

UWI10-16-01R - AEOUT: DATA DICTIONARY

TABLE OF CONTENTS

Document Summary	2
UWI10-16-01R - aeout: Data Dictionary	3
Section 1: Identifiers	3
Section 2: Study-wide	4
Section 3: Event Details	5

Document Summary

Property	Value
Document Title	UWI10-16-01R - aeout: Data Dictionary
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Entries	16
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UWI10-16-01R - aeout: Data Dictionary

Section 1: Identifiers

Variable	Label	Description	Format Text
build_dt	Build Date	Build Date	SAS Date
PT	Patient ID	Patient ID	Char

Section 2: Study-wide

Variable	Label	Description	Format Text
protocol	Protocol	Protocol	1="UWI09-8-02 (C2003)" 2="UWI10-16-01R (C2003)" 3="UWI10-16-01R (C2012)"
rand_dt	Date participant was randomized	Date participant was randomized	SAS Date
treatment	Treatment given to participant	Treatment given to participant	1="Placebo" 2="20 mg Retinoid 9cUAB30" 3="40 mg Retinoid 9cUAB30" 4="80 mg Retinoid 9cUAB30" 5="160 mg Retinoid 9cUAB30" 6="240 mg Retinoid 9cUAB30"

Section 3: Event Details

Variable	Label	Description	Format Text
ae_action	Change (if any) in agent dose due to adverse event	Change (if any) in agent dose due to adverse event	1="Agent Withdrawn" 4="Agent Dose Not Changed" 6="Not Applicable"
ae_attribution	Likelihood adverse event was caused by treatment	Likelihood adverse event was caused by treatment	1="Unrelated" 2="Unlikely" 3="Possible" 4="Probable"
ae_ctcae_term	CTCAE Term v4.0	CTCAE Term v4.0	Char
ae_end_dt	End date of adverse event	End date of adverse event	SAS Date .M="Missing"
ae_event	Adverse event as described verbatim	Adverse event as described verbatim	Char
ae_grade	Severity of adverse event	Severity of adverse event	1="Mild" 2="Moderate" 3="Severe"
ae_meddra_v12	MedDRA v12.0 Code	MedDRA v12.0 Code	Numeric .O="No MedDRA Code Associated with CTCAE Term"
ae_onset_dt	Onset date of adverse event	Onset date of adverse event	SAS Date
ae_outcome	Outcome of adverse event	Outcome of adverse event	1="Recovered/Resolved" 2="Recovering/Resolving" 3="Not recovering/Not Resolved" 4="Recovered/Resolved with sequelae" 6="Unknown"
ae_sae	Serious adverse event?	Serious adverse event?	0="No"
ae_tox_group	Toxicity Group	Toxicity Group	6="Eye disorders" 7="Gastrointestinal disorders" 8="General disorders and administration site conditions" 11="Infections and infestations" 12="Injury, poisoning and procedural complications" 13="Investigations" 14="Metabolism and nutrition disorders" 15="Musculoskeletal and connective tissue disorders" 16="Neoplasms benign, malignant and unspecified (incl cysts and polyps)" 17="Nervous system disorders" 19="Psychiatric disorders" 20="Renal and urinary disorders" 21="Reproductive system and breast disorders" 22="Respiratory, thoracic and mediastinal disorders" 23="Skin and subcutaneous tissue disorders" 25="Surgical and medical procedures" 26="Vascular disorders"

