

MDA2013-02-02 - Interval 2 Questionnaire Data Dictionary

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Document Summary

Property	Value
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MDA2013-02-02 - Interval 2 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 2 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	_3652_10950_Other_reason_specify	What Was The Reason You Were Taking It? Other Reason (Specify):		Char
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_week	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_specify	Aspirin Taken (Specify):		Char
01. Principal	_3652_10961_11A_What_Aspirin_med	What Aspirin Medication Did You Take? (Include Topicals, OTC And Precipitor)		Char

Class	Variable	Label	Description	Format Text
01. Principal	_3652_10962_11 D_Taken_any_as piri	Since Your Last Study Questionnaire, Have You Taken Aspirin Or Any Medications Containing Aspirin?		"No"="No" "Yes"="Yes"
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

Class	Variable	Label	Description	Format Text
01. Principal	_3654_10975_Other_reason	What Was The Reason You Were Taking It? Other Reason		Char
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_Specify_number_days_	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 #?		"0"="0" "1"="1" "2"="2" "3"="3" "4"="4" "5"="5" "N/A"="N/A" "NA"="NA"
01. Principal	_3655_10980_14_A_Have_you_receive	Have You Received This Study Pill Bottle?		"False"="False" "True"="True"
01. Principal	_3655_10981_14_B_Was_this_bottle_	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_Specify_start_date	Start Date:		SAS Date
01. Principal	_3655_10984_15_No_of_study_pills	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_many_day	For How Many Days In Total Did You Not Take Your Pills?		"Specify"="Specify"

Class	Variable	Label	Description	Format Text
01. Principal	_3655_11473_Specify_number_of_da	Specify Number Of Days:		Numeric
01. Principal	_3655_11474_Unrelated_illness	Reason For Stopping Study Agent: Unrelated Illness		"False"="False" "True"="True"
01. Principal	_3655_11475_If_other_please_spec	If Other, Please Specify		Char
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	_3656_10899_mm_dd_yyyy	(mm/dd/yyyy)		Numeric
01. Principal	_3656_10902_9A_When_did_you_visit	When Did You Visit The Dr. Or Have The Same Day Procedure? (Description)		Char
01. Principal	_3656_10903_9B_What_was_the_purp	What Was The Purpose Of This Visit?		"Checkup"="Checkup" "Follow-up to a earlier diagnosis"="Follow-up to a earlier diagnosis" "New diagnosis"="New diagnosis"
01. Principal	_3656_10904_9C_What_was_the_reas	What Was The Reason Or Diagnosis?		"Reason or diagnosis"="Reason or diagnosis"

Class	Variable	Label	Description	Format Text
01. Principal	_3656_10908_Hospital_Clinic	Hospital/Clinic		"MEDVAMC"="MEDVAMC" "Mayo Clinic Rochester"="Mayo Clinic Rochester" "Mayo Clinic"="Mayo Clinic" "Medical Center of Southeast Texas"="Medical Center of Southeast Texas" "Minute Clinic CC Family Practice"="Minute Clinic CC Family Practice" "NMH"="NMH" "Nash General"="Nash General" "North Memorial Clinic"="North Memorial Clinic" "Northway Family Medicine"="Northway Family Medicine" "Owen Sound Family Health"="Owen Sound Family Health" "St. Cloud"="St. Cloud" "St. Luke's Hospital- TMC"="St. Luke's Hospital- TMC" "St. Luke's"="St. Luke's"
01. Principal	_3656_10909_mm_yyyy	mm-yyyy		Char
01. Principal	_3656_10911_Year	Year		Char
01. Principal	_3656_10912_Reason_or_diagnosis	Reason Or Diagnosis		Char
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?		"Specify"="Specify"
01. Principal	VAR119	Reason Or Diagnosis		Char
01. Principal	VAR121	What Was The Reason Or Diagnosis?		"Reason or diagnosis"="Reason or diagnosis"
01. Principal	VAR123	What Was The Purpose Of This Visit?		"Checkup"="Checkup" "Follow-up to a earlier diagnosis"="Follow-up to a earlier diagnosis" "New diagnosis"="New diagnosis"
01. Principal	VAR128	When Did You Visit The Dr. Or Have The Same Day Procedure? (Description)		Char

Class	Variable	Label	Description	Format Text
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
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

Class	Variable	Label	Description	Format Text
01. Principal	VAR65	What Aspirin Medication Did You Take? (Include Topicals, OTC And Preciptor)		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"
01. Principal	VAR71	What Over-The-Counter Medication Did You Take?		Char
01. Principal	VAR74	What Over-The-Counter Medication Did You Take?		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]"

