										ANNEX	III X	q 1
		ST	UDY D	ESIGN AN	STUDY DESIGN AND SCHEDULE OF ASSEMENTS	F ASSE	MENTS	70				
Phase	Scr	Screening	D	Single-Blind placebo run-	Single-Blind placebo run-in	Dout	Double-blind	ind	Fo11	Follow-up		
						a	Placebo					
						ď	Dose 1					
				-		ď	Dose 2				i	
						ď	Dose 3					
Assessment												
Visit	-	2		ж		4		5		. 9		7
Week	0	,1		7	m	4	5	9.	7	8	6	10
Informed consent	×											
Inclusion criteria	×			- *		×	=				-	
History	×											
Physical exam	×			×		×				×		×
Effectiveness:												
Primary variable	×	×	×			×		×		×		×
Secondary variable	×	×	×			×		×		×		×
Safety:												
Adverse effects	×	×	×			×		· ×		×		×
Lab, tests	×	×	×			×		×		×		×
Body weight	×		×			×				×		×

BILLING CODE 4160–01–C

ANNEX IV a

AUDIT CERTIFICATES (if available)

The audit certificate is a document indicating:

⁻ The audit (type, identification number)

⁻ The audited system, clinical trial, or organization $% \left(1\right) =\left(1\right) \left(1\right)$

⁻ The audit dates

⁻ The date of release of the audit report