

NWU2016-08-02 - Off Study Data Dictionary

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Document Summary

Property	Value
Document Title	NWU2016-08-02 - Off Study: Data Dictionary
Date Created	08/25/2025
Sections	2
Entries	13
Document Filename	dictionary_off.rtf

NWU2016-08-02 - Off Study: Data Dictionary

Section 1: Identifiers

Class	Variable	Label	Description	Format Text
01. Principal	ptid	Participant ID		Char

Section 2: Off Study

Class	Variable	Label	Description	Format Text
01. Principal	off_agend	Agent End Date		Char
01. Principal	off_agend_hep	Reason Off Agent - Hepatic Decompensation Event (Specify)		Char
01. Principal	off_agend_oth	Reason Off Agent - Other (Specify)		Char
01. Principal	off_agend_reason	Reason Off Agent		"1"="AE/SAE" "11"="Pregnancy" "12"="Withdraw consent" "13"="Close monitoring of patient is not possible after interruption of agent" "14"="Hepatotoxicity requiring permanent discontinuation of agent" "15"="Development of recurrent hepatotoxicity upon rechallenge" "2"="Completed protocol-prescribed intervention" "3"="Completed treatment" "4"="Concomitant medication" "5"="Death" "6"="Inadequate agent supply" "7"="Lost to follow-up" "8"="Medical contraindication" "9"="Non-compliant participant" "Hepatic Decompensation Event, specify"="Hepatic Decompensation Event, specify" "Other, specify"="Other, specify"
01. Principal	off_agend_time	Agent End Time		Char
01. Principal	off_comments	Comments		Char
01. Principal	off_date	Off Study Date		Char
01. Principal	off_date_time	Off Study Time		Char
01. Principal	off_last_date	Date Of Last Contact		Char
01. Principal	off_last_date_time	Time Of Last Contact		Char
01. Principal	off_os_oth	Reason Off Study - Other (Specify)		Char

Class	Variable	Label	Description	Format Text
01. Principal	off_os_reason	Reason Off Study		"1"="Adverse Event" "10"="Protocol Violation" "11"="Study Complete" "12"="Ineligible" "2"="Death" "3"="Disease Progression" "4"="Lost to follow-up" "6"="Participant Withdrawal" "7"="Participant Refused Follow-Up" "8"="Physician Decision" "9"="Protocol Defined Follow-up Completed" "Other, specify"="Other, specify"