Participant ID:	Date of Registration:	
Local ID:	Letters:	
Status:		
Site:		

OT05 - Annual Follow-Up V	Visit
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* These fields are required in order to SAVE the form							
			* These	fields are	e required	in order to COM	IPLETE the form
Date of Visit: *		~	Date				
Interviewer User ID: *							
B. MEDICAL HISTORY						[]
1. Have there been any ch	anges in he	ealth s	ince the last scl	neduled v	visit	⊖Yes ⊖No	
2. Have there been any changes in concomitant medications since last scheduled visit							
C. GENERAL PHYSICAL E	XAM						
1. Collect the following ph	ysical asses	smen	ts:				
a. Seated arm blood pressure:			Systolic mmHc		Di	iastolic mmHg	
b. Weight:			· · · · · · · · · · · · · · · · · · ·	kg	_		
C. Height:				cm			in
d. Abdominal circumferen	ice:			cm			in
2. Record whether the foll normal or abnormal upon			re reported as r	ormal or	r abnorma	al by the particip	pant and
Review of systems	1) Particip reported r		2) Normal	on exam	n? If Eithe Explain	r is Abnormal, :	, a)
a. HEENT	⊖Yes	⊃No	⊖Yes(No			
b. Neck	⊖Yes	⊃No	\bigcirc Yes (No			
c. Thyroid	⊖Yes	⊃No	\bigcirc Yes (No			
d. Lungs	⊖Yes(⊃No	⊖Yes(No			
e. Chest/Breasts	⊖Yes(⊃No	\bigcirc Yes (No			
f. Heart/Circulatory	⊖Yes	⊃No	⊖Yes(No			
g. Abdomen	⊖Yes	⊃No	\bigcirc Yes (No			
h. Musculoskeletal	⊖Yes	⊃No	\bigcirc Yes (No			
i. Neurologic	⊖Yes(⊃No	⊖Yes(No			
j. Genitourinary/Testes	⊖Yes(⊃No	⊖Yes(No			
k. Skin/Nails	⊖Yes(⊃No	\bigcirc Yes (No			
I. Lymph nodes	⊖Yes(⊃No	⊖Yes(No			
m. Other	⊖Yes(⊃No	⊖Yes(No			
If OTHER, Specify							
3. For subjects less than 18 yrs of age, record the participant's sexual development using the Tanner scale:				e Tanner scale:			
a. Breast (Female)	⊖s	tage 1	OStage 2	Stage 3	3 or great	er	

b. Genitalia (Male) OStage 1 OStage 2 OStage 3 or greater				
c. Pubic Hair (both)				
D. PREGNANCY MONITORING				
1. If FEMALE, does the participa	ant have reproductive potential?			
2. Is the female participant sex	ually active?			
If YES to question D1 above, continue (If not, proceed to Section E.)				
a. Does she currently use a form	n of birth control?			
b. Does she plan on becoming p	pregnant in the next 6 months?			
c. Was urine pregnancy test co	mpleted at this visit?			
If yes, 1) was the test result po	sitive? OYes ONo			
E. COMPLIANCE				
How many doses has the participant missed since the last study visit?				
Is the participant currently takir	ig study drug? O Yes O No			
F. PROCEDURES PERFORMED				
The following procedures should be performed during this visit:				
1. Lifestyle Questionnaire				
2. Dispensation/return of study drug (if YES, complete the Study Drug Dispensation Ad/mmm/yyyy and Return Form - OT14)				