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

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| **Chief Investigator Name:** |  |

Clinical Review and Approval – TRIAL APPROVAL

|  |  |  |  |  |  |  |  |
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| 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 at first site | **Yes / No / NA** |  | **Yes / No / NA** | *Approval Date needed* |  |  |
|  | (Co-)Sponsorship agreement | **Yes / No / NA** |  | **Yes / No / NA** | *Final Signature Date needed* |  |  |
|  | 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** |  |  |  |
|  | CRFs completed | **Yes / No / NA** |  | **Yes / No / NA** |  |  |  |
|  | Database finalised | **Yes / No / NA** |  | **Yes / No / NA** |  |  |  |
|  | Relevant trial documents completed | **Yes / No / NA** |  | **Yes / No / NA** | e.g. monitoring plan |  |  |

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| Required Documents | | **Received**  *(delete as appropriate)* | Version No. and date of document *(where applicable)* | Approved  *(delete as appropriate)* | Comments | Initials/Date | |
| **Sponsor** | **Date** |
| **Staff documentation** | | |  |  |  | | |
|  | CV & GCP for Chief Investigator | **Yes / No / NA** |  | **Yes / No / NA** |  |  |  |
|  | CVs for relevant trial office 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** |  |  |  |
| **Pharmacy-specific documentation** | |  |  | | | | |
|  | Current Investigator Brochure version / date of SmPC for each IMP | **Yes / No / NA** |  | **Yes / No / NA** |  |  |  |
|  | Confirmation that unblinding procedures are in place | **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)* |
|  |  |  |  |  |