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	Treatment ID	2											
Adverse Events	AE	INN	3							PREMIUM / EDEN	Adverse Events		INN	Not editable
Adverse Events	AE	Trade name	4							PREMIUM / EDEN	Adverse Events		Trade Name	Not editable
Adverse Events	AE	Onset Date	5							PREMIUM / EDEN	Adverse Events		Onset Date	
Adverse Events	AE	Outcome Date	6							PREMIUM / EDEN	Adverse Events		Outcome, date	
Adverse Events	AE	Drug management	7	0 = ? 1 = Unchanged 2 = Reduction of dose 3 = Temporarily withdrawn 4 = Permently withdrawn						PREMIUM / EDEN	Adverse Events		Drug management	
Adverse Events	AE	Abate	8	0 = Unknown or No 1 = Yes						PREMIUM / EDEN	Adverse Events		Drug management -> Reaction abated after withdrawal	
Adverse Events	AE	Outcome	9	0 = ? 1 = Recovery without sequelae 2 = Recovery with sequelae 3 = No recovery yet 4 = Death, drug-related						PREMIUM / EDEN	Adverse Events		Outcome	
Adverse Events	AE	Manifestations	10							PREMIUM / EDEN	Adverse Events		Manifestations	
Adverse Events	AE	Medication	11							PREMIUM / EDEN	Adverse Events		Medication, if any	
Adverse Events	AE	From exam	12	0 = Not an exam result 1 = exam result										
Adverse Events	AE	When	13	0 = ? 1 = During drug administration 2 = Later, after						PREMIUM / EDEN	Adverse Events		When	
Adverse Events	AE	Seriousness	14	0 = ? 1 = Not serious 2 = Serious						PREMIUM / EDEN	Adverse Events		Seriousness -> ? / Not serious / Serious	
Adverse Events	AE	Severity-Medically significant	15	0 = Unknown or No 1 = Yes						PREMIUM / EDEN	Adverse Events		Seriousness -> Serious -> Medically significant	
Adverse Events	AE	Severity-Hospitalization	16	0 = Unknown or No 1 = Yes						PREMIUM / EDEN	Adverse Events		Seriousness -> Serious -> Requiring hospitalization	
Adverse Events	AE	Severity-Congenital anomaly	17	0 = Unknown or No 1 = Yes						PREMIUM / EDEN	Adverse Events		Seriousness -> Serious -> Congenital anomaly	
Adverse Events	AE	Severity-Disability	18	0 = Unknown or No 1 = Yes						PREMIUM / EDEN	Adverse Events		Seriousness -> Serious -> Severe or permanent disability	
Adverse Events	AE	Severity-Life threatening	19	0 = Unknown or No 1 = Yes						PREMIUM / EDEN	Adverse Events		Seriousness -> Serious -> Life-threatening	
Adverse Events	AE	Severity-Death	20	0 = Unknown or No 1 = Yes						PREMIUM / EDEN	Adverse Events		Seriousness -> Serious -> Death	

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	Drug relationship	21	0 = ? 1 = No 2 = Yes						PREMIUM / EDEN	Adverse Events		Drug relationship suspected	
Adverse Events	AE	AE ID	22											