DOCUMENTS REQUIRED TO WRITE A CLINICAL STUDY REPORT (CSR)

Tools and Administrative Information

1. Protocol number or study number
2. Study number in ClinicalTrials.gov
3. Number and name of each clinical study site or center
4. Sponsor's in-house style guide, if applicable, and published style guide, if applicable (eg, *AMA Manual of Style, 10th Edition*)
5. Clinical study report template in Microsoft *Word*, if available
6. Adverse event (AE) and/or serious adverse event (SAE) narrative template, if applicable (ie, if there were AEs and/or SAEs reported in the clinical study, and if those events will be written as narratives for inclusion in the CSR)
7. Clinical study report project timeline
8. For interim reports, the cutoff date for clinical study data to be presented in the interim report
9. Name, title, and contact information for sponsor's representative who will approve and sign CSR
10. Description of naming conventions for clinical study report files, if applicable
11. Names and contact information of sponsor personnel with whom the writer will work to draft the CSR
12. Information on how to store, archive, and circulate draft and final CSR, if applicable
13. Directions as to who will store, archive, and circulate draft and final CSR
14. Decision from the sponsor as to which investigational product name will be used consistently in the CSR, if applicable (especially if the product name has undergone changes since protocol was written)
15. Names and addresses of CROs used and description of their role in the study, if applicable
16. Sponsor's content- or process-related SOPs that apply to writing clinical study reports
17. Description of sponsor's ideal label for the investigational drug product (optional)
18. Clinical development plan (optional)

19. *ICH Guideline E3, The Structure and Content of Clinical Study Reports*
20. *FDA Guidance for Industry: Submission of Abbreviated Reports and Synopses in Support of Marketing Applications*, if applicable
21. *European Medicines Agency (EMEA) – Note for Guidance on the Inclusion of Appendices to Clinical Study Reports in Marketing Authorisation Applica*tions, if applicable

Content

1. Clinical data as tables, listings, and figures (TLFs)
2. Screening logs for subject disposition (if not provided in TLFs)
3. Case report forms (CRFs) of subjects who had serious adverse events (SAEs)
4. Milestone study period dates: dates when first subject enrolled, last subject enrolled, and last subject completed study
5. List of IRBs/IECs/DMC addresses and chairperson's name
6. Sample study-specific master Informed Consent Forms for protocol and all amendments
7. Study-specific case report forms (CRFs)
8. Safety (AE and/or SAE) narratives, if applicable
9. Statistical Analysis Plan (SAP; sometimes called the Data Analysis Plan, or DAP), if applicable
10. Pharmacokinetics (PK) report, if applicable
11. Pharmacodynamic report, if applicable
12. Toxicology report, if applicable
13. Immunogenicity report, if applicable
14. List of references (abstracts or manuscripts) from publications derived from clinical study data
15. PDF files of all medical literature supporting the study and cited in the CSR
16. Original clinical study protocol and all amendments (preferably as Microsoft *Word*files)
17. Investigator brochure (version(s) used in the study, preferably as a Microsoft *Word*file(s))
18. Chairperson and address of DMC/Steering Committee, if applicable
19. List of site names, numbers, and locations
20. Name of the company who managed clinical trial supply

21. Names and addresses of laboratory facilities used
22. Laboratory certificates and normal ranges for all laboratories
23. Investigators' CVs
24. List of investigational drug batch numbers and list of subjects (by subject number) receiving each batch of investigational drug
25. List of protocol violations and/or deviations (if not included in TLFs)
26. List of investigators and study personnel, mailing and e-mail addresses, telephone and fax numbers ; if lead principal investigator, identify and include contact information
27. List of names and contact information of sponsor's personnel who participated in the clinical study: medical monitor (usually an MD), biostatistician, and clinical research associate(s)