**Summary study monitoring report (UK)**

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| **Study summary** | | | | | | | | | |
| **Monitoring reporting period :** | | **From:** DD/MM/YYYY | | | | **To:** DD/MM/YYYY | | | |
| **Name** | |  | | | | | | | |
| **IRAS Number** | |  | | | | | | | |
| **CI** | |  | | | | | | | |
| **Current protocol version** | |  | | | | | | | |
| **Current RSI** | | Version  Date | | | | | | | |
| **When was the RSI last checked by the CI? Has this been documented?** | |  | | | | | | | |
| **Number of Amendments** | | Substantial | |  | Non-Substantial | |  | | |
| **Number of Protocol Amendments** | | Substantial | |  | Non-Substantial | |  | | |
| **Amendment log** | | *Attach* | | | | | | | |
| **Sites** | | No. of sites in Total:  No. of sites in UK Total:  Specify location within Barts Health or Queen Mary: | | | | | | | |
| **Specify Target and Cap if applicable** |  |  | #In set up |  | #Active | |  | #Closed |  |
| **Recruitment** | | No. of patients recruited in Total:  No. of Patients recruited in UK Total:  No. of Patients recruitment at Barts Health:  Target:  Are you on schedule? Yes/ No  If No give details | | | | | | | |
| **Estimated End date:** | |  | | | | | | | |
| **Actual EoT Date** | |  | | CSR due date | *Insert if applicable or enter N/A* | | | | |

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| **Pharmacovigilance** | |
| **Number of SAEs** | *If possible attach PV database print out* |
| **Number of SUSARs** | *If possible attach PV database print out* |
| **Number of SARs** | *If possible attach PV database print out* |

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| **Study detail** | | | | | |
| **Trial Committees** | **Name of committee** | **Frequency of meeting** | **Date of last meeting** | | **Date minutes sent to JRMO** |
|  |  |  | |  |
|  |  |  | |  |
|  |  |  | |  |
| **Annual report due date** |  | Date last one submitted | |  | |
| **DSUR due date** |  | Date last one submitted | |  | |
| **Was submission of any annual reports delayed? If so, why?** |  | | | | |
| **Deviation log up to date** | Yes/No | | | | |
| **Number of Deviation** |  | | | | |
| **Deviation log** | *Attach* | | | | |
| **Database Change control log** | *Attach* | | | | |
| **Any changes to source data locations? Please detail if so** |  | | | | |

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| **Monitoring** | | | | | | |
| **Monitoring frequency as per Monitoring Plan** |  | | | | | |
| **Did monitoring happen as schedule? Please specify** | Yes/No | | | | | |
| **If NO please specify** | Site | Date of last onsite visit | Date visit due | Actual date performed | Visit pending – date boked | Comments |
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| **Summary of UK Sites Monitoring in last reporting period** | | | | | | |
| **Date visits performed** | **Site name and visit Type**  **(e.g. Barts- Pharmacy)** | **Site Status (Closed, Pending, etc.)** | **All findings from previous visit resolved? (if No, please clarify)** | | **Comment**  ***(Please provide brief summary /comment of sites compliance/ CRF completion/ resources and other concerns of note)*** | |
|  |  |  | YES/NO | |  | |
|  |  |  |  | |  | |
|  |  |  |  | |  | |
| **Did Central monitoring occur?** | Yes /No | If yes provide/attach summary | | | | |
| **Summary of findings from this reporting period** | | | | | | |
| **Category** | | **Other** | | **Major** | | **Critical** |
| **1a) Essential Documents (study)** | | *e.g. 10* | | *5* | | *0* |
| **1b) Essential Documents (Approval)** | |  | |  | |  |
| **2) Vendors / Contracts and subcontractors / Finance / finance** | |  | |  | |  |
| **3) Informed consent procedures** | |  | |  | |  |
| **4) Inclusion and exclusion criteria** | |  | |  | |  |
| **5) IMP and non-IMP** | |  | |  | |  |
| **6) Training / Staffing** | |  | |  | |  |
| **7) Deviation study procedures** | |  | |  | |  |
| **8) Pharmacovigilance** | |  | |  | |  |
| **9) Randomisation and cohort allocation / unblinding** | |  | |  | |  |
| **10) Data management (Source data + CRF)** | |  | |  | |  |
| **11) Study equipment** | |  | |  | |  |
| **12) Computer systems** | |  | |  | |  |
| **13) Deviations to GCP / Regulations** | |  | |  | |  |

*\*Please copy this table for additional countries*

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| --- | --- | --- | --- |
| **CI comment on overall study progress:** | |  | |
|  | **Name:** | **Signature:** | **Date:** |
| **Chief Investigator** |  |  |  |
| **Study Co-ordinator** |  |  |  |

*PLEASE NOTE: an electronic signature is acceptable (with the CI copied in on email submission).*