

# MDA2016-08-02 - Off Study Data Dictionary

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## Document Summary

| Property          | Value                                      |
|-------------------|--|
| Document Title    | MDA2016-08-02 - Off Study: Data Dictionary |
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| Sections          | 3  |
| Entries           | 19   |
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## MDA2016-08-02 - Off Study: Data Dictionary

### Section 1: Identifiers

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

## Section 2: Study-wide

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| Class         | Variable             | Label                   | Description | Format Text   |
|---------------|----------------------|-------------------------|-------------|---|
| 01. Principal | <b>Accession</b>     | Accession Number        |             | Numeric   |
| 01. Principal | <b>Form</b>          | Form                    |             | "Off Study"="Off Study"                                       |
| 01. Principal | <b>Institution</b>   | Registering Institution |             | "M. D. Anderson Cancer Center"="M. D. Anderson Cancer Center" |
| 01. Principal | <b>Interval</b>      | Interval                |             | "Event Interval not available"="Event Interval not available" |
| 01. Principal | <b>Interval_Date</b> | Interval Date           |             | SAS Date  |
| 01. Principal | <b>Reg_Date</b>      | Registering Date        |             | Char  |
| 01. Principal | <b>Trial</b>         | Trial                   |             | "MDA2016-08-02"="MDA2016-08-02"                               |

## Section 3: Off Study

| Class         | Variable                                | Label  | Description | Format Text   |
|---------------|---|--|-------------|---|
| 01. Principal | <b>_238_10172_Participant_did_not_t</b> | Participant Did Not Take Any Concomitant Medications   |             | "False"="False"<br>"True"="True"  |
| 01. Principal | <b>_238_10192_Off_Study_Date</b>        | Off Study Date   |             | Char  |
| 01. Principal | <b>_238_10193_Date_of_Last_Contact</b>  | Date Of Last Contact   |             | Char  |
| 01. Principal | <b>_238_10194_Agent_End_Date</b>        | Agent End Date   |             | Char  |
| 01. Principal | <b>_238_10197_Participant_did_not_h</b> | Participant Did Not Have Any Adverse Events  |             | "False"="False"<br>"True"="True"  |
| 01. Principal | <b>_238_10218_Form_Date</b>             | Form Date  |             | Char  |
| 01. Principal | <b>_238_10223_Not_Applicable</b>        | Agent End Date Not Applicable  |             | "False"="False"<br>"True"="True"  |
| 01. Principal | <b>_238_11511_Check_this_box_if_the</b> | Check This Box If The Participant Did Not Have Any Agent Modifications                                     |             | "False"="False"<br>"True"="True"  |
| 01. Principal | <b>_238_12592_Off_Study_Reason</b>      | Reason Off Study: (Mark Only Primary Reason. Reasons Other Than Completed Study Require Explanation Below) |             | "Adverse Event"='Adverse Event'"Death (complete Death Report CRF & SAE form" = "Death (complete Death Report CRF & SAE form'<br>"Disease Progression"="Disease Progression"<br>"Ineligible"="Ineligible"<br>"Lost to follow-up"="Lost to follow-up"<br>"Other, specify"="Other, specify"<br>"Participant Refused Follow-up"="Participant Refused Follow-up"<br>"Participant Withdrawal"="Participant Withdrawal"<br>"Physician Decision"="Physician Decision"<br>"Protocol Defined Follow-up Completed"="Protocol Defined Follow-up Completed"<br>"Protocol Violation" = "Protocol Violation" = "Protocol Violation"<br>"Study Complete"="Study Complete" |

| Class         | Variable                                      | Label   | Description | Format Text   |
|---------------|---|---|-------------|---|
| 01. Principal | <b><u>_238_12592_Off_Study_Reason_Des</u></b> | Reason Off Study:<br>(Mark Only Primary Reason. Reasons Other Than Completed Study Require Explanation Below)<br>(Desc) |             | "Adverse Event/Serious Adverse Event (Complete AE CRF & SAE form, if applicable)"="Adverse Event/Serious Adverse Event (Complete AE CRF & SAE form, if applicable)"<br>"Death (complete Death Report CRF & SAE form)"="Death (complete Death Report CRF & SAE form)"<br>"Disease Progression"="Disease Progression"<br>"Ineligible"="Ineligible"<br>"Lost to follow-up"="Lost to follow-up"<br>"Other, specify"="Other, specify"<br>"Participant Refused Follow-up"="Participant Refused Follow-up"<br>"Participant Withdrawal"="Participant Withdrawal"<br>"Physician Decision"="Physician Decision"<br>"Protocol Defined Follow-up Completed"="Protocol Defined Follow-up Completed"<br>"Protocol Violation" = "Protocol Violation" = "Protocol Violation"<br>"Study Complete"="Study Complete" |
| 01. Principal | <b><u>_238_12593_Reason_Explanation</u></b>   | Reason Explanation  |             | Char  |