

# MAY2017-09-01 - ADVERSE EVENTS: DATA DICTIONARY

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## Document Summary

Property	Value
Document Title	MAY2017-09-01 - Adverse Events: Data Dictionary
Date Created	02/26/2020
Sections	2
Entries	19
Document Filename	dictionary_safety.rtf

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## MAY2017-09-01 - Adverse Events: Data Dictionary

### Section 1: Identifiers

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Variable	Label	Description	Format Text
<b>SUBJECT</b>	Participant ID	Participant ID	Char

## Section 3: Adverse Events

Variable	Label	Description	Format Text
<b>ACTIONXX</b>	Action	Action	"Agent dose not changed"="Agent dose not changed" "Agent withdrawn"="Agent withdrawn" "Not applicable"="Not applicable"
<b>AERXX</b>	Reported As SAE?	Reported As SAE?	2="No"
<b>arm</b>	Arm	Arm	"A"="A" "B"="B"
<b>COMTOXOTH</b>	Comments	Comments	"Rectal bleeding due to sigmoidoscopy and not due to study drug"="Rectal bleeding due to sigmoidoscopy and not due to study drug"
<b>droppedxx</b>	Off Study Due To This AE?	Off Study Due To This AE?	1="Yes" 2="No"
<b>ENDDTXX</b>	Event End Date	Event End Date	SAS Date
<b>EVALDTXX</b>	Adverse Event Reported Date	Adverse Event Reported Date	SAS Date
<b>NOAE</b>	Did Participant Experience Adverse Events?	Did Participant Experience Adverse Events?	0="Yes" 1="No"
<b>ONGOINGXX</b>	Ongoing	Ongoing	0="Unchecked"
<b>ONSETDTXX</b>	Event Onset Date	Event Onset Date	SAS Date
<b>OUTCOMEXX</b>	Outcome	Outcome	"Recovered/resolved"="Recovered/resolved"
<b>socxx</b>	MedDRA System Organ Class (v12.0)	MedDRA System Organ Class (v12.0)	7="Gastrointestinal Disorders" 8="General Disorders and Administration Site Conditions" 14="Metabolism and Nutrition Disorders" 15="Musculoskeletal and Connective Tissue Disorders" 17="Nervous System Disorders" 19="Psychiatric Disorders" 22="Respiratory, Thoracic and Mediastinal Disorders" 23="Skin and Subcutaneous Tissue Disorders"
<b>studprocrelxx</b>	AE Procedure Related?	AE Procedure Related?	1="Yes" 2="No"
<b>TOX_RLXX</b>	AE Attribution	AE Attribution	1="Unrelated" 2="Unlikely" 3="Possible" 4="Probable"
<b>TOXXX</b>	Adverse Event Term (v4.0)	Adverse Event Term (v4.0)	Numeric
<b>TOXXX_SP</b>	Adverse Event Term Specify (v4.0)	Adverse Event Term Specify (v4.0)	Char
<b>VALXX</b>	AE Grade	AE Grade	1="Mildadverse event" 2="Moderate adverse event" 3="Severe adverse event"
<b>VERBATIMXX</b>	Adverse Event Verbatim Term	Adverse Event Verbatim Term	Char