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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\*\***

|  |  |
| --- | --- |
| **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 Site  Name of individual reporting from site: |
| Other (Not reported by Site) |
| If other, please specify: |

|  |  |
| --- | --- |
| 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: | |

|  |  |
| --- | --- |
| 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: | |

|  |  |
| --- | --- |
| 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:

|  |
| --- |
|  |

Any additional Corrective Actions / Preventative Actions requested by Sponsor:

|  |
| --- |
|  |

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?

|  |
| --- |
|  |

**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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