

TRIAL MASTER FILE INDEX

<Trial Code>

GENERAL DOCUMENTS

(relevant correspondence should be archived in each specific section)

1. **Trial Staff List** (study team, centres list)
2. **Investigator's Brochure(s) and updates** (and/or SmPC is applicable)
3. **Protocol, Protocol Amendment(s), Amended Protocol(s)**
 - Synopsis
 - Protocol - Sponsor signature page(s)
 - Amendment(s) - Sponsor signature page(s)
 - EUDRACT No. request
4. **CRF Documentation**
 - Blank paper CRF or eCRF screen print-outs
 - CRF completion / Data entry guidelines /updates

CRF (by centres and by progressive patient code)

 - Original signed and dated CRF or printouts generated by Remote Data Capture System (RDCS) and/or CD-ROM
 - Data Clarification Forms /queries
5. **Informed Consent Form** (all versions)
6. **Additional written information provided to the patient** (all versions) - *Patient Diary, Letter to the General Practitioner, Patient Cards, etc.*
7. **Clinical Trial Agreements and updates** (*executed*)
8. **Insurance policy / certificate (by country, if any)**
9. **Central Clinical Laboratory**

(Create specify sections for different labs/tests)

 - Signed Agreement Laboratory, Invoices and Finance
 - CV labs personnel – Head and key personnel (not required if accreditation certificate available)
 - Accreditation/Certification (released by the Quality System organization and by the HA)
 - Normal range values (if any)
 - Manual for sample collection, handling and shipment - including blank forms
 - Labels (if any)
 - Analytical Protocol ((if applicable-including validation method documents)

TRIAL MASTER FILE INDEX

<Trial Code>

- Shipment Forms / confirmation of receipt
- Monitoring documentation (if any)
- Results / Reports

10. Investigational Product (s)

- IMPD
- Manual for IP handling (including blank forms)
- Samples of labels (including new labels and instruction for IP re-labelling, if any)
- Certificates of analysis (if any)
- GMP certificates
- QP- GMP declaration
- IVRS docs (if any)
- Other IP docs

11. Other trial material

12. Patient's Registration

- Blank forms
- Completed Patient Screening & Randomization Log

13. IP Safety

- Trial-specific procedure for SAE (including blank forms)
- Line Listings (SUSARs) with distribution docs
- DSURs with distribution docs
- SAE re-conciliation procedure and report

14. IP Safety (by centres)

- SAEs/FU notification (by PI to Sponsor)
- Study Specific SUSARs (Notification by the FROM to CA, coordinating EC)
- IP Specific SUSARs from other studies (if received by the Marketing Authorization Holder)
- Other safety documents

15. Monitoring documentation

- Monitoring Plan
- Monitoring Visit Report templates
- Monitoring Visit tracking

TRIAL MASTER FILE INDEX

<Trial Code>

16. Data Management

- Data Management Plan
- Data Base documentation
- Data entry convention/guideline
- Data Validation Plan
- Data Management Report

17. Statistics

- Statistical Analysis Plan
- Analysis database structure
- Data Analysis conventions
- Analysis output
- Statistical Report

18. Audit documentation

19. Minutes of meetings (e.g. Investigator's meeting, TC, etc.)

20. Study specific training (attendees list, documents used during the training)

21. Other Documentation:

- List of SOPs used in the study
- Newsletter
- Manuscripts, Publications, Abstracts, ClinTrial.gov

22. Protocol GCP Deviations:

- Guideline for Protocol / GCP deviations
- Deviazioni critiche dale GCP – Notifica ad AIFA

23. Clinical Trial Reports (Interim, final, amendment / addenda)

COUNTRY DOCUMENTS

<specify country>

(To be used when Competent Authority provides a central approval for a multicentre trial)

1. Applications and Approvals, Notifications & correspondence with CA
2. Other country-specific documents

TRIAL MASTER FILE INDEX

<Trial Code>

CENTER DOCUMENTS

<specify centre and Principal Investigator name>

1. **Protocol, Protocol Amendment(s), Amended Protocol(s)**
 - Protocol Investigator signature page(s) (original)
 - Amendment (s) Investigator signature page(s) (original)
2. **Local Informed Consent Form** (local blank copy – all versions submitted to EC/CA)
3. **Additional written information provided to the patient** (e.g. *Patient Diary* etc., local blank copy – all versions submitted to EC/CA.)
4. **Clinical Trial Agreement** (*executed*)
5. **EC and Competent Authority**
 - Applications and Approvals (including EC composition)
 - General and Safety notifications
6. **Site Staff documentation:**
 - Delegation Log
 - CV (Principal Investigator and Sub-Investigators)
 - Training of site personnel (e.g. CRF, GCP etc.)
7. **Local Laboratories**
 - Normal range values
 - Accreditation/Certification
8. **Investigational Product**
 - First Supply checklist
 - Shipment Order
 - Shipping documents
 - Resupply Requests
 - Accountability Forms
 - Return Form or Certificate of local destruction
 - Reconciliation Form
 - Other documents
9. **Other trial material**
 - Documentation

TRIAL MASTER FILE INDEX

<Trial Code>

10. Monitoring documentation

(each Monitoring Visit Report should be archived along with the relevant Monitoring Visit Confirmation and Follow-up Letters to the Investigator and pertinent correspondence)

- Source document location list
- Monitoring Visit Log
- Pre-study Visit Report
- Site Initiation Visit Report
- Monitoring Visit Reports
- Close-out Visit Report
- Telephone contact reports

11. Protocol GCP Deviations:

- Protocol / GCP deviations Log
- Deviazioni critiche dalle GCP – Notifica ad AIFA

12. Notification of Clinical Trial Report (Interim, final, amendment/ addenda)