**1. Study Design and Protocol Documents**

* **Clinical Study Protocol (CSP):** Outlines the study objectives, design, methodology, statistical considerations, and organization.
* **Protocol Amendments:** Any revisions to the original protocol, including rationale and impact.
* **Investigator’s Brochure (IB):** Background information on the investigational product, including preclinical and earlier phase data.
* **Statistical Analysis Plan (SAP):** Detailed description of the planned statistical methods and analyses.

**2. Regulatory and Ethical Documentation**

* **Informed Consent Forms (ICFs):** Copies of the consent documents used and any revisions.
* **Ethics Committee/IRB Approvals:** Documentation of review and approval from ethical bodies.
* **Regulatory Submission Documents:** Communications with regulatory authorities and submission dossiers.

**3. Operational and Data Management Documents**

* **Case Report Forms (CRFs)/Electronic CRFs (eCRFs):** The instruments used for data collection.
* **Subject Enrollment/Screening Logs:** Records of patient recruitment and eligibility.
* **Data Management Plan:** Outline of procedures for data collection, cleaning, and validation.
* **Monitoring Reports:** Regular site monitoring visit reports and any audit findings.
* **Protocol Deviation Reports:** Listings and rationales for deviations from the protocol.

**4. Safety and Efficacy Data Documents**

* **Adverse Event (AE) and Serious Adverse Event (SAE) Reports:** Detailed summaries and listings of safety events.
* **Interim Analysis Reports (if applicable):** Interim data assessments for safety and/or efficacy.
* **Efficacy Analysis Summaries:** Tables, figures, and text summarizing primary and secondary endpoint results.
* **Pharmacokinetic/Pharmacodynamic (PK/PD) Reports:** For trials where these assessments are relevant.
* **Laboratory Data Summaries:** Comprehensive lab results, including any central lab reports.
* **Imaging or Biomarker Reports:** If applicable, reports on imaging findings or biomarker analyses.

**5. Final Reporting and Appendices**

* **Final Clinical Study Report (CSR):** The complete narrative report summarizing the trial design, conduct, analyses, and conclusions.
* **Patient Disposition and Flow Diagrams:** Visual representations of patient progress through the study (e.g., CONSORT diagrams).
* **Appendices and Supplemental Materials:**
  + Detailed listings (e.g., individual subject data listings)
  + Additional tables and figures supporting the primary report
  + Copies of statistical outputs and programming code (if required)
* **Quality Assurance and Audit Reports:** Any internal or external audit findings related to data integrity and trial conduct.
* **Investigator Site Files (ISFs)/Monitoring Visit Summaries:** Summaries that support the trial’s operational integrity.