| **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 |  |  |  |  |  |  |