CDASH SAE Addendum

Use Case

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The Case

- Medical device study
- SAE/SADE forms in the EDC tool
- Evaluation form for Safety and Regulatory
- Process supports BfArM form to be submitted in XML
- Company Decision: BfArM form basis for internal review & communication
- Limited use in single studies
- Not an implemation of a safety data system

In the AE/SAE // ADE/SADE Form (1)

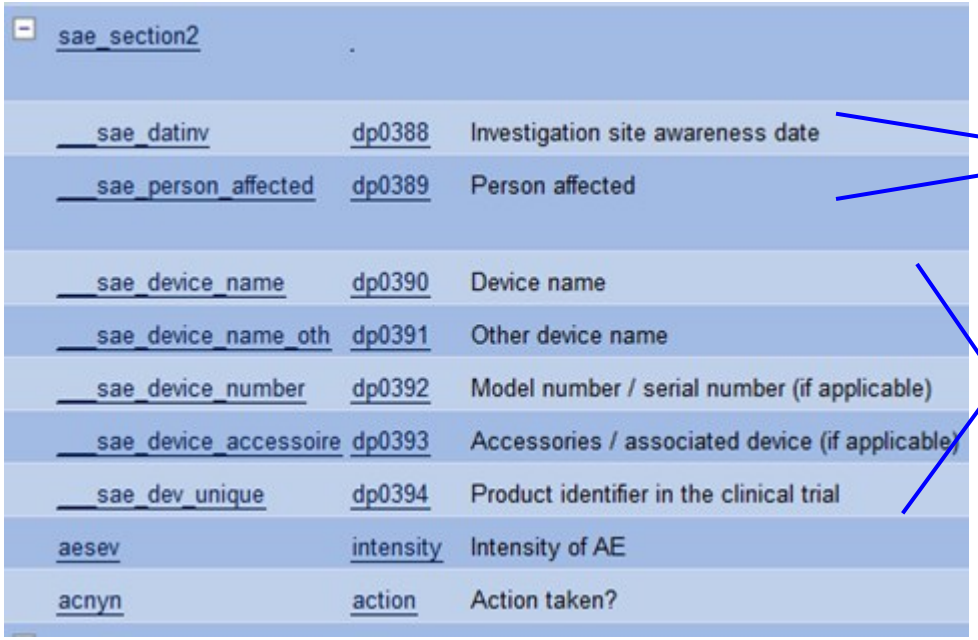
First group of items: no way to find a name

	aehypo	dp0057	Did the subject have a symptomatic hypoglycemia episode?
	com1	.	A symptomatic hypoglycaemia episode is defined as an AE with symptoms consistent with hypoglycaemia and may be confirmed by blood glucose values <70mg/dL (<3.9mmol/L)
−	sympthypo	.	
	___hlSympHypo	.	Symptomatic Hypoglycemia
	___aehypo_gbvalue_mg	dp0070	BG-value, if available
	___aehypo_gbvalue_mmol	dp0071	BG-value, if available
	___aehypo_actiongluc	dp0076	Action taken
	___aehypo_assistance	dp0077	Was assistance of another person required?

In the AE/SAE // ADE/SADE Form (2)

serious	dp0205	Is the AE serious?	Should be AESER
el4	.		
aespid	aeNr	AE/ADE number	✓
aespid_s	dp0307	SAE/SADE number	Found: SAEID
aeterm	desc	Adverse Event Term	✓
aeterm_forListDisplay	dp0483	Adverse Event Term	Term for screen summary table
sae_section1	.		
___sae_classification	dp0386	Classification of the SAE	Not found: is the SAE expected/unexpected?
___sae_term_long	dp0387	Detailed description of the event	Short narrative…
aestdat	dateOnset	Start Date	✓
aeendat	dateRes	End Date	✓
aeong	dp0308	Ongoing	✓

In the AE/SAE // ADE/SADE Form (3)



sae_section2		
sae_datinv	dp0388	Investigation site awareness date
sae_person_affected	dp0389	Person affected
sae_device_name	dp0390	Device name
sae_device_name_oth	dp0391	Other device name
sae_device_number	dp0392	Model number / serial number (if applicable)
sae_device_accessoire	dp0393	Accessories / associated device (if applicable)
sae_dev_unique	dp0394	Product identifier in the clinical trial
aesev	intensity	Intensity of AE
acnyn	action	Action taken?

Not found:
required only for devices

SDTM var names
in device domains
No CDASH names so far

✓

✓

Items from Other Places in eCRF (1)

Center information section of the eCRF

	Question Text	Prompt	E2B Variable Name	E2B Data Element	SDTM or CDASH Variable Names
1	Where are you located?	Country of the primary source	primarysourcecountry	A.1.1	SRCCNTY
2	Where did the primary event for the safety case occur?	Country where the event occurred	occurcountry	A.1.2	OCCCNTY

Rather SDTM variables – in eCRF: admin data section

In the AE/SAE // ADE/SADE Form (1)

Admin part of the eCRF

	Question Text	Prompt	E2B Variable Name	E2B Data Element	SDTM or CDASH Variable Names
3	What is the first name of the reporter?	Reporter first name	reportergivenname	A.2.1.1b	SAERPTRNM
4	What is the last name of the reporter?	Reporter last name	reporterfamilyname	A.2.1.1d	SAERPTRFNM
5	What is the sponsor study number?	Sponsor Study Number	sponsorstudynum	A.2.3.2	STUDYID

In no way, a system developer will give such names to user name items in a eCRF system

In the Sponsor Evaluation Form

evallog	dp0422	Safety evaluation log
sae_s_medeval	dp0411	Safety evaluation
sae_s_bfarm_ref	dp0397	NCA's case # (if known)
sae_s_othNCA	dp0398	Identify to which other NCA's this report was also submitted
sae_s_report_type	dp0399	Type of report
sae_s_date_next	dp0400	Expected date of next report (if applicable)
sae_classification	dp0401	Classification of the SAE
sae_term_long	dp0416	Detailed description of the event
sae_acninit	dp0417	Initial actions by the sponsor
aerelp	dp0404	Relationship to medical procedure
aerel	dp0405	Relationship to medical device
aereloth	dp0406	Relationship to other cause
aereltxt	dp0418	Reason

Not found: BfArM specific

Not found: Is the SAE expected/unexpected?

Short narrative…

Conclusion

- **CDASH SAE addendum focusses on a *drug safety database* for SAE in clinical studies and from marketed drugs**
- **No development so far for medical device SAEs (from registration studies) and Incidents(from marketed devices)**
  [volunteers may start….]