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| Form number | **51.008B** | Version  | **4.0** |
| Title | **Protocol Deviation Review Form** |

**\*\*To be attached to Form 51.008A, Part 1 of the protocol deviation Form related to this deviation**

**For category 3 and 4 deviations please consult with Governance Manager or Lead Pharmacist\*\***

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| **Study title** |  |
| **R&D Reference Number** |  |
| **Site Name**  |  |
| **Principal Investigator**  |  |
| **Date of report**  |  |
| **Date of deviation**  |  |
| **Date PI became aware** |  |
| **Date the Chief Investigator was informed of the deviation** |  |
| **Date reported to the Sponsor and name of individual reported to(\*monitor, RGM or lead pharmacist- earliest date to be recorded)** |  |

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| 1. Source of deviation  |
| Reported by SiteName of individual reporting from site: |
| Other (Not reported by Site) |
| If other, please specify: |

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| 2. What type of deviation occurred? (please tick all that apply) |
| Consent  |  |
| Eligibility |  |
| Safety Reporting |  |
| Regulatory |  |
| Data Capture |  |
| Investigational Medicinal Product |  |
| Other,  |  |
| If other, please specify: |

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| 3. Chief Investigator review  |
| Safety of Patients – Was there a safety issue arising from this deviation? |
| Yes  |  |
| No |  |
| Potentially could there have been a safety issue as a result of this type of deviation? |
| Yes |  |
| No |  |
| Chief Investigator Name:Signature:Date: |
| 4. Statistician review  |
| Is it possible the deviation could have more than a minimal effect on the primary and secondary endpoints  |
| Yes |  |
| No |  |
| If No, please briefly justify |
| Could the root cause of this deviation impact on other studies?  |
| Yes |  |
| No |  |
| Does the deviation relate to an exploratory endpoint? |
| Yes |  |
| No |  |
| If Yes, please describe impact on reaching the endpoint |

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| 4. Does the IDMC need to comment?  |
| Yes |  |
| No |  |
| If yes, please provide details: |

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| 5. Does the trial steering committee need to comment?  |
| Yes |  |
| No |  |
| If yes, please provide details: |

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| --- | --- |
| Protocol Deviation Number (Q-pulse): |  |

Additional information requested by Sponsor:

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Any additional Corrective Actions / Preventative Actions requested by Sponsor:

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|  |

Root Cause identifed by Sponsor (do not leave blank):

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| --- | --- | --- | --- |
| Have the affected patient(s) remained in this trial? | Yes | No | NA |
|  |  |  |  |

If yes, which patients?

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|  |

**Sponsors categorisation of deviation**

 Category 1: Minor issues detected

 *Minor issues of non-compliance of an administrative or technical nature are detected that do not compromise patient safety or the integrity of the trial data*

 Category 2: Major issues detected

*Major issues are detected that could affect the conduct of the trial but do not constitute a serious breach of GCP of the protocol*

 Category 3: Serious issues detected

*Serious issues are detected that may impact on patient safety and/or integrity of the data. This may include potential serious breaches of GCP and/or the trial protocol*

Category 4: Critical issues detected

*Critical issues are detected that have a significant and/or immediate impact on patient safety and/or integrity of the data. This may include potential serious breaches of GCP and/or the protocol*

**Sponsor review**

 No further action necessary

 Request additional information from Site

 Recommend for-cause monitoring visit

 Escalate to Governance Manager (category 3 and 4 only)

**N.B: CI to be notified of ALL protocol deviations via monthly report for review. The deviations will be reviewed by the Trial management team.**

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| **Sponsor review**  |
| Reviewed by |  |
| Designation |  |
| Signature |  | Date |  |

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