

# UAZ2014-03-01 - Adverse Events Data Dictionary

## TABLE OF CONTENTS

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|  |   |
|--|---|
| Document Summary.....                                | 2 |
| UAZ2014-03-01 - Adverse Events: Data Dictionary..... | 3 |
| Section 1: Identifiers .....                         | 3 |
| Section 2: Study-wide .....                          | 4 |
| Section 3: Adverse Events .....                      | 5 |

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## Document Summary

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# UAZ2014-03-01 - Adverse Events: Data Dictionary

## Section 1: Identifiers

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

## Section 2: Study-wide

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| Class         | Variable               | Label            | Description | Format Text  |
|---------------|------------------------|------------------|-------------|--|
| 01. Principal | <b>institutioncode</b> | Institution Code |             | "CA011 - USC"="CA011 - USC"<br>"CA016 - Cedars"="CA016 - Cedars"<br>"CA067 - UCSD"="CA067 - UCSD"<br>"CA088 - UCI"="CA088 - UCI"<br>"MD043 - Johns Hopkins"="MD043 - Johns Hopkins"<br>"NCICCR - NCI-CCR"="NCICCR - NCI-CCR" |

## Section 3: Adverse Events

| Class         | Variable                        | Label                  | Description | Format Text  |
|---------------|---------------------------------|------------------------|-------------|--|
| 01. Principal | <b>action</b>                   | Action                 |             | "1 Agent Withdrawn"="Agent Withdrawn"<br>"2 Agent Dose Reduced"="Agent Dose Reduced"<br>"3 Agent Dose Increased"="Agent Dose Increased"<br>"4 Agent Dose Not Changed"="Agent Dose Not Changed"<br>"5 Unknown"="Unknown"<br>"6 Not Applicable"="ot Applicable"                            |
| 01. Principal | <b>adverseevents</b>            | Adverse Events         |             | "None"="None"  |
| 01. Principal | <b>aereportdate</b>             | AE Report Date         |             | SAS Date   |
| 01. Principal | <b>aeverbatimterm</b>           | AE Verbatim Term       |             | Char   |
| 01. Principal | <b>attribution</b>              | Attribution            |             | "1 Unrelated"="Unrelated"<br>"2 Unlikely"="Unlikely"<br>"3 Possible"="Possible"<br>"4 Probable"="Probable"<br>"5 Definite"="Definite"  |
| 01. Principal | <b>comments</b>                 | Comments               |             | Char   |
| 01. Principal | <b>droppedduetothis<br/>sae</b> | Dropped Due To This AE |             | "1 Yes"="Yes"<br>"2 No"="No"   |
| 01. Principal | <b>eventonsetdate</b>           | Event Onset Date       |             | SAS Date   |
| 01. Principal | <b>grade</b>                    | Grade                  |             | "1 Mild"="Mild"<br>"2 Moderate"="Moderate"<br>"3 Severe"="Severe"<br>"4 Life-Threatening"="Life-Threatening"<br>"5 Death"="Death"  |
| 01. Principal | <b>outcome</b>                  | Outcome                |             | "1 Recovered Resolved"="Recovered Resolved"<br>"2 Recovering Resolving"="Recovering Resolving"<br>"3 Not Recovering Not Resolved"="Not Recovering Not Resolved"<br>"4 Recovered Resolved with Sequelae"="Recovered Resolved with Sequelae"<br>"5 Fatal"="Fatal"<br>"6 Unknown"="Unknown" |
| 01. Principal | <b>reportedassae</b>            | Reported As SAE        |             | "1 Yes"="Yes"<br>"2 No"="No"   |
| 01. Principal | <b>resolveddate</b>             | Resolved Date          |             | SAS Date   |

| Class         | Variable               | Label               | Description | Format Text   |
|---------------|------------------------|---------------------|-------------|---|
| 01. Principal | <b>toxicityctcae40</b> | Toxicity CTCAE v4.0 |             | "Abdominal distension"="Abdominal distension"<br>"Abdominal pain"="Abdominal pain"<br>"Alanine aminotransferase increased"="Alanine aminotransferase increased"<br>"Allergic rhinitis"="Allergic rhinitis"<br>"Anorexia"="Anorexia"<br>"Arthralgia"="Arthralgia"<br>"Arthritis"="Arthritis"<br>"Aspartate aminotransferase increased"="Aspartate aminotransferase increased"<br>"Atrial flutter"="Atrial flutter"<br>"Back pain"="Back pain"<br>"Bladder spasm"="Bladder spasm"<br>"Blurred vision"="Blurred vision"<br>"Bone pain"="Bone pain"<br>"Breast pain"="Breast pain"<br>"Bronchial infection"="Bronchial infection"<br>"Bruising"="Bruising"<br>"Chills"="Chills"<br>"Cognitive disturbance"="Cognitive disturbance"<br>"Conjunctivitis"="Conjunctivitis"<br>"Constipation"="Constipation"<br>"Cough"="Cough"<br>"Dehydration"="Dehydration"<br>"Depressed level of consciousness"="Depressed level of consciousness"<br>"Depression"="Depression"<br>"Diarrhea"="Diarrhea"<br>"Dizziness"="Dizziness"<br>"Dysgeusia"="Dysgeusia"<br>"Dyspepsia"="Dyspepsia"<br>"Dyspnea"="Dyspnea"<br>"Ear pain"="Ear pain"<br>"Edema face"="Edema face"<br>"Edema limbs"="Edema limbs"<br>"Ejaculation disorder"="Ejaculation disorder"<br>"Epistaxis"="Epistaxis"<br>"Eye disorders - Other, specify"="Eye disorders - Other, specify"<br><br>[continued...] |

| Class         | Variable   | Label | Description | Format Text   |
|---------------|--|-------|-------------|---|
| 01. Principal | <b>[...continued]</b><br><b>toxicityctcaev40</b> |       |             | <p>[...continued]</p> <p>"Eye pain"="Eye pain"<br/> "Fall"="Fall"<br/> "Fatigue"="Fatigue"<br/> "Fever"="Fever"<br/> "Flank pain"="Flank pain"<br/> "Flatulence"="Flatulence"<br/> "Flu like symptoms"="Flu like symptoms"<br/> "Flushing"="Flushing"<br/> "Gastroesophageal reflux disease"="Gastroesophageal reflux disease"<br/> "Gastrointestinal pain"="Gastrointestinal pain"<br/> "General disorders and administration site conditions - Other, specify"="General disorders and administration site conditions - Other, specify"<br/> "Generalized muscle weakness"="Generalized muscle weakness"<br/> "Headache"="Headache"<br/> "Hematuria"="Hematuria"<br/> "Hemorrhoidal hemorrhage"="Hemorrhoidal hemorrhage"<br/> "Hot flashes"="Hot flashes"<br/> "Hyperglycemia"="Hyperglycemia"<br/> "Hyperhidrosis"="Hyperhidrosis"<br/> "Hypertension"="Hypertension"<br/> "Hypotension"="Hypotension"<br/> "Injection site reaction"="Injection site reaction"<br/> "Insomnia"="Insomnia"<br/> "Lethargy"="Lethargy"<br/> "Lip pain"="Lip pain"<br/> "Localized edema"="Localized edema"<br/> "Lymph node pain"="Lymph node pain"<br/> "Malaise"="Malaise"<br/> "Muscle weakness lower limb"="Muscle weakness lower limb"<br/> "Musculoskeletal and connective tissue disorder - Other, specify"="Musculoskeletal and connective tissue disorder - Other, specify"<br/> "Myalgia"="Myalgia"</p> <p>[continued...]</p> |

| Class         | Variable   | Label | Description | Format Text  |
|---------------|--|-------|-------------|--|
| 01. Principal | <b>[...continued]</b><br><b>toxicityctcaev40</b> |       |             | <p>[...continued]</p> <p>"Nasal congestion"="Nasal congestion"<br/> "Nausea"="Nausea"<br/> "Neuralgia"="Neuralgia"<br/> "Neutrophil count decreased"="Neutrophil count decreased"<br/> "Non-cardiac chest pain"="Non-cardiac chest pain"<br/> "Oral pain"="Oral pain"<br/> "Pain in extremity"="Pain in extremity"<br/> "Pain of skin"="Pain of skin"<br/> "Palpitations"="Palpitations"<br/> "Papulopustular rash"="Papulopustular rash"<br/> "Paresthesia"="Paresthesia"<br/> "Pharyngitis"="Pharyngitis"<br/> "Pleural effusion"="Pleural effusion"<br/> "Presyncope"="Presyncope"<br/> "Prostatic pain"="Prostatic pain"<br/> "Pruritus"="Pruritus"<br/> "Rash maculo-papular"="Rash maculo-papular"<br/> "Rectal hemorrhage"="Rectal hemorrhage"<br/> "Rectal pain"="Rectal pain"<br/> "Renal and urinary disorders - Other, specify"="Renal and urinary disorders - Other, specify"<br/> "Reproductive system and breast disorders - Other, specify"="Reproductive system and breast disorders - Other, specify"<br/> "Respiratory, thoracic and mediastinal disorders - Other, specify"="Respiratory, thoracic and mediastinal disorders - Other, specify"<br/> "Restlessness"="Restlessness"<br/> "Rhinitis infective"="Rhinitis infective"<br/> "Sinus disorder"="Sinus disorder"<br/> "Sinus tachycardia"="Sinus tachycardia"<br/> "Sinusitis"="Sinusitis"</p> <p>[continued...]</p> |



| Class         | Variable   | Label | Description | Format Text  |
|---------------|--|-------|-------------|--|
| 01. Principal | <b>[...continued]</b><br><b>toxicityctcaev40</b> |       |             | [...continued]<br>"Skin and subcutaneous tissue disorders - Other, specify"="Skin and subcutaneous tissue disorders - Other, specify"<br>"Sneezing"="Sneezing"<br>"Sore throat"="Sore throat"<br>"Stomach pain"="Stomach pain"<br>"Surgical and medical procedures - Other, specify"="Surgical and medical procedures - Other, specify"<br>"Syncope"="Syncope"<br>"Testicular pain"="Testicular pain"<br>"Toothache"="Toothache"<br>"Trismus"="Trismus"<br>"Upper respiratory infection"="Upper respiratory infection"<br>"Urinary frequency"="Urinary frequency"<br>"Urinary incontinence"="Urinary incontinence"<br>"Urinary retention"="Urinary retention"<br>"Urinary tract infection"="Urinary tract infection"<br>"Urinary tract pain"="Urinary tract pain"<br>"Urinary urgency"="Urinary urgency"<br>"Urticaria"="Urticaria"<br>"Vascular disorders - Other, specify"="Vascular disorders - Other, specify"<br>"Vomiting"="Vomiting"<br>"Weight loss"="Weight loss"<br>"Wheezing"="Wheezing"<br>"White blood cell decreased"="White blood cell decreased" |

| Class         | Variable                | Label                | Description | Format Text  |
|---------------|-------------------------|----------------------|-------------|--|
| 01. Principal | <b>toxicitygroupdra</b> | Toxicity Group (DRA) |             | "Blood and lymphatic system disorders"="Blood and lymphatic system disorders"<br>"Cardiac disorders"="Cardiac disorders"<br>"Congenital, Familial And Genetic Disorders"="Congenital, Familial And Genetic Disorders"<br>"Ear and labyrinth disorders"="Ear and labyrinth disorders"<br>"Endocrine Disorders"="Endocrine Disorders"<br>"Eye disorders"="Eye disorders"<br>"Gastrointestinal disorders"="Gastrointestinal disorders"<br>"General disorders and administration site conditions"="General disorders and administration site conditions"<br>"Hepatobiliary Disorders"="Hepatobiliary Disorders"<br>"Immune System Disorders"="Immune System Disorders"<br>"Infections and infestations"="Infections and infestations"<br>"Injury, poisoning and procedural complications"="Injury, poisoning and procedural complications"<br>"Investigations"="Investigations"<br>"Metabolism and nutrition disorders"="Metabolism and nutrition disorders"<br>"Musculoskeletal and connective tissue disorders"="Musculoskeletal and connective tissue disorders"<br>"Neoplasms Benign, Malignant And Unspecified (Incl Cysts And Polyps)"="Neoplasms Benign, Malignant And Unspecified (Incl Cysts And Polyps)"<br>"Nervous system disorders"="Nervous system disorders"<br>"Pregnancy, Puerperium And Perinatal Conditions"="Pregnancy, Puerperium And Perinatal Conditions"<br>"Psychiatric disorders"="Psychiatric disorders"<br>"Renal and urinary disorders"="Renal and urinary disorders"<br><br>[continued...] |

| Class         | Variable   | Label | Description | Format Text  |
|---------------|--|-------|-------------|--|
| 01. Principal | <b>[...continued]</b><br><b>toxicitygroupdra</b> |       |             | [...continued]<br>"Reproductive system and breast disorders"="Reproductive system and breast disorders"<br>"Respiratory, thoracic and mediastinal disorders"="Respiratory, thoracic and mediastinal disorders"<br>"Skin and subcutaneous tissue disorders"="Skin and subcutaneous tissue disorders"<br>"Social Circumstances"="Social Circumstances"<br>"Surgical and medical procedures"="Surgical and medical procedures"<br>"Vascular disorders"="Vascular disorders" |