

Export						Modifications between previous version				EDMUS Data Entry Field				
Data	File Name	Variable Name	Column Position	Encoding	Comment	New column	Old name	Old column position	Old encoding	Configuration	Panel	Tab	Label	Comment
Adverse Events	AE	Patient ID	1											
Adverse Events	AE	AE ID	2					22						
Adverse Events	AE	Treatment ID	3					2						
Adverse Events	AE	INN	4					3		PREMIUM / EDEN	Adverse Events		INN	Not editable
Adverse Events	AE	Trade name	5					4		PREMIUM / EDEN	Adverse Events		Trade Name	Not editable
Adverse Events	AE	Onset Date	6					5		PREMIUM / EDEN	Adverse Events		Onset Date	
Adverse Events	AE	Outcome Date	7					6		PREMIUM / EDEN	Adverse Events		Outcome, date	
Adverse Events	AE	Drug management	8	0 = ? 1 = Unchanged 2 = Reduction of dose 3 = Temporarily withdrawn 4 = Permently withdrawn				7		PREMIUM / EDEN	Adverse Events		Drug management	
Adverse Events	AE	Abate	9	0 = Unknown or No 1 = Yes				8		PREMIUM / EDEN	Adverse Events		Drug management -> Reaction abated after withdrawal	
Adverse Events	AE	Outcome	10	0 = ? 1 = Recovery without sequelae 2 = Recovery with sequelae 3 = No recovery yet 4 = Death, drug-related				9		PREMIUM / EDEN	Adverse Events		Outcome	
Adverse Events	AE	Manifestations	11					10		PREMIUM / EDEN	Adverse Events		Manifestations	
Adverse Events	AE	Medication	12					11		PREMIUM / EDEN	Adverse Events		Medication, if any	
Adverse Events	AE	From exam	13	0 = Not an exam result 1 = exam result				12						

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Data	File Name	Variable Name	Column Position	Encoding	Comment	New column	Old name	Old column position	Old encoding	Configuration	Panel	Tab	Label	Comment
Adverse Events	AE	When	14		value "?" exported = option "?" selected value "During drug administration" exported = option "During drug administration" selected value "Later" exported = option "Later, after" selected and no precision entered about the delay after drug administration value "After [X] minute(s)"/ "After [X] hour(s)"/ "After [X] day(s)"/ "After [X] month(s)"/ "After [X] year(s)" exported (where X is a number) = option "Later, after" selected with a precision entered about the delay after drug administration			13		PREMIUM / EDEN	Adverse Events		When	
Adverse Events	AE	Seriousness	15	0 = ? 1 = Not serious 2 = Serious				14		PREMIUM / EDEN	Adverse Events		Seriousness -> ? / Not serious / Serious	
Adverse Events	AE	Severity-Medically significant	16	0 = Unknown or No 1 = Yes				15		PREMIUM / EDEN	Adverse Events		Seriousness -> Serious -> Medically significant	
Adverse Events	AE	Severity-Hospitalization	17	0 = Unknown or No 1 = Yes				16		PREMIUM / EDEN	Adverse Events		Seriousness -> Serious -> Requiring hospitalization	
Adverse Events	AE	Severity-Congenital anomaly	18	0 = Unknown or No 1 = Yes				17		PREMIUM / EDEN	Adverse Events		Seriousness -> Serious -> Congenital anomaly	
Adverse Events	AE	Severity-Disability	19	0 = Unknown or No 1 = Yes				18		PREMIUM / EDEN	Adverse Events		Seriousness -> Serious -> Severe or permanent disability	
Adverse Events	AE	Severity-Life threatening	20	0 = Unknown or No 1 = Yes				19		PREMIUM / EDEN	Adverse Events		Seriousness -> Serious -> Life-threatening	
Adverse Events	AE	Severity-Death	21	0 = Unknown or No 1 = Yes				20		PREMIUM / EDEN	Adverse Events		Seriousness -> Serious -> Death	
Adverse Events	AE	Drug relationship	22	0 = ? 1 = No 2 = Yes				21		PREMIUM / EDEN	Adverse Events		Drug relationship suspected	