**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**  | VersionDate |
| **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).*