Standardization of Adjudication Outcomes Data Modelling using CDISC standards

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Background

Results of an adjudication process are of very high value as they validate study results. Considering the impact of this adjudication data on decision making regarding the safety and effectiveness of a medicinal product, there is currently no standard in place for the submission of this data.

Proposal

Adjudication Outcome data has the “results” of an adjudication process. This leads us to look for a flexible structure that can accommodate various types of adjudication data. For that purpose, a standalone Findings About domain is selected. The key factor for success of this approach is to define and control the data modelling using controlled terminology.

AO, Adjudication Outcome

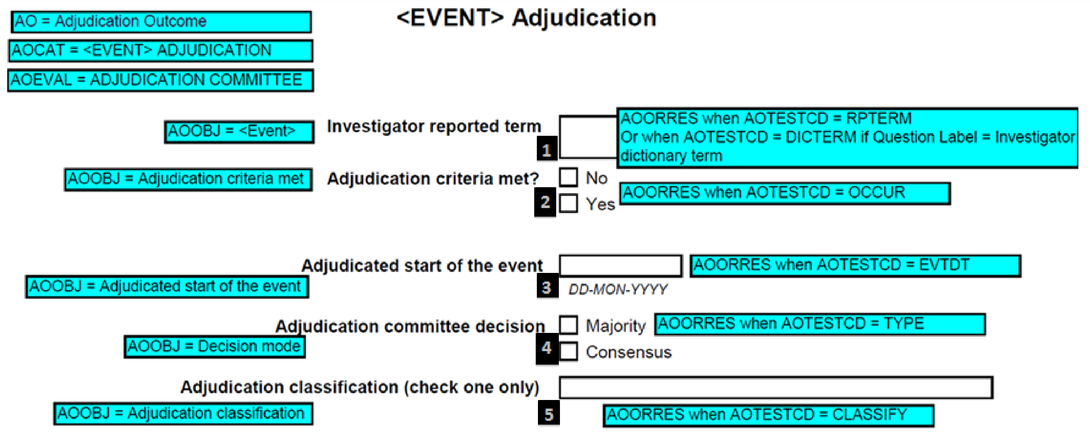
Description/Overview for Adjudication Data Domain Model

The Adjudication Outcome (AO) follows a similar approach as the Skin Response (SR) in taking advantage of the Findings About concept that is Findings About an Event or an Intervention and uses a different domain code instead of FA. The data will present one record per adjudication outcome per result, per date and subject.

Discussion of the variables that play a specific role in the implementation of the AO domain beyond their traditional role defined by SDTM

Variable Name	Description	Assumptions
AOCAT	Category	The variable will be used for the classification of the outcomes being adjudicated. When modelling, we define each category with the <event> followed by ADJUDICATION. This is done to enable the reviewer to identify the correct set of adjudication results(e.g. MACE EVENT ADJUDICATION).
AOOBJ	Object of the Observation	The variable is assigned the text of the question asked to the adjudicator. No controlled terminology is assigned to this field for flexibility and traceability to the collection instrument (CRF).(e.g. Adjudication criteria meet, Decision mode)
AOTEST, AOTESTCD	Adjudication Test	The variable will be associated with controlled terminology to enable a standardized interpretation of the results(e.g. OCCURRENCE, TYPE, CLASSIFY).
AOEVAL	Evaluator	The variable is expected. Role of the person who provided the evaluation. Used only for results that are subjective (e.g., assigned by a person or a group). Examples: ADJUDICATION COMMITTEE, INDEPENDENT ASSESSOR, RADIOLOGIST.
AOEVALID	Evaluator Identifier	The Evaluator Identifier variable is used in conjunction with AOEVAL to provide an additional level of detail when multiple assessors play the role identified in AOEVAL, values of AOEVALID will attribute a row of data to a particular assessor. The AOEVALID variable is subject to CDISC Controlled Terminology. Examples: RADIOLOGIST, RADIOLOGIST 1 or RADIOLOGIST 2.
AODTC	Date of adjudication assessment	This field represents the date of the adjudication process. Dates that are a result of the process of adjudication are modelled as a result(e.g. DATE OF EVENT).

Sample Collection Instrument



Sample Collected Data

USUBJID	AOCAT	AOOJB	AOTEST	AOORRES	AOEVAL	AODTC
S001	MACE EVENT ADJUDICATION	Investigator reported term	REPORTED TERM	Stroke	1 ADJUDICATION COMMITTEE	2014-05-28
S001	MACE EVENT ADJUDICATION	Adjudication criteria met	OCCURENCE	Y	2 ADJUDICATION COMMITTEE	2014-05-28
S001	MACE EVENT ADJUDICATION	Adjudicated start of the event	DATE OF EVENT	2013-07-03	3 ADJUDICATION COMMITTEE	2014-05-28
S001	MACE EVENT ADJUDICATION	Decision mode	TYPE	Consensus	4 ADJUDICATION COMMITTEE	2014-05-28
S001	MACE EVENT ADJUDICATION	Adjudication classification	CLASSIFY	ISCHEMIC	5 ADJUDICATION COMMITTEE	2014-05-28

Sample Listing of Adjudicated MACE events

Listing 14.1.x
Adjudicated MACE events: strokes
Safety Set

Treatment group: XXXX

Study/ Country/ Subject Identifier	Age/ Sex/ Race	Actual Treatment	Reported Term	Treatment Emergent	Start date/ day	Stroke criteria met?/ Stroke classification	Adjudication Committee decision
XXXX/ XXX/ XXXX	XX/ X/ XX	XXXXXXX	Stroke 1	Y	2013-07-03/ 478 3	Yes/ ISCHEMIC 2 5	Consensus 4

Sample Analysis Tables

Table 14.1
Exposure adjusted incidence rates for adjudicated and confirmed treatment emergent major adverse cardiovascular events (MACE) by preferred term – entire treatment period
Safety Set

Adjudicated and confirmed MACE Events	Any A xxx mg N=xxx n/EX	(IR)	XX% CI	Any B xxx mg N=xxx n/EX	(IR)	XX% CI
MACE events	X/XX.X	(X.X)	(X.X, X.X)	X/XX.X	(X.X)	(X.X, X.X)
Myocardial Infarction	X/XX.X	(X.X)	(X.X, X.X)	X/XX.X	(X.X)	(X.X, X.X)
1 Stroke	X/XX.X	(X.X)		X/XX.X	(X.X)	(X.X, X.X)
Cardiovascular Death	X/XX.X	(X.X)		X/XX.X	(X.X)	(X.X, X.X)

Adjudication criteria met = Yes 2

Table 14.2
Absolute and relative frequencies for adjudicated treatment emergent major adverse cardiovascular events (MACE) - entire treatment period
Safety Set

Adjudicated and confirmed MACE Events	Any A xxx mg N=xxx n (%)	Any B xxx mg N=xxx n (%)	Placebo N=xxx n (%)
Total number of patients with confirmed MACE	X (X.X)	X (X.X)	X (X.X)
Myocardial Infarction	X (X.X)	X (X.X)	X (X.X)
Yes	X (X.X)	X (X.X)	X (X.X)
No			
1 Stroke	X (X.X)	X (X.X)	X (X.X)
2 Yes	X (X.X)	X (X.X)	X (X.X)
No			