appendix

# Guiding Principles for Preserving Essential Documents for Drug Clinical Trials

## 1. Definition, basic requirements and scope of application

Essential documents for drug clinical trials refer to documents that evaluate the implementation and data quality of drug clinical trials. They are used to prove that researchers, sponsors and monitors have complied with the "Good Clinical Practice for Drug Clinical Trials" and related drug clinical trials during the clinical trial process. Legal and regulatory requirements for testing. The necessary documents for drug clinical trials serve as the basis for confirming the authenticity of clinical trial implementation and the integrity of the data collected. They are an important part of the sponsor's inspection and the drug regulatory department's inspection of clinical trials. They should comply with the "Good Clinical Practice for Drug Clinical Trials" Required document management requirements. This guideline applies to the preservation of necessary documents related to drug clinical trials for the purpose of applying for drug registration.

## 2. References

ICH E6 (R2) Guideline for good clinical practice 3. Appendix

### Appendix 1 Clinical Trial Preparation Stage

| | Required documents | Purpose | Investigator/ Clinical Trial Institution | Sponsor |
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| 1 | Researcher's Manual | Demonstrate that the sponsor has associated , the latest scientific research results and clinical trials on Information on possible harm to humans provided to research | X | X |
| 2 | Clinical trial protocol signed by the researcher (including a revised version that proves the agreement between the researcher and the sponsor), sample clinical trial protocol (including revised version), case report form | | X | X |

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| | | Report form sample | | |
| 3 | Information provided to subjects (sample) - Informed consent form (including all applicable translations) - Any other written information provided to subjects - Advertising for recruitment of subjects (if used) use) | Demonstrate informed consent Demonstrate that subjects were provided with written information of appropriate content and wording that supports the subject's ability to give fully informed consent to the clinical trial Demonstrate that the method used to recruit subjects was appropriate and Legitimate | X | X |
| 4 | Financial contracts for clinical trials | Certify investigators and clinical trial institutions and sponsors financial regulations regarding clinical trials among stipulates and signs a contract | X | X |
| 5 | Relevant documents for subject insurance (if any) | to prove that subjects can receive compensation if they suffer any damage related to the trial. | X | X |
| 6 | Research contract (or funding contract) signed between parties participating in the clinical trial, including: - Contract signed between the researcher and clinical trial institution and the sponsor - Investigator and clinical trial Institutions and contract signed by contract research organization - The written review and consent document of the contract ethics | Proof of signing the contract | X<br>X | X<br>X (when necessary)<br>X |
| 7 | committee signed by the sponsor and the contract research organization for the following items, signed and dated - The trial protocol and its revised version prove that the clinical trial has been reviewed by the ethics committee - Informed consent review ,agree. Confirm the version number and date of the document—any other written information provided to the subject—the subject's recruitment advertisement (if used) use) | | X | X |

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| | - Compensation for subjects (if any) - Other documents reviewed and agreed by the ethics committee (such as a sample case report form) | | | |
| 8 | Composition of the Ethics Committee | Prove that the composition of the ethics committee complies with the requirements of the "Good Clinical Practice Practice for Drugs" | X | X |
| 9 | The drug regulatory department certifies that the clinical trial has been approved by the drug testing protocol and the registered product regulatory department before the start of the clinical trial. The filing proves that the researcher | | X | X |
| 10 | Resume and other information signed by the researcher Qualification documents Resumes and other qualifications signed by doctors, nurses, pharmacists and other researchers authorized to participate in clinical trials proving the reference | has the qualifications and ability to complete the clinical trial and is able to conduct experiments on the subjects. medical Supervision Prove that participating researchers have the qualifications and ability to complete the relevant work of undertaking the clinical trial | X X | X X |
| 11 | values and reference value ranges for medical, laboratory, professional technical operations and related testing involved in the trial protocol. surround | Prove the reference values, reference value ranges and validity periods of each test | X | X |
| 12 | Medicine, laboratory, professional and technical operations Qualification certificates for operation and related testing accreditation certificate or qualification accreditation certificates) that have completed the test or have established quality control can meet the requirements and ensure the reliability of the test results or the external quality evaluation system or other verification system) | Prove that the medical, laboratory, professional (qualification technical operation and related testing facilities and proficiency | X (when necessary) | X |
| 13 | The sample packaging box label of the investigational drug proves that the label of the investigational drug complies with relevant regulations. | Proper instructions for use are provided to subjects to | | X |
| 14 | Description of the investigational drug and other trial-related materials (if not stated in the trial protocol or investigator's manual) | demonstrate that investigational drugs and other trial-related materials are properly stored, packaged, and distributed. and disposal | X | X |
| 15 | Investigational drugs and other test-related certificates | Investigational drugs and other test-related materials | | X |

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| | Material delivery records | The delivery date, batch number and delivery method of the material. The batch number and delivery status of investigational drugs can be tracked and can be held accountable | | |
| 16 | Inspection report of investigational drugs | Demonstrate the composition, purity, and strength of the | | X |
| 17 | Unblinding Procedures for Blind Trials | investigational drug. How to identify blinded investigational drug information during emergencies without destroying the blinding of other subjects. | X | X (Third party, if applicable) |
| 18 | total random table | Justify the randomization method for the subject population | | X (third party, if appropriate use) |
| 19 | Sponsor's pre-trial monitoring report | Prove that the clinical trial institution inspected by the sponsor is suitable for clinical trials | | X |
| 20 | Test start-up monitoring report | Demonstrate that all investigators and their teams are committed to clinical The trial process was evaluated | X | X |

## Appendix 2 Clinical trial ongoing stages

| | Required documents | Purpose | Investigator/ Clinical Trial Institution | Sponsor |
|---|---|---|---|---|
| 1 | Updated Researcher's Manual | Demonstrate that relevant information obtained is fed back to researchers in a timely manner | X | X |
| 2 | Any changes to the following content: - Trial protocol and its revised version, case report form - Informed consent - Any other written information provided to subjects - Subject recruitment advertisement (if used) The ethics committee will | Proof of revision information of effective documents during clinical trials | X | X |
| 3 | review the following content Written review and consent documents, signed and dated - Trial protocol modifications - Revisions of the following documents - Informed consent - Any other written information provided to the subjects - Subject recruitment advertisement (if used) - Ethics committee Any other review, consent documentation - follow-up review of the clinical trial (if necessary) | Documents proving that clinical trial modifications and/ revisions have been reviewed and approved by the ethics committee. Confirm file version number and date | X | X |
| 4 | The drug regulatory department certifies that the trial protocol complies with the drug regulatory department's modification and other document licensing and filing requirements | | X (when necessary) | X |
| 5 | The researcher's updated resume and other qualifications prove that the researcher has the qualifications and ability to complete clinical trials with this format, and the updated resumes of doctors, nursing supervisors, pharmacists and other researchers who are authorized to participate in clinical trials on subjects<br>Prove that the participating researchers have the qualifications and abilities and other qualifications to prove that they have completed the relevant work of the clinical trial. Updated medical, laboratory, and professional technical | | X<br>X | X<br>X |
| 6 | certifications. Reference values for each revised test, values. Scope and Validity Validity Range | operation and reference values for related tests and reference | X | X |

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| 7 | Updated medical, laboratory, professional and technical operation and related testing qualification certificates proving certificate or qualification certification of professional and have completed the test) or have established quality control the reliability of testing or external quality evaluation system systems) | that the medical, laboratory, (qualification accreditation technical operation and related testing facility certificates that systems and capabilities that can meet requirements to ensure results or other verification | X (when necessary) | X |
| 8 | method of investigational drugs and other trial-related materials. The shipment record number and shipment and the composition, purity, and specifications of the investigational drug can be traced and the results | Prove the delivery date, batch number and delivery status of investigational drug batches can be traced, | X | X |
| 9 | Inspection reports for new batches of investigational drugs | of visits and inspections by auditors can be verified. | | X |
| 10 | Monitoring visit report | | | X |
| 11 | Relevant communications other than on-site visits, liaison evidence, consensus or important issues related to the management of clinical trials, protocol record violations, trial implementation, reporting of adverse events - correspondence reports, etc. - Discussion of meeting minutes - phone records | | X | X |
| 12 | signed informed consent form | Prove that each subject's informed consent was obtained in accordance with the requirements of the Good Clinical Practice for Drug Clinical Trials and the trial protocol before participating | X | |
| 13 | Original medical documents | in the clinical trial, and prove the authenticity and completeness of the subject data collected in the clinical trial. Include all source documents, medical records, and medical | X | |
| 14 | Signed investigator's name, record date, and completed case report form | history of the subject related to the trial. Prove that the investigator or someone on the research team has | X (a copy) | X (original) |
| 15 | Case report form modification record | confirmed the values entered in the case report form. Prove that all CRFs have been documented | X (a copy) | X (original) |
| 16 | by the investigator. Any modifications made after the record was first filled out. Reports of serious adverse events and good events reported to the sponsor due to serious non-investigation, and reports of other related | | X | X |
| 17 | issues that can be submitted by the sponsor or researcher to the drug supervision and administration department or the ethics committee. Suspicious and unexpected serious adverse reactions and other safety information submitted by the management department and ethics committee | | X (when necessary) | X |

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| 18 | Safety information notified to investigators by the sponsor | Safety data notified by the sponsor to the researcher; Progress | X | X |
| 19 | committee; progress reports submitted by the sponsor submitted by the department to prove pre-trial screening | reports submitted by the researcher to the ethics to the drug regulatory department; progress reports Identity of subjects in the program. | X | X (when necessary) |
| 20 | Subject screening form | Researchers and clinical trial institutions must keep a list of all subjects | X | X (when necessary) |
| 21 | Subject identification code list | selected for the trial and their corresponding identification code tables to prepare the researchers and clinical trial institutions for identifying the subjects and proving the identity of the clinical trials. Subjects are enrolled | X | |
| 22 | Subject selection form | in chronological order. Proof that the investigational drug is used in accordance with the | X | |
| 23 | Registration form for investigational drugs in clinical trial institutions | protocol. Proof of authorized responsibilities and | X | X |
| 24 | Researchers' Responsibilities and Signature Page | signatures of all researchers participating in the clinical trial, including signatures of those who fill out or amend the case report form. Proof of repeated analysis. Storage | X | X |
| 25 | Records of retention of body fluid/tissue samples (if any) | location and identification of retained samples | X | X |

Appendix 3 After completion of clinical trial

| | Required documents | Purpose | researcher/ clinical trial facility | Sponsor |
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| 1 | Investigational drugs in clinical trial facilities registration form | Prove that the investigational drug complies with the requirements of the trial protocol use<br>Demonstrate acceptance of trials at a clinical trial facility<br>Final count of medicines used, including those issued to recipients the subject's count, the count recovered from the subject, and the count returned to the sponsor | X | X |
| 2. Destruction certificate of investigational drugs | | For investigational drugs that are proved to have not been used, the applicant shall Destroyed by the sponsor, or destroyed by the clinical trial institution | X (if in clinical Testing agency sales destroy) | X |
| 3 Subject identification code table | | Record the coding of all enrolled subjects' information table for use during follow-up visits. coding table Should be kept confidential and stored until the agreed time | X | |
| 4 Audit certificate (if required) | | Prove that an audit has been | | X |
| 5 End-of-test monitoring report | | conducted to prove that all clinical trial work has been completed, End of trial; preservation of necessary documents for clinical trials reasonable | | X |
| 6 Trial Grouping and Unblinding Certification | | Return all unblinding certificates that have occurred to the applicant Organizer | | X |
| 7 | Submitted by the researcher to the ethics committee Test completion documents | Demonstrate completion of testing | X | |
| 8 Clinical Trial Summary Report | | Justify clinical trial results and interpretations | X | X |

Note: "X" is a saved item.