

# MDA2013-02-02 - Interval 4 Questionnaire Data Dictionary

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## Document Summary

| Property          | Value   |
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## MDA2013-02-02 - Interval 4 Questionnaire: Data Dictionary

### Section 1: Identifiers

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| Class         | Variable    | Label | Description | Format Text |
|---------------|-------------|-------|-------------|-------------|
| 01. Principal | <b>MRNO</b> | MRNO  |             | Numeric     |

## Section 2: Study Wide

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

## Section 3: Interval 4 Questionnaire

| Class         | Variable                                | Label                            | Description | Format Text  |
|---------------|---|----------------------------------|-------------|--|
| 01. Principal | <b>_3649_10890_8_Seizures</b>           | Seizures?                        |             | "None"="None"  |
| 01. Principal | <b>_3649_10890_8_Seizures_Desc_</b>     | Seizures? (Description)          |             | "None"="None"  |
| 01. Principal | <b>_3649_10891_7_Trouble_Breathing</b>  | Trouble Breathing?               |             | "None"="None"<br>"Some"="Some"   |
| 01. Principal | <b>_3649_10891_7_Trouble_Breathing_</b> | Trouble Breathing? (Description) |             | "None"="None"<br>"Some"="Some"   |
| 01. Principal | <b>_3649_10892_6_Blood_on_stool</b>     | Blood On Stool?                  |             | "None"="None"<br>"Some"="Some"   |
| 01. Principal | <b>_3649_10892_6_Blood_on_stool_De</b>  | Blood On Stool? (Description)    |             | "None"="None"<br>"Some"="Some"   |
| 01. Principal | <b>_3649_10893_5_Itching</b>            | Itching?                         |             | "Don't know"="Don't know"<br>"None"="None"<br>"Some"="Some"                      |
| 01. Principal | <b>_3649_10893_5_Itching_Desc_</b>      | Itching? (Description)           |             | "Don't know"="Don't know"<br>"None"="None"<br>"Some"="Some"                      |
| 01. Principal | <b>_3649_10894_4_Loss_of_Appetite</b>   | Loss Of Appetite?                |             | "None"="None"  |
| 01. Principal | <b>_3649_10894_4_Loss_of_Appetite_</b>  | Loss Of Appetite? (Description)  |             | "None"="None"  |
| 01. Principal | <b>_3649_10895_3_Stomach_Cramps</b>     | Stomach Cramps?                  |             | "Don't know"="Don't know"<br>"None"="None"<br>"Severe"="Severe"<br>"Some"="Some" |
| 01. Principal | <b>_3649_10895_3_Stomach_Cramps_De</b>  | Stomach Cramps? (Description)    |             | "Don't know"="Don't know"<br>"None"="None"<br>"Severe"="Severe"<br>"Some"="Some" |
| 01. Principal | <b>_3649_10896_2_Heartburn</b>          | Heartburn?                       |             | "None"="None"<br>"Severe"="Severe"<br>"Some"="Some"                              |
| 01. Principal | <b>_3649_10896_2_Heartburn_Desc_</b>    | Heartburn? (Description)         |             | "None"="None"<br>"Severe"="Severe"<br>"Some"="Some"                              |
| 01. Principal | <b>_3649_10897_1_Nausea_or_vomiting</b> | Nausea Or Vomiting?              |             | "None"="None"<br>"Severe"="Severe"<br>"Some"="Some"                              |
| 01. Principal | <b>_3649_10898_Visit_Date</b>           | Visit Date                       |             | SAS Date   |

| Class         | Variable  | Label   | Description | Format Text  |
|---------------|---|---|-------------|--|
| 01. Principal | <b>_3649_14013_Co<br/>mpleted_by</b>              | Completed by:   |             | "Site designee (questionnaire as source)"="Site designee (questionnaire as source)"<br>"Site designee (responses entered directly to eCRF, no paper sour)"="Site designee (responses entered directly to eCRF, no paper sour"      |
| 01. Principal | <b>_3649_14013_Co<br/>mpleted_by__De<br/>sc_</b>  | Completed by<br>(Description):  |             | "Site designee (questionnaire as source)"="Site designee (questionnaire as source)"<br>"Site designee (responses entered directly to eCRF, no paper source)"="Site designee (responses entered directly to eCRF, no paper source)" |
| 01. Principal | <b>_3650_10899_m<br/>m_dd_yyyy</b>                | Dr. Visit Date  |             | Char   |
| 01. Principal | <b>_3650_10900_10_<br/>Since_your_last_<br/>s</b> | Since Your Last Study Questionnaire, Have You Been Hospitalized Overnight?  |             | "No"="No"<br>"Yes"="Yes"   |
| 01. Principal | <b>_3650_10901_9_<br/>Seen_Dr_or_visit<br/>ed</b> | 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"<br>"Yes"="Yes"   |
| 01. Principal | <b>_3650_10902_9A_<br/>When_did_you_<br/>visi</b> | When Did You Visit The Dr. Or Have The Same Day Procedure?  |             | Char   |
| 01. Principal | <b>_3650_10903_9B_<br/>What_was_the_<br/>purp</b> | What Was The Purpose Of This Visit?   |             | Char   |
| 01. Principal | <b>_3650_10904_9C_<br/>What_was_the_<br/>reas</b> | What Was The Reason Or Diagnosis?   |             | Char   |
| 01. Principal | <b>_3650_10906_9E_<br/>Another_Dr_visi<br/>t_</b> | 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"<br>"Yes [please complete supplement pages as necessary]"="Yes [please complete supplement pages as necessary]"   |
| 01. Principal | <b>_3650_10907_10<br/>D_Do_you_have_<br/>anot</b> | Do You Have Another Hospitalization On A Different Date To Report?  |             | "No"="No"  |
| 01. Principal | <b>_3650_10908_Ho<br/>spital_Clinic</b>           | Hospital/Clinic   |             | Char   |
| 01. Principal | <b>_3650_10909_m<br/>m_yyyy</b>                   | Hospital/Clinic Visit Date  |             | Char   |

| Class         | Variable                                 | Label   | Description | Format Text   |
|---------------|--|---|-------------|---|
| 01. Principal | <b>_3650_10911_Year</b>                  | Year  |             | Char  |
| 01. Principal | <b>_3650_10912_Reason_or_diagnosis</b>   | Reason Or Diagnosis   |             | Char  |
| 01. Principal | <b>_3652_10950_Other_reason_specify</b>  | What Was The Reason You Were Taking It? Other Reason (Specify):   |             | Char  |
| 01. Principal | <b>_3652_10951_11F_Reason_of_taking</b>  | What Was The Reason You Were Taking It? (Choose The Primary Reason)   |             | "Cold/flu"="Cold/flu"<br>"Headache"="Headache"<br>"Other reason"="Other reason" |
| 01. Principal | <b>_3652_10952_Other_specify</b>         | What Was The Dose Per Pill Or Other Form? Other (Specify):  |             | Char  |
| 01. Principal | <b>_3652_10953_11E_What_was_the_dos</b>  | What Was The Dose Per Pill Or Other Form?   |             | "81 mg (baby aspirin)"="81 mg (baby aspirin)"<br>"Don't know"="Don't know"      |
| 01. Principal | <b>_3652_10954_Specify</b>               | 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 | <b>_3652_10955_11D_How_many_pills_p</b>  | How Many Pills/Gums/Other Forms Per Day Did You Take On Average On The Days When You Were Taking It?            |             | Char  |
| 01. Principal | <b>_3652_10956_specify</b>               | In What Form Did You Take This Aspirin Medication? (Specify):   |             | Char  |
| 01. Principal | <b>_3652_10957_11C_In_what_form_did</b>  | In What Form Did You Take This Aspirin Medication?  |             | "Pill tablet"="Pill tablet"   |
| 01. Principal | <b>_3652_10958_specify_days_per_week</b> | How Often On A Weekly Basis, Were You Taking It? (Specify #) Days Per Week:                                     |             | Numeric   |
| 01. Principal | <b>_3652_10959_11B_How_often_on_a_w</b>  | How Often On A Weekly Basis, Were You Taking It?  |             | Char  |
| 01. Principal | <b>_3652_10960_Aspirin_taken_specify</b> | Aspirin Taken (Specify):  |             | Char  |
| 01. Principal | <b>_3652_10961_11A_What_Aspirin_med</b>  | What Aspirin Medication Did You Take? (Include Topicals, OTC And Precipitor)                                    |             | Char  |

| Class         | Variable  | Label   | Description | Format Text  |
|---------------|---|---|-------------|--|
| 01. Principal | <b>_3652_10962_11<br/>D_Taken_any_as<br/>piri</b> | Since Your Last Study Questionnaire, Have You Taken Aspirin Or Any Medications Containing Aspirin?                          |             | "No"="No"<br>"Yes"="Yes"   |
| 01. Principal | <b>_3653_10963_12_<br/>Taken_any_OTC_<br/>med</b> | Since Your Last Study Questionnaire, Have You Taken Any Over-The-Counter Medications, Other Than The Vitamins And Minerals? |             | "No"="No"<br>"Yes"="Yes"   |
| 01. Principal | <b>_3653_10964_12<br/>A_What_over_th<br/>e_co</b> | What Over-The-Counter Medication Did You Take?  |             | Char   |
| 01. Principal | <b>_3653_10965_Sp<br/>ecify_over_the_c<br/>ou</b> | Specify Over-The-Counter Medication   |             | Char   |
| 01. Principal | <b>_3653_10966_12<br/>B_Reason_of_tak<br/>ing</b> | What Was The Reason You Were Taking It? (Choose The Primary Reason)   |             | Char   |
| 01. Principal | <b>_3653_10967_Oth<br/>er_reason</b>              | What Was The Reason You Were Taking It? Other Reason:   |             | Char   |
| 01. Principal | <b>_3653_10968_12<br/>C_How_often_on<br/>_ave</b> | How Often, On Average, On A Weekly Basis, Were You Taking It?   |             | Char   |
| 01. Principal | <b>_3653_10969_Sp<br/>ecify_days_per_<br/>wee</b> | How Often, On Average, On A Weekly Basis, Were You Taking It? Days Per Week   |             | Char   |
| 01. Principal | <b>_3653_10970_12<br/>D_Do_you_have_<br/>addi</b> | Do You Have Additional Over-The-Counter Medications To Report?  |             | "No"="No"<br>"Yes [please complete supplemental pages as necessary]"="Yes [please complete supplemental pages as necessary]" |
| 01. Principal | <b>_3654_10971_13_<br/>Taken_any_presc<br/>ri</b> | Since Your Last Study Questionnaire, Have You Taken Any New Prescription Medications?                                       |             | "No"="No"<br>"Yes"="Yes"   |
| 01. Principal | <b>_3654_10972_13<br/>A_What_prescrip<br/>tio</b> | What Prescription Medication Did You Take?  |             | Char   |
| 01. Principal | <b>_3654_10973_Sp<br/>ecify_prescriptio<br/>n</b> | Specify Prescription Medication   |             | Char   |
| 01. Principal | <b>_3654_10974_13<br/>B_Reason_of_tak<br/>ing</b> | What Was The Reason You Were Taking It? (Choose The Primary Reason)   |             | Char   |



| Class         | Variable                                 | Label   | Description | Format Text  |
|---------------|--|---|-------------|--|
| 01. Principal | <b>_3654_10975_Other_reason</b>          | What Was The Reason You Were Taking It? Other Reason  |             | Char   |
| 01. Principal | <b>_3654_10976_13_C_How_often_on_ave</b> | How Often, On Average, On A Weekly Basis, Were You Taking It?   |             | Char   |
| 01. Principal | <b>_3654_10977_Specify_number_days_</b>  | How Often, On Average, On A Weekly Basis, Were You Taking It? Days Per Week   |             | Char   |
| 01. Principal | <b>_3654_10978_13_D_Do_you_have_addi</b> | Do You Have Additional Types Of Prescription Medications To Report?   |             | "No"="No"<br>"Yes [please complete supplemental pages as necessary]"="Yes [please complete supplemental pages as necessary]"           |
| 01. Principal | <b>_3655_10979_14_Bottle</b>             | Study Bottle #?   |             | Char   |
| 01. Principal | <b>_3655_10980_14_A_Have_you_receive</b> | Have You Received This Study Pill Bottle?   |             | "False"="False"<br>"True"="True"   |
| 01. Principal | <b>_3655_10981_14_B_Was_this_bottle_</b> | Was This Bottle Damaged Or Was There Any Other Problem?   |             | "False"="False"  |
| 01. Principal | <b>_3655_10982_14_C_Usable</b>           | Study Pill Bottle Usable?   |             | "False"="False"<br>"True"="True"   |
| 01. Principal | <b>_3655_10983_Specify_start_date</b>    | Start Date:   |             | SAS Date   |
| 01. Principal | <b>_3655_10984_15_No_of_study_pills</b>  | 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"<br>"5 - 6 pills"="5 - 6 pills"<br>"7 pills"="7 pills"<br>"None - Off study pills"="None - Off study pills" |
| 01. Principal | <b>_3655_10985_16_Any_period_of_a_w</b>  | Since Your Last Study Questionnaire, Was There Any Period Of A Week Or More When You Did Not Take Your Study Pills? |             | "No"="No"<br>"Yes (go to 16A)"="Yes (go to 16A)"   |
| 01. Principal | <b>_3655_10986_14_D_On_what_date_did</b> | On What Date Did You Start Taking Pills From This Bottle?   |             | Char   |
| 01. Principal | <b>_3655_11472_16_A_For_how_many_day</b> | For How Many Days In Total Did You Not Take Your Pills?   |             | "Specify"="Specify"  |
| 01. Principal | <b>_3655_11473_Specify_number_of_da</b>  | Specify Number Of Days:   |             | Numeric  |
| 01. Principal | <b>_3655_11474_Unrelated_illness</b>     | Reason For Stopping Study Agent: Unrelated Illness  |             | "False"="False"<br>"True"="True"   |

| Class         | Variable                                 | Label   | Description | Format Text  |
|---------------|--|---|-------------|--|
| 01. Principal | <b>_3655_11475_If_other_please_spec</b>  | If Other, Please Specify  |             | Char   |
| 01. Principal | <b>_3655_11476_Vacation</b>              | Reason For Stopping Study Agent: Vacation   |             | "False"="False"<br>"True"="True"   |
| 01. Principal | <b>_3655_11477_Perceived_symptom_or</b>  | Reason For Stopping Study Agent: Perceived Symptom Or Side Effect   |             | "False"="False"  |
| 01. Principal | <b>_3655_11478_Lost_Bottle</b>           | Reason For Stopping Study Agent: Lost Bottle  |             | "False"="False"  |
| 01. Principal | <b>_3655_11479_Other</b>                 | Reason For Stopping Study Agent: Other  |             | "False"="False"<br>"True"="True"   |
| 01. Principal | <b>_3655_11480_Refuse_to_answer</b>      | Reason For Stopping Study Agent: Refuse To Answer   |             | "False"="False"  |
| 01. Principal | <b>_3658_10964_12A_What_over_the_co</b>  | What Prescription Medication Did You Take?  |             | "Don't know"="Don't know"<br>"Specify"="Specify"   |
| 01. Principal | <b>_3658_10965_Specify_over_the_cou</b>  | Specify Prescription Medication   |             | Char   |
| 01. Principal | <b>_3658_10966_12B_Reason_of_taking</b>  | What Was The Reason You Were Taking It? (Choose The Primary Reason)   |             | "Arthritis/joint pain"="Arthritis/joint pain"<br>"Back pain"="Back pain"<br>"Cold/flu"="Cold/flu"<br>"Don't know"="Don't know"<br>"Headache"="Headache"<br>"Heartburn"="Heartburn"<br>"Indigestion"="Indigestion"<br>"Other reason"="Other reason" |
| 01. Principal | <b>_3658_10967_Other_reason</b>          | What Was The Reason You Were Taking It? Other Reason  |             | "Allergies"="Allergies"<br>"Nausea"="Nausea"<br>"Sinus"="Sinus"<br>"Supplement"="Supplement"<br>"Vertigo"="Vertigo"<br>"supplement"="supplement"   |
| 01. Principal | <b>_3658_10968_12C_How_often_on_ave</b>  | How Often, On Average, On A Weekly Basis, Were You Taking It?   |             | "Don't know"="Don't know"<br>"Less than one day per week"="Less than one day per week"<br>"Specify"="Specify"  |
| 01. Principal | <b>_3658_10969_Specify_days_per_week</b> | How Often, On Average, On A Weekly Basis, Were You Taking It? (Specify Number) Days Per Week                      |             | Numeric  |
| 01. Principal | <b>VAR100</b>                            | 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"<br>"5 - 6 pills"="5 - 6 pills"<br>"7 pills"="7 pills"<br>"None - Off study pills"="None - Off study pills"   |

| Class         | Variable      | Label   | Description | Format Text  |
|---------------|---------------|---|-------------|--|
| 01. Principal | <b>VAR102</b> | Since Your Last Study Questionnaire, Was There Any Period Of A Week Or More When You Did Not Take Your Study Pills?                                 |             | "No"="No"<br>"Yes (go to 16A)"="Yes (go to 16A)"   |
| 01. Principal | <b>VAR104</b> | On What Date Did You Start Taking Pills From This Bottle?   |             | Char   |
| 01. Principal | <b>VAR106</b> | For How Many Days In Total Did You Not Take Your Pills?   |             | "Specify"="Specify"  |
| 01. Principal | <b>VAR117</b> | How Often, On Average, On A Weekly Basis, Were You Taking It?   |             | "Don't know"="Don't know"<br>"Less than one day per week"="Less than one day per week"<br>"Specify"="Specify"  |
| 01. Principal | <b>VAR120</b> | What Was The Reason You Were Taking It? (Choose The Primary Reason)   |             | "Arthritis/joint pain"="Arthritis/joint pain"<br>"Back pain"="Back pain"<br>"Cold/flu"="Cold/flu"<br>"Don't know"="Don't know"<br>"Headache"="Headache"<br>"Heartburn"="Heartburn"<br>"Indigestion"="Indigestion"<br>"Other reason"="Other reason" |
| 01. Principal | <b>VAR123</b> | What Prescription Medication Did You Take?  |             | "Don't know"="Don't know"<br>"Specify"="Specify"   |
| 01. Principal | <b>VAR22</b>  | Nausea Or Vomiting?   |             | "None"="None"<br>"Severe"="Severe"<br>"Some"="Some"  |
| 01. Principal | <b>VAR28</b>  | Since Your Last Study Questionnaire, Have You Been Hospitalized Overnight?  |             | "No"="No"<br>"Yes"="Yes"   |
| 01. Principal | <b>VAR30</b>  | 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"<br>"Yes"="Yes"   |
| 01. Principal | <b>VAR32</b>  | When Did You Visit The Dr. Or Have The Same Day Procedure?  |             | Char   |
| 01. Principal | <b>VAR34</b>  | What Was The Purpose Of This Visit?   |             | Char   |
| 01. Principal | <b>VAR36</b>  | What Was The Reason Or Diagnosis?   |             | Char   |
| 01. Principal | <b>VAR38</b>  | Var38   |             | Char   |

| Class         | Variable     | Label   | Description | Format Text  |
|---------------|--------------|---|-------------|--|
| 01. Principal | <b>VAR40</b> | 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"<br>"Yes [please complete supplement pages as necessary]"="Yes [please complete supplement pages as necessary]" |
| 01. Principal | <b>VAR42</b> | Do You Have Another Hospitalization On A Different Date To Report?  |             | "No"="No"  |
| 01. Principal | <b>VAR50</b> | What Was The Reason You Were Taking It? (Choose The Primary Reason)   |             | "Cold/flu"="Cold/flu"<br>"Headache"="Headache"<br>"Other reason"="Other reason"  |
| 01. Principal | <b>VAR53</b> | What Was The Dose Per Pill Or Other Form?   |             | "81 mg (baby aspirin)"="81 mg (baby aspirin)"<br>"Don't know"="Don't know"   |
| 01. Principal | <b>VAR56</b> | How Many Pills/Gums/Other Forms Per Day Did You Take On Average On The Days When You Were Taking It?  |             | Char   |
| 01. Principal | <b>VAR59</b> | In What Form Did You Take This Aspirin Medication?  |             | "Pill tablet"="Pill tablet"  |
| 01. Principal | <b>VAR62</b> | How Often On A Weekly Basis, Were You Taking It?  |             | Char   |
| 01. Principal | <b>VAR65</b> | What Aspirin Medication Did You Take? (Include Topicals, OTC And Preciptor)   |             | Char   |
| 01. Principal | <b>VAR67</b> | Since Your Last Study Questionnaire, Have You Taken Aspirin Or Any Medications Containing Aspirin?  |             | "No"="No"<br>"Yes"="Yes"   |
| 01. Principal | <b>VAR69</b> | Since Your Last Study Questionnaire, Have You Taken Any Over-The-Counter Medications, Other Than The Vitamins And Minerals?   |             | "No"="No"<br>"Yes"="Yes"   |
| 01. Principal | <b>VAR71</b> | What Over-The-Counter Medication Did You Take?  |             | Char   |

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