



NKTIREC FORM 7.0: SITE VISIT REPORT

REC Protocol No.		Date of the Visit:	
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Study Title:	
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Principal Investigators:		Phone:	
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Department:		Address:	
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Sponsor		Address:	
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Total number of expected subjects:		Total subjects enrolled:	
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Are site facilities appropriate? <input type="checkbox"/> Yes <input type="checkbox"/> No	Comment:
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Are informed consent documents updated to the version approved by the NKTIREC? <input type="checkbox"/> Yes <input type="checkbox"/> No	Comment:
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Are there any SAE/SUSAR reports not previously reported to the NKTIREC? <input type="checkbox"/> Yes <input type="checkbox"/> No	Comment:
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Are there any events of protocol noncompliance not previously reported to the NKTIREC? <input type="checkbox"/> Yes <input type="checkbox"/> No	Comment:
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Are all Case Report Forms up to date? <input type="checkbox"/> Yes <input type="checkbox"/> No	Comment:
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Are all other approved documents (e.g., advertisements) used in accordance with the approved study protocol?

Comments:

Yes No

Are there any significant findings in this visit that could affect participant's/subject's rights, safety or welfare

Comments:

Yes No

Overall, does the study site provide adequate protection for the rights, safety, or welfare of study participants/subjects?

Comments:

Yes No

How well are study participants/subjects protected?

Comments:

GOOD
 FAIR
 NOT GOOD

Are there further actions or queries resulting from this site visit?

Comments:

Yes No

Any outstanding tasks or results of visit?

Give details:

Yes No

Duration of visit: (hours)

Starting from:

Finish:

COMPLETED BY THE FOLLOWING NKTI REC MEMBER/ REPRESENTATIVES:

NAME	SIGNATURE	DATE
<Name 1>		<dd/mm/yyyy>
<Name 2>		<dd/mm/yyyy>
<Name 3>		<dd/mm/yyyy>



RECOMMENDED ACTION: (For NKTI REC use only)

- NO FURTHER ACTION
- REQUEST INFORMATION: (specify)
- RECOMMEND FURTHER ACTION: (specify)

- PENDING, IF MAJOR CLARIFICATIONS ARE REQUIRED BEFORE A DECISION CAN BE MADE

PRIMARY REVIEWER

Signature _____

Date: <dd/mm/yyyy>

Name

<Title, Name, Surname>