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| --- | --- | --- | --- | --- |
| **Study Title:** |  | | | |
| **Study Reference number:** | |  | **EudraCT number:** |  |
| **Investigational Product(s):** | |  | | |

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| **Site name:** |  | | **Site No:** |  |
| **Principal Investigator Name:** | |  | | |

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| --- | --- |
| **Clinical Trials Pharmacist:** | **Clinical Trials Laboratory lead:** |
| **Pharmacy Address:** | **Laboratory Address:** |

Clinical Review and Approval

|  |  |  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Required Documents | | **Received**  *(delete as appropriate)* | Version No. and date of document *(where applicable)* | Approved  *(delete as appropriate)* | Comments | Initials/Date | |
| **Sponsor** | **Date** |
| **Approval documentation** | | |  |  |  | | |
|  | Competent authority notification or approval to conduct study. | **Yes / No / NA** |  | **Yes / No / NA** |  |  |  |
|  | Approval letter and amendments | **Yes / No / NA** |  | **Yes / No / NA** | *Approval Date needed* |  |  |
|  | Ethics Approval Letter | **Yes / No / NA** |  | **Yes / No / NA** | *Approval Date needed* |  |  |
|  | R&D Permission | **Yes / No / NA** |  | **Yes / No / NA** | *Approval Date needed* |  |  |
|  | (Co-)Sponsorship agreement | **Yes / No / NA** |  | **Yes / No / NA** | *Final Signature Date* |  |  |
|  | All relevant signed study contracts | **Yes / No / NA** |  | **Yes / No / NA** |  |  |  |
|  | Technical Agreement(s) if applicable | **Yes / No / NA** |  | **Yes / No / NA** | No. submitted: |  |  |
|  | Adequate clinical trials insurance in place | **Yes / No / NA** |  | **Yes / No / NA** |  |  |  |
| **Trial process confirmation** | | |  |  |  | | |
|  | Current Approved Protocol | **Yes / No / NA** |  | **Yes / No / NA** |  |  |  |
|  | Database ready for site | **Yes / No / NA** |  | **Yes / No / NA** |  |  |  |
| Required Documents | | **Received**  *(delete as appropriate)* | Version No. and date of document *(where applicable)* | Approved  *(delete as appropriate)* | Comments | Initials/Date | |
| **Sponsor** | **Date** |
|  | Localised study documents completed | **Yes / No / NA** |  | **Yes / No / NA** |  |  |  |
| **Site staff documentation** | | |  |  |  | | |
|  | CVs for relevant staff | **Yes / No / NA** |  | **Yes / No / NA** |  |  |  |
|  | Evidence of training for relevant staff (including GCP and study/site-specific) | **Yes / No / NA** |  | **Yes / No / NA** |  |  |  |
|  | Evidence of training for study | **Yes / No / NA** |  | **Yes / No / NA** | *Completed training log* |  |  |
|  | Initiation visit completed | **Yes / No / NA** |  | **Yes / No / NA** | *Date of visit needed* |  |  |
| **Pharmacy-specific documentation** | |  |  | | | | |
|  | Current Investigator Brochure version / date of SmPC for each IMP | **Yes / No / NA** |  | **Yes / No / NA** |  |  |  |
|  | Confirmation from Pharmacy that IMP has been received and stored correctly | **Yes / No / NA** |  | **Yes / No / NA** |  |  |  |
|  | Confirmation from Pharmacy of QP release | **Yes / No / NA** |  | **Yes / No / NA** |  |  |  |
|  | Confirmation that unblinding documents are in Pharmacy | **Yes / No / NA** |  | **Yes / No / NA** |  |  |  |
|  | Pharmacy confirmation of readiness form signed | **Yes / No / NA** |  | **Yes / No / NA** |  |  |  |
| **Laboratory-specific documentation** | | |  |  |  | | |
|  | Equipment available and calibrated | **Yes / No / NA** |  | **Yes / No / NA** |  |  |  |
|  | Laboratory confirmation of readiness form signed | **Yes / No / NA** |  | **Yes / No / NA** |  |  |  |

### GREEN LIGHT Authorisation from sponsor

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| --- | --- | --- | --- | --- |
| Job Title | **Name (print)** | **Signature** | **Date (dd/mm/yy)** | **Decision**  *(Approve /*  *Resubmission required)* |
|  |  |  |  |  |