| **Documents** | | **Present** | | | **Comments** | **Action Required** | |
| --- | --- | --- | --- | --- | --- | --- | --- |
| Yes | No | N.A |  | Yes | No |
| **Reviewe date : xx-xx-xxxx** | | | | | | | |
| 1. **Contact information** | | | | | | | |
| Contact information |  | |  |  |  |  |  |
| 1. **Protocol/amendements** | | | | | | | |
| Signed, dated protocol | |  |  |  | Version: Date: |  |  |
| Signed, dated protocol amendment | |  |  |  | Version: Date: |  |  |
| 1. **Documents EC/CA** | | | | | | | |
| EC approval, including submitted documents | |  |  |  |  |  |  |
| EC Memberlist | |  |  |  |  |  |  |
| Correspondence EC | |  |  |  |  |  |  |
| CA approval, including submitted documents | |  |  |  |  |  |  |
| Correspondence CA | |  |  |  |  |  |  |
| Other approvals, if relevant | |  |  |  |  |  |  |
| Advertisement | |  |  |  |  |  |  |
| Letter to General Practitioner | |  |  |  |  |  |  |
| Annual report EC/CA | |  |  |  |  |  |  |
| End of Trial Notifications to EC and CA | |  |  |  |  |  |  |
| Final Study report to EC and CA | |  |  |  |  |  |  |
| 1. **Study Site team** | | | | | | | |
| CV’s site staff | |  |  |  |  |  |  |
| GCP certificates site staff | |  |  |  |  |  |  |
| Delegation log | |  |  |  |  |  |  |
| Trainingslog | |  |  |  |  |  |  |
| 1. **Agreements** | | | | | | | |
| Letter of authorization/ feasibility letter | |  |  |  |  |  |  |
| Signed Clinical Trial Agreement | |  |  |  | Date: |  |  |
| Signed other agreements:   * Pharmacy * Laboratory | |  |  |  | Date:  Date: |  |  |
| 1. **Insurance** | | | | | | | |
| Subject insurance certificate | |  |  |  | Insurance no. :  Valid from ….. till …. |  |  |
| Liability insurance certificate | |  |  |  | Insurance no. :  Valid from ….. till …. |  |  |
| Other relevant documentts | |  |  |  |  |  |  |
| 1. **Patient information sheet and informed consent form** | | | | | | | |
| Blank patient information sheet and informed consent form | |  |  |  | Version: Date: |  |  |
| Translated patient information sheet and informed consent form, including translation certificates | |  |  |  | Version: Date: |  |  |
| Signed, dated informed consent forms | |  |  |  |  |  |  |
| 1. **Patient identification** | |  |  |  |  |  |  |
| Screening and inclusion log | |  |  |  |  |  |  |
| Patient identification log | |  |  |  |  |  |  |
| 1. **eCRF /source documents** | | | | | | | |
| Blank CRF | |  |  |  | Version: Date: |  |  |
| eCRF completion guidelines | |  |  |  | Version: Date: |  |  |
| Diaries/questionnaires | |  |  |  | Version: Date: |  |  |
| Source documents (worksheets) | |  |  |  |  |  |  |
| Other relevant study documents | |  |  |  |  |  |  |
| 1. **Safety** | |  |  |  |  |  |  |
| Blank SAE report, including SAE completion instructions | |  |  |  |  |  |  |
| Completed SAE reports / follow-up reports | |  |  |  |  |  |  |
| Safety information from Sponsor | |  |  |  |  |  |  |
| 1. **Investigational Product** | | | | | | | |
| Signed, dated Investigator Brochure(s)/SPCs | |  |  |  | Version: Date: |  |  |
| IMPD | |  |  |  | Version: Date: |  |  |
| Investigational Product documentation (including shipment records) | |  |  |  |  |  |  |
| Investigational Product accountability | |  |  |  |  |  |  |
| Instructions for handling Investigational Product | |  |  |  | Version: Date: |  |  |
| Randomization list | |  |  |  |  |  |  |
| Unblinding procedures | |  |  |  |  |  |  |
| 1. **Laboratory** | |  |  |  |  |  |  |
| Clinical laboratory normal values | |  |  |  |  |  |  |
| Clinical laboratory accreditation/certification | |  |  |  |  |  |  |
| Laboratory manuals | |  |  |  | Version: Date: |  |  |
| Shipment records of laboratory samples | |  |  |  |  |  |  |
| Record of retained body fluid/tissue samples (if any | |  |  |  |  |  |  |
| 1. **Monitoring** | | | | | | | |
| Site initiation visit report | |  |  |  |  |  |  |
| Monitor visit log | |  |  |  |  |  |  |
| Follow-up mail monitoring visits | |  |  |  |  |  |  |
| Other relevant documentation | |  |  |  |  |  |  |
| 1. **Clinical Trial File Notes** | |  |  |  |  |  |  |
| Signed, dated Clinical Trial File Notes | |  |  |  |  |  |  |
| 1. **Correspondence** | | | | | | | |
| Relevant correspondence | |  |  |  |  |  |  |
| 1. **Other** | | | | | | |  |
| Audit certificate | |  |  |  |  |  |  |