

**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>&lt;list items&gt;</i>  .....  .....  .....				

Study Code: <XXX>

<visit date>

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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>&lt;enter main patient characteristics as per protocol eligibility criteria&gt;</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"/>	

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

Remark on Item No.	Expanded Comments
	<i>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.</i>

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