

PRE-STUDY VISIT REPORT

TRIAL TITLE:			
TRIAL CODE			
SPONSOR			
CRA			
SITE Nr.			
PRINCIPAL INVESTIGATOR			
INSTITUTION NAME			
DEPARTMENT / UNIT			
VISIT DATE dd/mmm/yyyy		TYPE OF CONTACT	VISIT <input type="checkbox"/> CALL <input type="checkbox"/>

Attendees

NAME	ROLE

A – Pre-Study Documents and Information

N°		Yes	No	N/A	COMMENTS
1	Clinical Study Synopsis provided to Investigator?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
2	Clinical Study Protocol provided to Investigator? (Version:)	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
3	Items presented to/discussed with the site staff: <i><list items></i> 				

Study Code: <XXX>

<visit date>

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Titolo Modello: Pre-study Visit Report

CONFIDENZIALE

Modello: T.CLI04.05/3

Data Effettiva: 10.07.2023

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4	Confidentiality Agreement signed by Investigator?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
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B – Clinical Study Protocol

N°		Yes	No	N/A	COMMENTS
5	Any general remarks/comments on the Clinical Study Protocol?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
6	Any remarks/comments on the Inclusion/exclusion criteria?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
7	Is the schedule of activities feasible and acceptable for the patients?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

C – Patient Accrual

N°		Yes	No	N/A	COMMENTS
8	How many patients with <i><enter main patient characteristics as per protocol eligibility criteria></i> are followed at the site per year?				
9	Do you have conflicting commitments (e.g. competitive ongoing/planned studies)?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
10	Expected enrolment rate (patients per year)				

D – Site Staff

N°		Yes	No	N/A	COMMENTS
11	Is the site staff adequately qualified/experienced to carry-out all procedures required by the study protocol?				
12	Have medical specialists from other departments been identified as required by protocol (e.g., cardiologist, dermatologist, etc.)?				
13	Considering all other research-related commitments, does the site staff have adequate time to conduct the study?				

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E – Site Facilities

<use this section to document the availability of any study-specific facility/equipment, which was not included in the Site Qualification Visit Report>

N°		Yes	No	N/A	COMMENTS
14		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
15		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	
16		<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	

Would it be feasible to perform the clinical study at site?	<input type="checkbox"/>	<input type="checkbox"/>
Any anticipated issue which may delay clinical study start? If yes, specify:	<input type="checkbox"/>	<input type="checkbox"/>

Remark on Item No.	Expanded Comments
	Please use this section to expand on the previous comments or to add any further useful information. If the comment refers to a specific item, please enter the number of the item the comment is referred to.

Report prepared by CRA Print name and role:	Signature:	(dd/mmm/yyyy)
Report reviewed and approved by COC Print name:	Signature:	(dd/mmm/yyyy)