MDA2013-02-02 - Interval 3 Questionnaire Data Dictionary

TABLE OF CONTENTS

Document Summary

Property	Value
Document Title	MDA2013-02-02 - Interval 3 Questionnaire: Data Dictionary
Date Created	05/20/2024
Sections	3
Entries	121
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MDA2013-02-02 - Interval 3 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 3 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_T rouble_Breathing**	Trouble Breathing?		"None"="None" "Some"="Some"
01. Principal	**_3649_10891_7_T rouble_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_It ching**	Itching?		"Don't know"="Don't know" "None"="None" "Some"="Some"
01. Principal	**_3649_10893_5_It ching__Desc_**	Itching? (Description)		"Don't know"="Don't know" "None"="None" "Some"="Some"
01. Principal	**_3649_10894_4_L oss_of_Appetite**	Loss Of Appetite?		"None"="None"
01. Principal	**_3649_10894_4_L oss_of_Appetite_ _**	Loss Of Appetite? (Description)		"None"="None"
01. Principal	**_3649_10895_3_ Stomach_Cramp s**	Stomach Cramps?		"Don't know"="Don't know" "None"="None" "Severe"="Severe" "Some"="Some"
01. Principal	**_3649_10895_3_ Stomach_Cramp s__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_vomit ing**	Nausea Or Vomiting?		"None"="None" "Severe"="Severe" "Some"="Some"
01. Principal	**_3649_10898_Vis it_Date**	Visit Date		SAS Date

Class	Variable	Label	Description	Format Text
01. Principal	**_3649_14013_Completed_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_Completed_by__Desc_**	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_mm_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_visited**	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_visit_**	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_10D_Do_you_have_anot**	Do You Have Another Hospitalization On A Different Date To Report?		"No"="No"
01. Principal	**_3650_10908_Hospital_Clinic**	Hospital/Clinic		Char
01. Principal	**_3650_10909_mm_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_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

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_prescr i**	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

MDA2013-02-02 - Interval 3 Questionnaire: Data Dictionary
05/20/2024

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_13C_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_13D_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_14A_Have_you_receive**	Have You Received This Study Pill Bottle?		"False"="False" "True"="True"
01. Principal	**_3655_10981_14B_Was_this_bottle_**	Was This Bottle Damaged Or Was There Any Other Problem?		"False"="False"
01. Principal	**_3655_10982_14C_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_14D_On_what_date_did**	On What Date Did You Start Taking Pills From This Bottle?		Char
01. Principal	**_3655_11472_16A_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	_3657_10972_13A_What_prescriptio	What Prescription Medication Did You Take?		"Specify"="Specify"
01. Principal	_3657_10973_Specify_prescription	Specify Prescription Medication		Char
01. Principal	_3657_10974_13B_Reason_of_taking	What Was The Reason You Were Taking It? (Choose The Primary Reason)		"Arthritis/joint pain"="Arthritis/joint pain" "Asthma"="Asthma" "Bone Density"="Bone Density" "Depression/Anxiety"="Depression/Anxiety" "Diabetes"="Diabetes" "Diuretic"="Diuretic" "Eye condition"="Eye condition" "GERD"="GERD" "Gout"="Gout" "High BP"="High BP" "High cholesterol"="High cholesterol" "Infection"="Infection" "Other Pain"="Other Pain" "Other reason"="Other reason" "Prostate"="Prostate" "Skin condition"="Skin condition" "Sleep problems"="Sleep problems" "Swelling / inflammation"="Swelling / inflammation" "Thyroid Function"="Thyroid Function" "Urinary problem"="Urinary problem"
01. Principal	_3657_10975_Other_reason	What Was The Reason You Were Taking It? Other Reason		Char

Class	Variable	Label	Description	Format Text
01. Principal	**_3657_10976_13 C_How_often_on _ave**	How Often, On Average, On A Weekly Basis, Were You Taking It?		"Don't know"="Don't know" "Less than one day per week"="Less than one day per week" "Specify"="Specify"
01. Principal	**_3657_10977_Sp ecify_number_da ys_**	How Often, On Average, On A Weekly Basis, Were You Taking It? (Specify Number) Days Per Week		Numeric
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	**VAR117**	How Often, On Average, On A Weekly Basis, Were You Taking It?		"Don't know"="Don't know" "Less than one day per week"="Less than one day per week" "Specify"="Specify"
01. Principal	**VAR120**	What Was The Reason You Were Taking It? (Choose The Primary Reason)		"Arthritis/joint pain"="Arthritis/joint pain" "Asthma"="Asthma" "Bone Density"="Bone Density" "Depression/Anxiety"="Depression/Anxiety" "Diabetes"="Diabetes" "Diuretic"="Diuretic" "Eye condition"="Eye condition" "GERD"="GERD" "Gout"="Gout" "High BP"="High BP" "High cholesterol"="High cholesterol" "Infection"="Infection" "Other Pain"="Other Pain" "Other reason"="Other reason" "Prostate"="Prostate" "Skin condition"="Skin condition" "Sleep problems"="Sleep problems" "Swelling / inflammation"="Swelling / inflammation" "Thyroid Function"="Thyroid Function" "Urinary problem"="Urinary problem"
01. Principal	**VAR123**	What Prescription Medication Did You Take?		"Specify"="Specify"

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 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"
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]"