**Joint Research Management Office**

***Source Data Verification* *Monitoring Form***

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| 1. **GENERAL INFORMATION**
 |
| **Study Title:** | **Sponsor:** |
| **Study IRAS number:** | **CI:** |
| Site: | Site number: |
| PI: | Date of visit:  |
| Study coordinator: | Type of visit (i.e. visit no., COV): |
| Names of all study personnel met during this visit: | Name of the monitor:  |
| Locations and departments visited: | Risk level of this study (as defined by the JRMO): |
| Next scheduled visit date (refer to study monitoring plan): |  |
| **Summary of the Visit:** |
| ***Please ensure a comment is inserted regarding meeting with PI.*** |

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| **2. SOURCE DATA VERIFICATION (SDV) (AS PER MONITORING PLAN)**  |
| SDV was performed on: (List CRFs reviewed i.e. GP letters have been sent, Quality of life questionnaires, patients diary card)  |
| Participant # | CRF section |
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| I confirm that apart from those data points listed below, a full reviewed of data points was performed and were found to be correct, accurate and source was identified. |

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| Participant # | CRF section |
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| I confirm that apart from those data points listed below, a full reviewed of data points was performed and were found to be correct, accurate and source was identified. |

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| **3. PARTICIPANT MEDICAL NOTES/ SOURCE DATA** |
| Please List Source data (one row per source): | e.g. paper medical records, electronic system- millennium, E-MR print outs, PACS etc) |
| Name  | Type  | If electronic – has this been validated? |
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| **4. INFORMED CONSENT / ELIGIBILITY CRITERIA** |
| Consent form present for all participants on screening log? Yes [ ]  No[ ]  |
| PIS v | ICF v | Date signed by | Name of researcher receiving consent | Researcher on delegation log? | Boxes initialled | Satisfies inclusion / exclusion criteria | Status (If withdrawn, why?) | Comments |
| Participant | Researcher |
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| Does the date on the first informed consent form predate any study related activities? | Yes[ ]  | Yes[ ]  | Yes[ ]  | *Insert date on the first consent* | Comments |

| **5. CRFs SDV performed on** **(Visit no.)** | **Query no.** | **Comments** | **Action** | **Date query resolved/ comments** |
| --- | --- | --- | --- | --- |
| **Patient no.** |
|  | 1 |  |  |  |
|  | 2 |  |  |  |
|  | 3 |  |  |  |
| For sections reviewed:  |  | *Comments:* |
| Assessments and tests completed in line with the protocol? | Yes [ ]  No[ ]  |  |
| Does the frequency (and dose) of prescription match what is stated in the protocol? | Yes [ ]  No[ ]  |  |
|  | Yes [ ]  No[ ]  |  |
| Are all **AEs** accounted for and recorded in the CRF? | Yes [ ]  No[ ]  |  |
| Have all AEs been followed up and closed? | Yes [ ]  No[ ]  |  |
| Are all **SAEs** accounted for and recorded in the CRF? | Yes [ ]  No[ ]  |  |
| Have all SAEs been followed up and closed? | Yes [ ]  No[ ]  |  |
| Have all SUSARs been recorded in CRF and reported to the sponsor? | Yes [ ]  No[ ]  |  |
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| **Patient no.** |
|  | 1 |  |  |  |
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|  | 3 |  |  |  |
| For sections reviewed:  |  | *Comments:* |
| Assessments and tests completed in line with the protocol? | Yes [ ]  No[ ]  |  |
| Does the frequency (and dose) of prescription match what is stated in the protocol? | Yes [ ]  No[ ]  |  |
|  | Yes [ ]  No[ ]  |  |
| Are all **AEs** accounted for and recorded in the CRF? | Yes [ ]  No[ ]  |  |
| Have all AEs been followed up and closed? | Yes [ ]  No[ ]  |  |
| Are all **SAEs** accounted for and recorded in the CRF? | Yes [ ]  No[ ]  |  |
| Have all SAEs been followed up and closed? | Yes [ ]  No[ ]  |  |
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| **Patient no.** |
|  | 1 |  |  |  |
|  | 2 |  |  |  |
|  | 3 |  |  |  |
| For sections reviewed:  |  | *Comments:* |
| Assessments and tests completed in line with the protocol? | Yes [ ]  No[ ]  |  |
| Does the frequency (and dose) of prescription match what is stated in the protocol? | Yes [ ]  No[ ]  |  |
|  | Yes [ ]  No[ ]  |  |
| Are all **AEs** accounted for and recorded in the CRF? | Yes [ ]  No[ ]  |  |
| Have all AEs been followed up and closed? | Yes [ ]  No[ ]  |  |
| Are all **SAEs** accounted for and recorded in the CRF? | Yes [ ]  No[ ]  |  |
| Have all SAEs been followed up and closed? | Yes [ ]  No[ ]  |  |
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| 6. SUMMARY OF FINDINGS AND ACTIONS |
| **Finding Number**  | **Finding type (please see key for details)** | **Summary of findings** | **Corrective action and person carrying out this action** | **Severity (Critical, Major, Other)** | **Proposed timeline to resolve** | **Date action completed** |
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| 7. SIGNATURES AND REVIEW |
| Completed by: |
| Study Monitor  | **Name:** **Email:**  | Date:  | Signature |
| Reviewed by  |
| Research Governance and GCP Manager | **Name:** **Email:**  | Date  | Signature |