International Journal of Clinical Trials
Alam M et al. Int J Clin Trials. 2021 Feb;8(1):101-110
http://www.ijclinicaltrials.com
pISSN 2349-3240 | eISSN 2349-3259
DOI: https://dx.doi.org/10.18203/2349-3259.ijct20210150

Review Article

Archival and management of clinical trial documents

Mehnaaz Alam[1]*, D. Yamini Sai Nikitha[1], Sai Sugun Jala[2], Gulam Khaleel Ahmed[2]

[1]Clinosol Research Pvt Limited, Dwaraka Nagar, Visakhapatnam, India
[2]Paraxel, Hyderabad, Telangana, India

Received: 07 August 2020
Revised: 20 October 2020
Accepted: 03 November 2020

***Correspondence:**
Dr. Mehnaaz Alam,
E-mail: mehnaazbetu.21@gmail.com

ABSTRACT

Clinical trial documents are all records, in any type which incorporates written, electronic, magnetic, optical records, scans, x-rays and electrocardiograms that describe or record the strategy, conduct and results of an effort, the factors poignant an effort and the actions taken. Such a record is thought as document and method is documentation. The documents collected before, throughout and once clinical trials give proof that the study was conducted, the information collected is correct and valid which the investigator and sponsor conducted the trial in line with ICH GCP tips is thought as Trial master file. because of exaggerated quality of studies, particularly medical specialty studies, and therefore the issue managing paper TMF's for various departments, most organizations have moved to eTMF. Archiving may be a key demand to guage post trial observance and analysis and to facilitate any analysis before initiation of an effort and deposit strategy should be developed. It includes the subsequent parts documents to be archived, amount of archiving, location, retrieval or access of archived documents, disaster recovery, procedure of clinical knowledge archiving, archiving by an ethics committee, archiving by the investigator. Archiving of trial documents helps to store knowledge safely and firmly for future use with facilities like secure systems and e-back up.

Keywords: Trial documents, Archival, Trial master file, Electronic trial master file, ICH-GCP

INTRODUCTION

As per the New medicine and trial Rules (2019) and Good clinical practice (GCP) guidelines by Central drugs standard control organization (CDSCO), all essential documents bearing on a trial should be archived. It's the responsibility of the sponsor to confirm that the documents and trial provides are archived for a minimum of 3 years once the completion of the trial, or submission to the regulatory authority.

SITE FOR AN ARCHIVE

As per the necessities of the sponsor, the archived document will be either at the sponsors or clinical research organizations (CROs) workplace or at every collaborating web site or at an off-site archival facility (third party archival facility). No matter the placement, it ought to be ensured that the confidentiality and integrity of the documents is satisfactorily maintained. The power ought to be reviewed by the sponsor or its selected personnel before the method of archival commences. Some key necessities that have got to be consummated by a possible facility are provision of adequate area, workers and instrumentation provision of stable environmental conditions to confirm that the documents, and alternative material aren't affected (controlled temperature and humidity). Care should be taken once magnetic media or pictures are archived. Security of the premises should be ensured that the power has provisions for restricted access, secured cupboards and entrant alarm. Also have Hazard management and Retrieval or Access of archived documents. The set up should specify that the documents

can have a restricted access. it's judicious to spot the small print of personnel who will access the archival facility. However, it ought to be processed that the administrative unit or committees might request access to those documents. Lastly the placement and construction of the building ought to be of adequate size to satisfy requirements (effective to sturdy winds and daylight on the contents of the archive) for consequent 15-20 years.[1]

DISASTER RECOVERY

The archival set up ought to embody a disaster management set up, to recover the documents just in case of associate emergency for instance, electronic copies will be made from all documents and knowledge that area unit archived. However, these electronic copies should be hold on at a location aside from the deposit facility and befits confidentiality necessities.

PROCEDURE

It ought to be such as that the method of deposit ought to solely be commenced after the final visit has been completed by the last trial participant and Trial master file and investigator web site file, are complete and verified for accuracy. All queries bearing on knowledge are resolved, information is secured, and therefore the knowledge has been analysed. The final report has been submitted and the other requirement such as by the sponsor, administrative unit, ethics committee, etc. associate deposit list is also useful, in guaranteeing that all essential documents and provides (if applicable) are archived. This document is also used as a model for developing an archival list.

MEMBERS LIABLE FOR ARCHIVAL

Institutional review board (IRB) / Independent Ethics Committees (IECs) are liable for all the gathering of relevant records (example: written procedures, membership lists, lists of occupation/ affiliation of members, submitted document, minutes of conferences, correspondence) and that they are obtainable to the restrictive authorities; investigators and/ establishments are needed to keep up the documents as per section eight of the ICH-GCP tips and takes preventive measures for the accidental or premature destruction of those documents, furthermore the sponsors are needed to retain the sponsor specific essential documents.

ARCHIVING BY THE ETHICS COMMITTEE(S)

Documents submitted to ethics committee (EC) for approval, should be confidential, and hold on as per their written standard operating procedure (SOPs). The EC(s) should archive all documents and records for an amount of a minimum of 5 years once the completion or termination of a trial. The sponsor and/or the restrictive body may additionally request for the records to be maintained for extended than 5 years. Records associated documents maintained by associate European Economic Community should be accessible for a review by the restrictive body. Documents that are maintained by associate European Economic Community, associated with a proposal area unit One text and a soft copy of the initial review proposal, and all connected documents.

ARCHIVING BY THE INVESTIGATOR

The investigator should maintain and archive essential documents bearing on a trial. These documents ought to be archived for for an amount of a minimum of 2 years, once the last approval of a promoting application or, for an amount of 2 years till there are not any unfinished or contemplated applications or, for a minimum of 2 years once the formal discontinuance of clinical development of the investigational product.[2]

DOCUMENTS TO BE ARCHIVED

Superseded documents

During a document's development (example: trial protocol development and release), the sponsor's/CRO's procedures might need input and review by numerous functions. The documentation to demonstrate that the method was followed ought to be maintained. outdated versions of ultimate documents area unit necessary to reconstruct the trial and may so be maintained within the TMF. outdated versions of sponsor-produced documents (example: trial protocol, IB and eCRF) ought to be gift within the investigator/institution TMF in a very manner to alter reconstruction while not the necessity to access the sponsor TMF, with proof of date of receipt, review and/or approval (when necessary) and date of implementation by the investigator/institution.[1,3]

Correspondence

Relevant correspondence that's necessary for reconstruction of key trial conduct activities and call ought to be maintained. This includes correspondence with ethics committees, knowledge safety observance committee and restrictive authorities (confirming sponsor approval of processes, documents and choices and therefore the communication relating to problems that arise within the trial conduct and the way they're dealt with). Similarly, electronic correspondence (e-mails and associated attachments between CROs, sponsor departments, investigator/institution) ought to be pronto obtainable and will be maintained electronically. It ought to be ensured that each sent and received correspondence is filed within the TMF.[2]

SOURCE DOCUMENTS

Source documents are the original documents ,data and records which includes hospital records, clinical and office charts, laboratory notes, memoranda, subject's diaries or evaluation checklists, pharmacy dispensing records, recorded data from automated instruments, copies or

transcription certified after verification as accurate copies, microfiches, photographic negatives, microfilm or magnetic media, x-rays, subject files, and records kept in pharmacy and at the laboratories and at the medico-technical departments involved in the clinical trials.

Site files are held by the principal investigator at sites and contain copies of the essential documents, local approvals, signed consent forms and completed data forms.[4]

Table 1: List of documents needed in clinical trial.[1,9]

Documents to be in files before a trial starts	Located in the file of the investigator	Located in the files of the sponsor
1. Investigator brochure	*	*
2. protocol and amendments and a sample case report	*	*
3. information given to trial subjects		
3.1 informed consent form	*	*
3.2 information sheet	*	*
3.3 adverts for recruits	*	*
4. financial agreement grant award letter	*	*
5. insurance statement		
5.1 indemnity form	*	*
6. signed agreements(between involved parties)	*	*
7. Dated documented approval of all trial related documents		
7.1. by REC	*	*
7.2. Composition of REC (where available)	*	*
8. Regulatory authority approval/ authorization (where required)	*	*
9. CV's of the following		
investigator	*	*
co-investigator	*	*
research nurse	*	*
10. normal values and ranges for medical/laboratory/technical procedures/tests included in the protocol	*	*
11. Certification/accreditation for medical/laboratory/ technical procedures/tests	*	*
12. Sample of labels attached to IMP containers		*
13. Instruction for handling investigational product	*	*
14. Shipping records for investigational products	*	*
15. Certificate of analysis of IMP shipped		*
16. Decoding procedures for blinded trials	*	*
17. Master randomisation list		*
18. Pre-trial monitoring report		*
19. Trial initiation monitoring report	*	*
Documents filled during the conduct of a study		
20. Relevant communications	*	*
20.1 letters	*	*
20.2 faxes	*	*
20.3 emails	*	*
20.4 meeting notes	*	*
20.5 notes of telephone calls	*	*

Continued.

Documents to be in files before a trial starts	Located in the file of the investigator	Located in the files of the sponsor
Documents to be in files before a trial starts	**Located in the file of the investigator**	**Located in the files of the sponsor**
21. Monitoring visit reports	***if it is sponsored**	*
22. Certificates of analysis for new batches of IMP's		*
23. Documents of IMP's and trial-related materials shipment	*	*
24. Updates of medical/laboratory/technical procedures and tests	*	*
25. Updates of normal values and ranges for procedures/tests included in the protocol	*	*
26. Signed informed consent forms	*	
27. Source documents	*	
28. Signed dated and completed case report forms (CRF)	***(copy)**	***(original)**
29. Documentation of CRF corrections	***(copy)**	***(original)**
30. Serious adverse events :notification by originating investigator to sponsor of SAE's and related reports	*	*
31. Serious adverse drug reactions reported by sponsor(if any) to regulatory authorities and ethics committees of unexpected serious adverse drug reactions and other safety information	*	*
32. Safety information	*	*
33. Interim or annual reports to regulatory bodies/ ethics	*	*
34. Subject screening log	*	*
35. Subject identification code list	*	
36. Subject enrolment log	*	
37. CV's for new investigators	*	*
38. Signature sheet	*	*
39. IMP accountability at the site	*	*
40. Record of retained body fluids/tissue samples	*	*
41. Investigator brochure updates	*	*
42. Amendments brochure updates	*	*
43. Ethical approval of amendments/revisions	*	*
Documents filed at the end of a trial **44. Investigation product accountability at site**	*	*
45. Documentation relating to IMP destruction	*	*
46. Completed subject identification code list	*	
47. Audit certificate(if available)	*	*
48. Final trial close –out monitoring report	*	*
49. Treatment allocation and decoding information		*
50. Final report by investigator to regulatory bodies/ethics	*	*
51. Clinical study report	*	*

DURATION OF ARCHIVING

The sponsor is accountable for determinative the length of the archiving needed for study documents and will} contemplate whether or not the results of an endeavor may or are going to be enclosed in promoting authorization application, and there ought to be any applicable regulative necessities at time of archiving, and any statement that is enclosed in protocol should be submitted to the regulative authorities. Just in case of hosted studies, the investigator

ought to ensure from the sponsor throughout the length of archiving and to the analysis and development (R and D) alongside the study documents that is needed throughout the method of archiving. In time of trust sponsored studies the length of archiving, at the beginning of the study are going to be in agreement by analysis and development (R and D) and also the chief investigator and reviewed and confirmed by writing on completion of study.[5]

Table 2: Period of archiving.

#	Category of study	Recommended period of retention of investigator site file	Location of investigator site file	Point at which site file can be destroyed
1	Investigational medicinal product (IMP) –sponsor	15 years	In a suitable location/ premises approved by research department or at an agreed off-site facility	15 years after the declaration of principle investigator(PI) of the end of the study
2	IMP Study- non-commercially sponsored	At least 5 years (longer if sponsor required)	Investigator should negotiate with the sponsor for the off-site storage of documents	The sponsor will notify the PI of when documents can be destroyed
3	IMP Study- commercially sponsored	At least 5 years(longer if sponsor requires)	Investigator should negotiate with the sponsor for the off-site storage of documents	The sponsor will notify the PI of when documents can be destroyed
4	Investigational device study-sponsor	As for IMP studies	As for IMP studies	15 years after the declaration by PI of the end of the study
5	Investigational device study- externally sponsored	As for IMP studies	As for IMP studies	As for IMP Studies
6	Surgical intervention study	As for IMP studies	As for IMP studies	15 years after the declaration by PI of the end of the study
7	Surgical intervention study- external sponsor	As for IMP studies	As for IMP studies	As for IMP studies
8	Non-interventional study	6 years	In a suitable location /premises or at an off-site facility as agreed with the sponsor	5 years after declaration by PI of the end of study

Preparing documents for archival

Research team responsibilities

All the documents for hosted or the trust sponsored studies area unit to be archived by the trust and should be submitted to the analysis and development (R and D) unit for archiving. The investigator ought to bear the trial archiving list and may forward to the analysis governance manager alongside the study documents that area unit needed for the archiving. The location file ought to be union during a appropriate lever arch file and should be labeled with name of investigator, study title, REC reference, and R and D reference and sponsor.

Research and development (R and D) responsibilities

Once the documents are received from the R and D, the named collector can make sure that all trial documents are placed in an appropriate archive box that chiefly depends on the quantity of documents to be archived and is permissible to archive over one study in one archive box. In before transferring the documents to the storage for archiving, the named collector should complete the R and D archiving log with details of the study archived which incorporates the subsequent information; archive box range, short title of the study, R and D reference, record reference, description of documents archived (i.e., web site file, pharmacy file, case report kind for patients), name and call details of sponsor, chief investigator/principal investigator, date and transfer of archiving, retention amount and expected destruction date. The archive box additionally has been labeled with the box range similar to that listed on the R and D archiving log and contents, details of the R and D account code for recharging of archive fees to the R and D department. The named collector can sponsor to tell them that study documents are archived by providing details of location and call details of the named collector. The R and D information (EPS) will be updated to replicate the study documents that are archived and also the sponsor are going to be notified.[6]

Table 3: TMF structure.

Zone name	Section name	Articraft name	TMF rm website (alternate name)	Sub articraft
Trial management	Trial oversight Trial team Trial committee Meetings General	Trial master file plan Trial management plan Trial oversight quality plan List of SOPs Monitoring plan Recruitment plan Audit certificate	Records management plan Central file maintenance plan File and archive plan	Core document list TMF report TMF transmittal form TMF set up request
Central trial documents	Product and trial documentation Reports general	IB Protocol synopsis Protocol amendment Financial disclosure summary	IB review document Summary of charges IB/QC document IB Validity extension	Protocol approval document Protocol QC document
Regulatory	Trial approval IMP Trial status reporting general	Regulatory authority decision Notification of regulatory identification number	Regulatory approval Withdrawal regulatory Application rejection	Condition approval notification Notification of Non-Approval
IRB/IEC or any other approvals	IRB or IEC trial approval Other committees Trial status reporting General	IRB or IEC Submission IRB or IEC approval Other submissions	Reviewer participation list correspondence	Protocol deviation report Interim Report Annual report
Site management	Site selection Site set up Site initiation Site management General	Site contact details Confidentiality agreement Acceptance of IB	Secrecy agreement Site selection documentation	Affiliation form ICH-GCP training certificate
IP and trail supplies	IP documentation IP release Process documentation IP allocation documentation Storage Non- IP documentation Interactive response Technology General	IP supply plan IP instructions for Handling IP sample plan	Pharmacy manual Device user manual IP manual	Label specification Proforma invoice Approval to ship
Safety reporting	Safety documentation Trial status reporting General	Safety management plan PV database line listing SAE report	Medical events of interest Periodic line listing	Agenda Minutes ISO certification
Central and local testing	Facility documentation Sample documentation General	Meeting material File note	Note to file	Presentation materials Recording
Third parties	Third party oversight Third party set up General	Relevant communications Tracking information	correspondence	Agenda Minutes
Data management	Data capture Database EDC management General	Validation documents Technical design document	EDC system specifications Core configuration specifications	Agenda Minutes
Statistics	Statistics oversight Randomisation Analyses Report General	Interim analysis Raw data sets Interim analysis programs	Correspondence Note to file	Agenda Minutes

Archival of trial master file

Articles fifty eight and fifty seven of the Regulation, each state that "the content of the clinical TMF shall be archived during a approach that ensures that it's promptly available" "and directly accessible, upon request, to the Member States." Article fifty eight of the Regulation and Article twenty of Directive 2005/28/EC, additionally state that "any alteration to the content of the test main file shall be traceable".

The TMF together with the audit path (for eTMF) ought to be archived fittingly to alter management when the test has finished. The dynamic character of the audit path ought to be preserved, once applicable. Archiving ought to be undertaken when the investigator/institution and sponsor have reviewed that their filed TMF documentation is complete. Access to archived data/documents ought to be befittingly restricted either by user access levels to the archive space of a server and/or by access controls to the storage location wherever the (electronic or paper) media are maintained.

In addition, the electronic documents or knowledge that are archived ought to be protected against unauthorised changes to take care of genuineness. It is vital that access to documents and knowledge is maintained for the complete archiving amount. This might embody maintaining the system (hardware and software) to access the info in its original archived format, or the utilization of a replacement system to emulate the recent software system or migration of the info into a replacement format to confirm continual access with new software system. This issue ought to be self-addressed by the organisation by written procedures. Media wont to store the info could probably deteriorate or become obsolete, therefore transfer to an alternate media would wish to be thought of. The media ought to be keep beneath acceptable conditions. Any transfer or migration has to be valid to confirm that migrated knowledge have an equivalent data because the original, together with information. The transfer of knowledge to new media as technology advances would wish to be thought of by the organisation.[7]

An external archive providing retention of paper documents or electronic media or electronic storage (eample: cloud-based center) could also be used for archiving of the TMF. Once associate degree external archive is employed by the sponsor or investigator/institution, they ought to undertake associate degree assessment of the quality of the power before use and continue quality assurance measures once the organisation has been contracted. There ought to be a proper agreement in situ between the sponsor/investigator/institution and also the external archive. In cases the external archive has many storage locations, the sponsor and/or investigator/institution ought to guarantee they're privy concerning the particular storage location of their TMF and notified if this changes. The agreement is usually recommended to incorporate provisions for matters of the sponsor or external archive going out of business.[3,6,14]

STORAGE AND ARCHIVING CONDITIONS

The documents need to be stored in a way that preserves their integrity and readability and restricts access to particular individuals only and the quality systems should maximize the probability of archiving these objectives.[2]

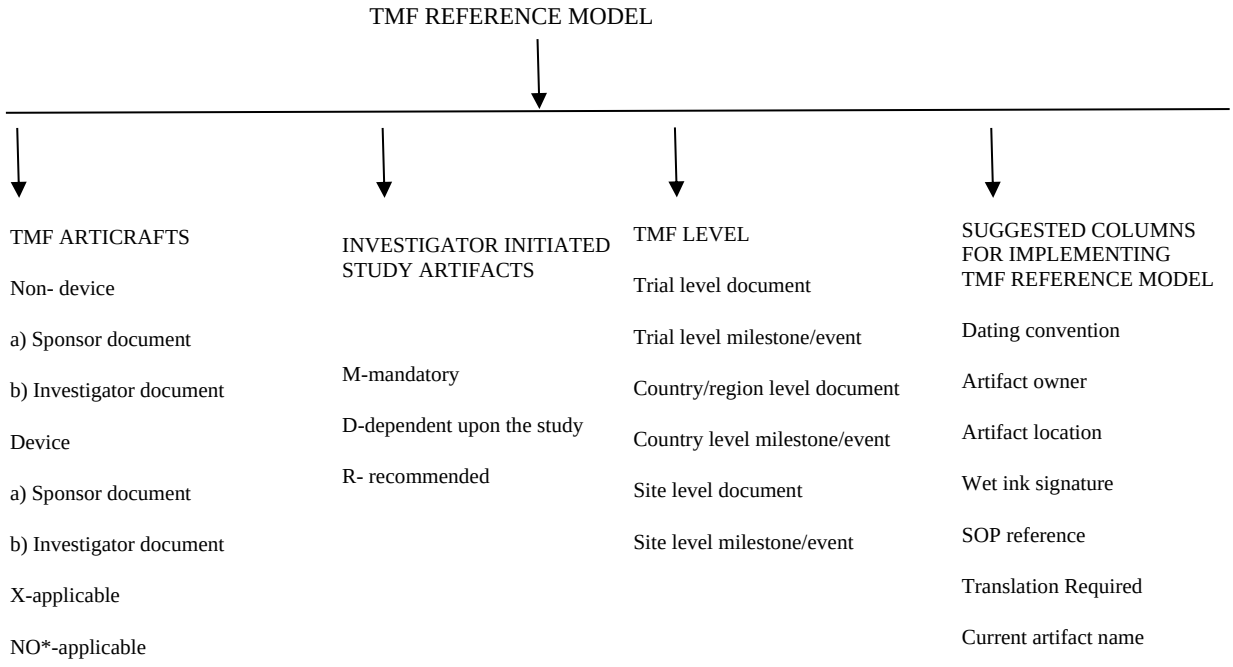

Figure 1: TMF file structure further categorised into following.

Storage whereas in use

Although research projects are on-going, study documents must be retained within a secure space with restricted access. The documents should be locked in a cupboard within a locked room and must be maintained in a legible condition with no delay of retrieval. Responsibility for the storage and maintenance of the study documents are the responsibility of the investigator or delegated individual.[2]

Long term storage/ archiving

According to ICH 5.2; adequate and suitable storage space for all the essential records should be made available and the facilities must be secure with appropriate environmental conditions and adequate protection from fire, flood, and unauthorized access.

And this may later lead to sub-contract where the sponsor of the trial is responsible for all the TMF documents, so if not the sponsor, the sponsor may check the adequate storage facilities in place. Lincolnshire clinical research facility and research and development subcontract the archiving of clinical research records to a commercial off-site (magnum services) archiving facility via the trust health record team. Magnum services are regularly ISO 9001 inspected. Built under a 24 hours monitor facility. All the entry doors are swipe card access. All the notes and documents are stored above ground levels, on raised shelves. Temperature and humidity is controlled. They have fire detection systems which don't use water sprinklers. All the staff are vetted and registered with the data protection act. Everything is bar-coded and stored in way to access easily and retrieval. Research study documents are archived under SOPs by using these facilities and other alternative facilities which has been agreed and documented during the NHS permission process.[8,9,12]

DESTROYING OF AN ARCHIVAL DOCUMENT

Archival documents can only be destroyed by a written permission which is obtained by the sponsor or contract research organisation (CRO) and investigator in accordance with the study protocol requirements and sponsor's SOPs and this information should be communicated to the research and development department, as all the essential documents have been retrieved from the storage to the R and D department for review by the named archivist ,prior to destruction. The named archivist will notify to the sponsor in written form when destruction has been completed. The destruction of the essential documents which is documented and signed by a person with a appropriate authority and this record will be retained permanently with the ULHT clinical records retention and disposal policy.[3,7,9]

ARCHIVING RESEARCH DATA ON COMPUTERS

It is the responsibility of the principle investigator to notify the named archivist as the electronic study data and it has to be archived. Electronic study data should be encrypted and copied onto a read-only media device for archiving the study documents, thus the study data held on computer servers must be deleted permanently, and it is the responsibility of the principle investigator who must look after the guidance from ULHT, ICT department as required.[9] It is also important to consider the accurate media for archiving electronic documentation. The selected accurate media should be done, as it is no longer produced or used/out of date during the scheduled period of storage and should be transferred to a newer or more appropriate media format if required.[10]

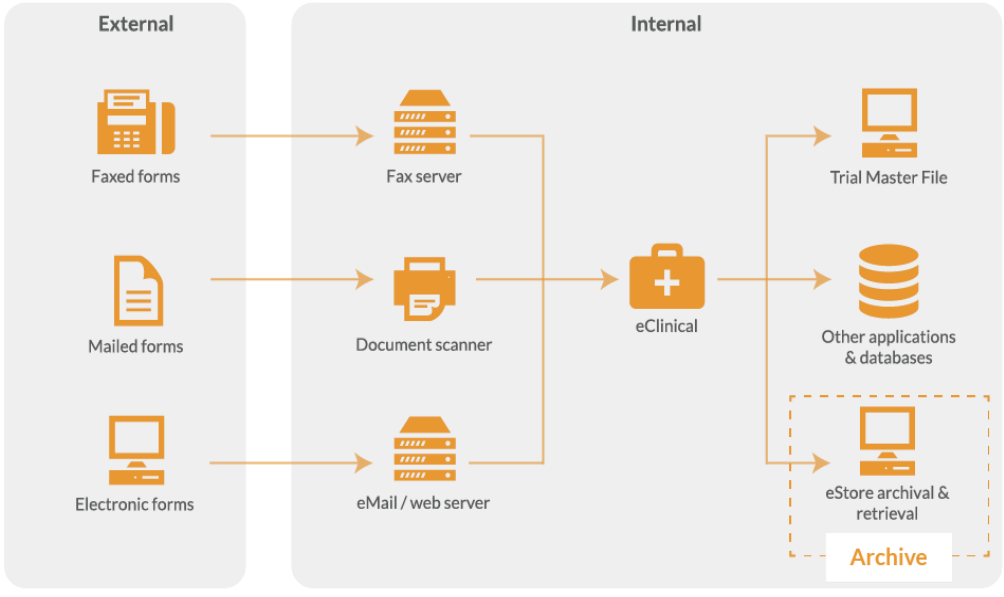

Figure 2: Archiving in computer.

PROCEDURES TO PROTECT ARCHIVES FROM HUMAN THREATS

Human activity can cause harm to the archived materials by both intentionally or accidentally. As per the SOPs we can reduce threats governing access to the archive. Preferably when materials has been archived it should not be released from the archive, as only a authorized will have access to either within a secure archive reading room or given with working copies of materials requested, where the materials are to be removed, authorization must obtain and a detailed catalogue of archive contents , loans, borrowers should be maintained; and there must be a tracking or recall mechanism for outstanding loans on regular basis. Access to the archive should be restricted to the authorized staff, contractors should be accompanied and observed at all the time and only the known contractors from authorized and the security-vetted sources must be used.[11]

The physical security of the archive should ensure the security staff and by providing a clear perimeter, illuminated and observed (which include by using security cameras and infra-red alert systems) security gates and fences, rapid access to emergency services; doors and windows, as they should be small and having additional security such as barring , double glazing and should be secure and close-fitting with thief resistant locks and there should be only a single visitor entrance. Emergency exists should open only from inside and should not be locked to prevent exit.[12]

PROCEDURES TO PROTECT ARCHIVES FROM PHYSICAL THREAT LIKE FIRE

The construction of the archival building must be fire resistant, and consider to be as close-fitting doors , fire-resistant internal compartments, enclosure of vertical shafts, such as stairwells, fire dampers in any ducting and there should be no unnecessary wiring and all the wiring should be regularly checked for compliance with appropriate standards. Any holes in the construction of the building which allows the passage of services such as wires and water pipes must be sealed around the piping or wiring. There should be adequate fire prevention mechanism such as total smoking rule, zoned fire alarms which are vandal and tamper proof, fire action notices and fire drills. In case of any occurance of fire there should be automatic alarm activation, closure of fire doors, emergency service contact, smoke extractors and fire suppression systems. Manual function includes fire extinguisher and fire hoses should be provided, any water or chemicals used in the fire fighting should be extracted or flow from the archive rapidly when the situation solved and unnecessary use of water or chemicals should be avoided.[2,12]

PROCEDURES TO PREVENT DETERIORATION OF ARCHIVAL MATERIAL

There are a number of ways of slowing the ageing process for the archival material. Temperature and humidity in the storage area is very important and an environmental monitoring equipment should be installed which gives accurate records of storage conditions and which can be archived themselves. As entry of some air movement is important to minimize the risk of fungal attack and providing shelving to permit this. Suitable light is required to avoid lights which may damage the sensitive documents and also the archive should be maintained in a way to easy clean and permit safe and easy movement done by the staff and the materials. Packing materials should be free from the chemicals as they causes easy deterioration of the contents and the labelling must be clear and ineradicable. The archive box should be reviewed to make sure that nothing which could contaminate or cause deterioration. As the plastic materials should be avoided as they are used as document folders which may lead to deterioration of the printed matter. If the archive is commercially operated, incoming archive material from all the sources should be reviewed by the following SOPs.[2,12]

BENEFITS OF ARCHIVING DATA

Archives where it is protected for long term against the loss, deterioration, inappropriate access and future incompatibility. Your datasets are stored safely and securely in the long term, Archives allow you to share your data in a strong (robust) way which includes visible, accessible, discoverable. You will be meeting the specified standards with university and founder policies. Once your data is uploaded to a data archive, the administrators of the archive are responsible for managing your data and can manage access to your data on your behalf if you like them, increases productivity, reduces redundancy/equipment use, automating manual process can save countless hours, data tracking made easy, cost effective, quality of the data, time saving and secure system and secure eback-ups.[13,14]

Table 4: Example of archival of study record.

Standard operating procedure for clinical research		
Archiving of study records		
SOP: **Effective date:** **Version number**		
Related policies:		
Appendices:	-	
Revision history:	-	
Approval date	Effective date	Review or revision date
-	-	-

CONCLUSION

Thinking of all the years of hard work which go into the development of a medicinal product—all the planning and training, the recruitment of investigators, obtaining of approvals, efforts of study subjects, monitoring, data processing and reporting, the meetings and travelling, and the hopes of pharmaceutical industry staff and potential patients. All of this could be wasted effort, brought to nothing because of archiving inadequacies. To obtain regulatory approval and to answer regulatory questions, you must have documentary proof. Assurances are not sufficient. Inspectors may view negligent archiving as a symptom of other negligence. Reassure them and yourselves by taking care of those essential documents. They are not called 'essential' for nothing.[2,15]

Funding: No funding sources
Conflict of interest: None declared
Ethical approval: Not required

REFERENCES

1. Introduction European medicine agency. clinical trial documents to before archiving is key sentence Chitra BARGAJE. Good documentation practice in clinical research. Perspective Clin Res. 2011;(2):59-63.
2. Archiving is key to end Long Eaton, charnley nickols associated Ltd.; GCP requirements for archiving essential documents; the quality assurance journal. 2000;207-10.
3. Raju S, Vijayalakshmi N, Suresh A. Archival of trail master file electronic trial master file eTMF an indispensable tool that collects and files essential documents of a clinical trial: a review. Int J Res Development Pharmacy Life Sci. 2016;1(15):2467-473.
4. Members responsible for archiving Clinical trials toolkit. archiving. Available at: http://www.ct-toolkit.ac.uk/routemap/archiving/. Accessed on 14 August, 2014.
5. Duration of archiving EU clinical trial directive accessed at (2001/20/Ec) EU commission directive 2003.
6. Clinical trial documents to before archiving is key sentence Chitra BARGAJE. Good documentation practice in clinical research. Perspective of clinical research. 2011;(2):59-63.
7. Storage and archival of clinical trial documents Christian d.kohl GCP compliant digital archiving of patient records of clinical trial subjects Journal clinical trial perspective. 2013;3(5):451-65.
8. CFR PART 11 SECTION 58.190. Archiving of Research data on computers. accessdata.fda.gov. Last accessed on 1st April, 2020.
9. New drug and clinical trial rules 2019. cdsco.gov.in. Last accessed on 19 March, 2019.
10. Doorn P, Tjalsma H. Introduction: archiving Research data Springer. Last accessed on 26th September 2007.
11. Kuchinke W, J Alerts, SC Semler, C Ohmann. CDISC standard- based electronic archiving of clinical trials. 2009;48(5):408:13.
12. Archiving the Phenome: Clinical Records Deserve Long-term Preservation Milton Corn, MD Journals of the American medical informatics association. 2009;16(1):1-6.
13. Hooper E. Archival of clinical trail documents 2nd edition published at 2008. The Institute of clinical research. Icr- global.org. Available at: https://icr-global.org/publications/archiving-clinical-trial-documents-2nd-edition/. Accessed on 14 August, 2014.
14. Paperless clinical trials: Myth or reality? Sandeep K. Gupta Indian journal of pharmacology july-august. 2015;47(4):349-353.
15. Systematic archiving and access to health research data: rationale, current status and way forward Manju Rani and Brian S Buckley Bulletin of World Health Organization. 2012;90(12): 932-39.
16. Hooper E. Archival of clinical trail documents 2nd edition published at 2008, The Institute of clinical research. icr- global.org. Available at: https://icr-global.org/publications/archiving-clinical-trial-documents-2nd-edition/. Accessed on 08 July, 2020.

Cite this article as: Alam M, Nikitha DYS, Jala SS, Ahmed GK. Archival and management of clinical trial documents. Int J Clin Trials 2021;8(1):101-10.