SITE VISIT REPORT

To the IEC Member:

Routine/for cause monitoring is part of the continuing oversight to ensure compliance with the conditions of the IEC approval of the protocol.

Please obtain an electronic copy of this Form, fill-out the requested information, and forward to the Secretariat both in electronic version and hard copy. Print in letter-sized paper with printer default set at A4.

I. PROTOCOL INFORMATION	**IEC Protocol Tracking No.**
Study Protocol No.	Protocol Approval Date:
Study Initiation Date:	Expected End Date:
Title:	Version Number, Date
Name of Principal Investigator	Contact Nos.:
Sponsor/CRO	
Study Site	

II. DATE OF SITE VISIT <dd/mm/yy> **DURATION OF VISIT** <hh/mm> **START OF VISIT** **END OF VISIT**	**SITE VISIT REPORT SUBMISSION DATE** <dd/mm/yy>
INFORMATION REQUIRED	**RESPONSE/ COMMENTS**
1. Summary of Protocol Participants	
1.1. Accrual ceiling set by IEC	
1.2. Total participants since the study begun	
1.2.1. Active Patients	
1.2.2. Patients who have completed the study	
1.3. Number of drop-outs	
2. Are site facilities appropriate? ☐ Yes ☐ NO (*explain/comment)*	
3. Was the latest IEC-approved version of the protocol used? ☐ Yes ☐ NO (*explain/comment)*	
4. Was the latest IEC-approved version of the ICFs used? ☐ Yes ☐ NO (*explain/comment*)	

5. Were all other documents (e.g. data collection forms) used in accordance with the conditions of the IEC approval? ☐ Yes ☐ NO *explain/comment*)	
6. Were consent/assent obtained from the participants? ☐ Yes ☐ NO (*If No, explain/comment*)	
7. Were there any SAEs not previously reported to IEC? ☐ Yes ☐ NO (*explain/comment*)	
8. Were the SAEs reported to IEC within 7 working days and SAE resulting in death within 24 hours? ☐ Yes ☐ NO (*explain/comment)*	
9. Were there any protocol non-compliance (deviations/violations) not previously reported to the iEC? ☐ Yes ☐ NO (*explain/comment)*	
10. Were there any unanticipated problems, adverse events and minor deviation not previously reported to the IEC? ☐ Yes ☐ NO (*explain/comment)*	
11. Were there any participant complaints not previously reported to the IEC? ☐ Yes ☐ NO (*explain/comment)*	
12. Are study documents and investigating product(s) kept safe and secure? ☐ Yes ☐ NO (*explain/comment)*	
13. Overall, are participant's rights, safety and welfare adequately protected? ☐ Yes ☐ NO (*explain/comment)*	
14. Any outstanding result of the visit? ☐ Yes (*give details*) ☐ NO (*explain/comment)*	

I declare that the above information/statements are true to the best of my personal knowledge and belief.

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Signature Over Printed Name of Visiting IEC Member ***Date***