

互 22. Exit and Re-entry

1 Exit

- Any patient may be discontinued from the study at any time at the discretion of the investigator or if it is the wish of the patient.
- To remove a patient from endoACRO you add the Exit form when initiating a new visit (by selecting it under Modules for the visit).
- The Exit form has to be **signed** for any effect to take place.
- Note! To delete an unsaved form added by mistake, go to Visit administration and click on the red symbol to the right of the form. Please contact PCG helpdesk if you have entered data in an Exit form by mistake.

2 Exit options

- There are four exit options: Death, Lost of follow-up, Withdrawal of informed consent and Discontinuation of Somavert.
- If the patient died: AE pages should be filled out. If a Serious Adverse Event Death is reported the Exit form is automatically added to the visit calendar and should be filled out.
- Withdrawal of informed consent: all patient data is blinded for Pfizer.

999-002	SENDER Fem DOE 1984-01		999-002			1984-01-29	
fisit administration		Add visit 5	Visit calendar			7 Add commer	g I <u>Add visi</u>
Asit Return visit		Proposed date 2011-05-29		Background	Return visit	Return visit	
Status Not initiated Planned Initiated Planned Initiated Model Status Status <thstatus< th=""></thstatus<>		Proposed date		2011-05-29	2011-06-09		
		31 1 2 3 4 5 6	Date	2010-05-29	2010-05-09	< Change >	
 Treatment Local lab 		14 15 16 17 18 19 20	Diagnosis	۸			
Ent		21 22 23 24 25 26 27 28 29 30 1 2 3 4	Comorbidities	۲			
1		5 6 7 8 9 10 11	Examinations	۲	۲	۲	
Save Cancel			Treatment	1	۲	۲	
1			Local lab	۲	۲	۲	
1			Additional Lab	۲			
1			Questionnaires 🗉	۲			
Open the visit, che			Oth. Examinations	۲			
Exit form in the Mo list and then save.	dule	/	Exit		٢		
		Exit form will be	Visit independent for	ms			
		ed to the visit ndar	Adverse Event	۲		Concomitant Medication	۲
	cale	ndar.	Somavert Treatment	۲		SSA/DA Treatment	۲
			Pituitary Dysfunctions	۲		Pituitary Surgery	۲
			Pituitary Radiotherapy	۲		Pituitary Imaging	۲
			Clinical Trials	0		Central IGFJ Request	

Central IGF-I

ACROSTUDY ID	GENDER Female DOB 1984-01-29		
999-002			
Exit, Return visit, 2010-06-09			
ACROSTUDY discontinuation da Data collected after this date can no Ion Retrospective documentation of data wh ACROSTUDY can still be done.	ger be documented in ACROSTUDY.		
7 Reason for discontinuation	© Death		
	C Lost of Follow-up		
	Cost of Pollow-up		
	 Withdrawal of informed consen 		

3 Re-entry

- Re-entry is possible for any exited patients when initiating a new visit and selecting the Re-entry form under Modules for the visit.
- If the patient has withdrawn the informed consent a new informed consent must be obtained.
- The Re-entry form has to be signed for any effect to take place.