Cold/flu" "Headache"="Headache" "Other reason"="Other reason"
01. Principal	**VAR53**	What Was The Dose Per Pill Or Other Form?		"81 mg (baby aspirin)"="81 mg (baby aspirin)" "Don't know"="Don't know"
01. Principal	**VAR56**	How Many Pills/Gums/Other Forms Per Day Did You Take On Average On The Days When You Were Taking It?		Char
01. Principal	**VAR59**	In What Form Did You Take This Aspirin Medication?		"Pill tablet"="Pill tablet"
01. Principal	**VAR62**	How Often On A Weekly Basis, Were You Taking It?		Char
01. Principal	**VAR65**	What Aspirin Medication Did You Take? (Include Topicals, OTC And Precriptor)		Char
01. Principal	**VAR67**	Since Your Last Study Questionnaire, Have You Taken Aspirin Or Any Medications Containing Aspirin?		"No"="No" "Yes"="Yes"
01. Principal	**VAR69**	Since Your Last Study Questionnaire, Have You Taken Any Over-The-Counter Medications, Other Than The Vitamins And Minerals?		"No"="No" "Yes"="Yes"

Class	Variable	Label	Description	Format Text
01. Principal	**VAR71**	What Over-The-Counter Medication Did You Take?		Char
01. Principal	**VAR74**	What Was The Reason You Were Taking It? (Choose The Primary Reason)		Char
01. Principal	**VAR77**	How Often, On Average, On A Weekly Basis, Were You Taking It?		Char
01. Principal	**VAR80**	Do You Have Additional Over-The-Counter Medications To Report?		"No"="No" "Yes [please complete supplemental pages as necessary]"="Yes [please complete supplemental pages as necessary]"
01. Principal	**VAR82**	Since Your Last Study Questionnaire, Have You Taken Any New Prescription Medications?		"No"="No" "Yes"="Yes"
01. Principal	**VAR84**	What Prescription Medication Did You Take?		Char
01. Principal	**VAR87**	What Was The Reason You Were Taking It? (Choose The Primary Reason)		Char
01. Principal	**VAR90**	How Often, On Average, On A Weekly Basis, Were You Taking It?		Char
01. Principal	**VAR93**	Do You Have Additional Types Of Prescription Medications To Report?		"No"="No" "Yes [please complete supplemental pages as necessary]"="Yes [please complete supplemental pages as necessary]"