

## INVESTIGATOR SITE FILE INDEX

<Trial Code>

<Investigator Name>

<Site No. and name>

*(relevant correspondence should be archived in each specific section)*

- 1. Investigator's Brochure(s) and updates** (and/or SmPC if applicable)
- 2. Protocol, Protocol Amendment(s), Amended Protocol(s)**
  - Synopsis
  - Protocol - Sponsor and Investigator signature page(s)
  - Amendment(s) - Sponsor and Investigator signature page(s)
- 3. CRF Documentation**
  - CRF completion / Data entry guidelines /updates
  - Source Document Location List
- 4. Informed Consent Forms** (local blank copy – all versions submitted to EC/CA)
- 5. Additional written information provided to the patient, approved by the EC/CA** (blank copies - *Patient Diary, Letter to the General Practitioner, Patient Cards, etc.*)
- 6. Clinical Trial Agreement and updates** (*executed*)
- 7. EC and Competent Authorities**
  - Applications and Approvals (including EC Composition)
  - Notifications (incl. safety)
- 8. Insurance policy /certificate**
- 9. Site Staff documentation**
  - Delegation Log
  - CV (Investigator, Sub-Investigators)
  - Training of site personnel (e.g. CRF, GCP etc.)
- 10. Site Laboratory**
  - Normal range values
  - Accreditation/Certification
  - Lab Director CV (if the certification is not available)
- 11. Central Laboratory**
  - Manual for sample collection, handling and shipment - including blank forms
  - Biological Samples Forms (tracking)
  - Sample Shipment Forms / confirmation of receipt

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### 12. Investigational Product (s)

- Storage/shipping conditions
- Manual for IP handling (including blank forms)
- Completed forms:
  - Shipping Forms /confirmation of receipt
  - Resupply Request Forms
  - Accountability Forms
  - Dispensing form
  - Reconciliation Forms
  - Return Forms or Local Destruction (approval by the Sponsor, Letter by the site for the delivery of IP to be destroyed, Certificate of IP destruction)

*(Some documents could be archived at the hospital pharmacy, please specify)*

### 13. Other trial material

- Documentation

### 14. Patient's Registration

- Procedures (including blank forms)
- Completed Patient Screening & Randomization Log
- Registration/confirmation of registration

### 15. IP Safety

- Trial-specific procedure for Serious Adverse Event (including blank forms)
- SAEs/FU notification (by PI to Sponsor)
- Trial Specific SUSARs Notification
- Other Safety documents

### 16. Monitoring documentation

- Site Initiation Visit report
- Site Monitoring Visit Log
- Site Monitoring Confirmation / Follow-up letters

### 17. Audit documentation

### 18. Minutes of meetings (Investigator's meeting, TC, etc.)

### 19. Trial specific training (attendees list, documents used during the training)

### 20. Other Documentation:

- Newsletter
- Manuscripts, Publications, Abstracts

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### 21. Protocol GCP Deviations:

- Guideline for Protocol / GCP deviations
- Protocol / GCP deviations Log

### 22. Summary of Clinical Trial Report (Interim, final, amendment / addenda)

### 23. Confidential section

- Patient Identification Code List
- Signed Informed Consent Forms (for each screened patient)

### 24. CRF

#### By patient:

- Original signed and dated CRF or Printouts generated by Remote Data Capture System – RDSCS and CD-ROM
- Data Clarification Forms/queries