

## 🍯 12. Adverse Event / Serious Adverse Event

## 1 Add an Adverse Event (AE)

- Click the Adverse Event log form for the selected patient. Click the "Add" button to add a new event. Fill out the form.
- If the event is serious select the Serious AE option and the form will be extended with more questions. When you save a serious adverse event (SAE) a SAE report will be generated and you will be directed to the Documents page so that you can view the report. See more information below.
- If a SAE death is reported for a patient, the Exit form will be added to the Visit calendar and you should create an exit with reason death for the patient.

	KR 999	00005	CTATUC	Activo	
			SIATUS	Active	
Adverse Event					
Add					
Background data				AE related to con-	1
Report date	1	2010 - Nov - :		comitant drug therapy?	· O NO O Yes
Onset date	1			Conmed	
Advarce Event				Not applicable	
Adverse Event			÷	0 0	
Seriousness				0 0	
Seriousness	1	O Non-serious			
		C Serious AE		0 0	
Deletid	0.1	04.1	-		
Related Is there a reasonable possibility that th	e AE is related to /	O No O Yes			
Somavert administration?		ONOOTES			
Has the AE resulted in:			Is	the AE:	
death	1	O No O Yes	lif	e-threatening	J O No O Yes
in-patient hospitalization or prolongati	on of existing /	O No O Yes	ar	AE that the Physician or company	1 ONO OVO
hospitalization	10 20	Onoores	ju	dges to be serious, or that is defined	ias Onto res
persistent or significant disability/ inca	pacity /	◎ No ◎ Yes	00	untry in which the AE occurred	
Congenital anomaly/ birth defect	1	O Ma O Maa	pr	egnanoy	1 ONIS O Vas
VILO INOVI		O NO O TES		V LO VILO V	· 0140 0 185
Outcome					
CRecovered					
Recovered with sequalae					
O Not Recovered					
O Not Recovered - Chronic					
Recovering					
O Death					
OOnknown					
Action:					
Action taken with Pegvisomant	1	-	-		
Did event abate after stoppng Per medication	gvisomant /				
Did event reappear after reintrodu	uction?				
Further information					
1					^
					-
LET LE	1000	~Ett		ACT IN A	Elle

## 2 Copy adverse event

- If an adverse event is similar to a previously added adverse event you can simply open the old event and copy it by clicking the "Copy" button.
- Note! Remember to change the copied row to reflect the new event.

Report date	/ 2010 - Int - 15 -	AE related to con- comitant drug therapy?	1 @ No O Yes
Dinset date	1 2010 - Jul - 15 -	Conmed >>	
	Tarre Tage - Los -	National State	
Adverse Event	Z [local skin reaction	Not applicable	
Seriousness		10	
Seriousness	7  Non-serious Serious AE	20 20	
Related s there a reasonable possibility that the AE is related to Somavert administration?	1 O No @ Yes	000000	
Has the AE resulted in:	J @ No C Yes	Is the AE: life-threatening	1 No O Yes
n-patient hospitalization or prolongation of existing hospitalization	/ @ No O Yes	an AE that the Physician or company judges to be serious, or that is defined a	, <sup>1</sup> @ No ⊖ Yes
persistent or significant disability/ incapacity	/ @ No ⊖ Yes	country in which the AE occurred	
Congenital anomaly/ birth defect	✓ @ No O Yes	pregnancy	J @ No O Yes
Dutcome			
C Recovered			
O Recovered with sequalae			
Not Recovered			
C Not Recovered - Chronic			
O Recovering			
(C) Death			
O Unknown			
Action:	A MARCO		
Did event abate after stoppng Pegvisomant	J Not Applicable -		
medication Did event reappear after reintroduction?	/ Not known +		

local akin reaction

## 3 Serious Adverse Event (SAE) report

 The SAE report is generated automatically when saving a SAE or the AE is a pregnancy. The system redirects to the Patient documents area on the Documents page, where the report is highlighted. The report is pre-filled with patient data available in the

	Patient documents			
	The document(s) highlighted below actions.	Click the symbol to		
	Document / Initiated	Updated	Generated by	regenerate the report.
Click the link to view the PDF report.		2010-10-12 14:41	DrTest	

highlighted. The report is pre-filled with patient data available in the Adverse Event form as well as other forms in Viedoc.

- Print out the report, fill in any missing data and send it to the Pfizer local Safety Department according to process described in the lesson "Serious Adverse Event Flow".
- To view the SAE reports generated for the patients at the center, click on the [Documents] menu link. In the Patient documents area there is a list of the patients which have SAE reports.
- The SAE report is regenerated automatically if you change anything in the SAE and then save it.
- If data has been changed in other forms included in the SAE report, for example Concomitant medication, the report should be regenerated to reflect the changes. Regenerate the report from the Documents page by clicking the regenerate symbol.
- If there are several versions of the SAE report there will be a plus sign in front of the PDF link. To view the different versions of the SAE report you click the plus sign.