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Trial Master File Archiving and the Decommissioning of Computerised Systems Used in Clinical Trials

A position paper written by a joint task force from the European CRO Federation and the eClinical Forum

Document History

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1 Executive Summary

Following the completion of a clinical trial, the essential documents that make up the TMF (Trial Master File) are retained and archived by the sponsor, the investigator and, in some cases, sub-contractors to the sponsor and/or investigator. Essential Documents are those documents that individually and collectively permit evaluation of the conduct of a trial and the quality of the data produced[1]. The essential documents consist of trial specific documents and non-trial specific documents.

Many of the computerised systems used during a trial are only used during the active data collection stage of the trial, which is often a shorter period of time than the retention period required for the archiving of the essential documents of the trial.

This position paper highlights 11 key positions and is divided into two chapters below. Chapter 4 contains positions about archiving given the distributed nature of the TMF, and chapter 5 contains positions concerning the archiving of data from computerised systems to allow those systems to be decommissioned. These positions address areas where regulatory expectations are not always seen as being aligned with industry practices.

2 Introduction

The full history of a clinical trial is distributed between sponsor, investigators and vendors. Referred to in regulatory texts as “Essential Documentation”, this trial history is retained in the TMF. For the purpose of this position paper the term “essential documents” is used to cover all records, data and documents. Changes in technology and the evolution of regulatory expectations on electronic systems over the past two decades have resulted in a situation where additional supplementary documentation may be needed to reconstruct some clinical trial activities.

At the end of the trial the sponsor and the investigators/institutions receive archive copies of the data from the computerised systems used during the clinical trial. Historically the archives from these systems would consist of PDF files (flat files) containing copies of the data entry forms from the systems involved. Archiving the data in only this format is no longer considered to be sufficient to permit evaluation of the conduct of a trial and the quality of the data produced.

The archival format should reflect the dynamic nature of the information being archived. The archives should include the patient data, audit trails of data entry, the query history, users’ access log and other relevant metadata. Controls should exist to preserve the integrity of the data held in the archive consistent with ALCOA+ principles.

It is sometimes assumed that the retention of such supplementary (albeit circumstantial) evidence of system-related events follows the same schedules as the other clearly identified TMF records. This position paper attempts to define key principles (“Positions”) for the content and the format of retained electronic documents in GCP environments, which also address some of the challenges that the clinical research industry is facing due to technology obsolescence and otherwise unavoidable data custody changes over time.

[1] Definition from ICH GCP E6

The overall concept by which essential documents make up the TMF has evolved over time. The essential documents consist of trial specific documentation but also of non-trial specific documents. The non-trial specific essential documents may be retained separately (as they are not specific to one trial) and are signposted in the sponsor TMFs in order to enable quick access. The location of these documents will vary depending on the type and source of the documents in question. Consequently, the TMF will span across multiple locations and be distributed among multiple parties. In the effort to characterise clinical trial documents the following main categories have been identified:

- Trial specific essential documents routinely maintained by the sponsor and investigator/institution in TMFs[2].
- Non-trial specific essential documents:
  - Non-trial specific essential documents, which are authored, approved and maintained in the same manner as trial-specific essential documents, e.g., product specific records applicable to more than one clinical trial.
  - Non-trial specific essential documents, which are created, maintained or retained in other sponsor systems (such as SOPs and training records), and which may be requested during monitoring, auditing or inspections.
  - Non-trial specific essential documents, which are created, maintained or retained in delegated parties' systems (such as vendor SOPs and vendor validation documentation)
- Non-essential documents, which come from applications which have not been developed per GCP and computerised system validation principles (such as Firewall and Server logs, IT logs, Emails) and may not meet ALCOA+ requirements.

This is shown in figure 1 below.

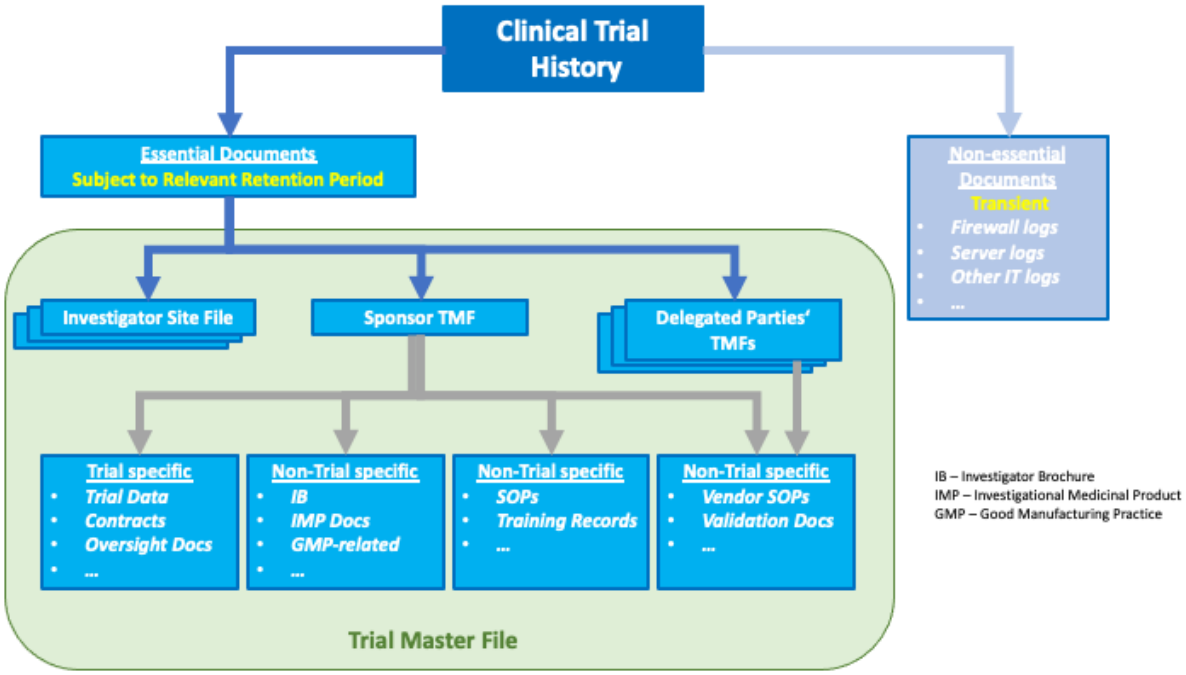

Figure 1 The Clinical Trial Documents.

[2] For example, the documents listed in ICH GCP E6 Section 8

The aggregation of trial and non-trial specific essential documents must allow for the seamless reconstruction of clinical development activities, must be open to audits and inspections, and must fulfil all regulatory and legal purposes for the full duration of applicable retention periods. This is the fundamental justification for the distributed nature of the TMF. The signposting to all parts of the TMF must be unambiguously delineated in the context of the contractual agreements pertinent to the clinical trial and the nature of the TMF content. Such materials (set forth as Non-Trial Specific Master Files – NTSMFs) may be owned and managed by multiple parties.

The responsibilities across these multiple parties engaged in the trial (but under the accountability of the trial sponsor) must be clearly articulated. A typical clinical trial would have contractual agreements, which govern data and record custody.

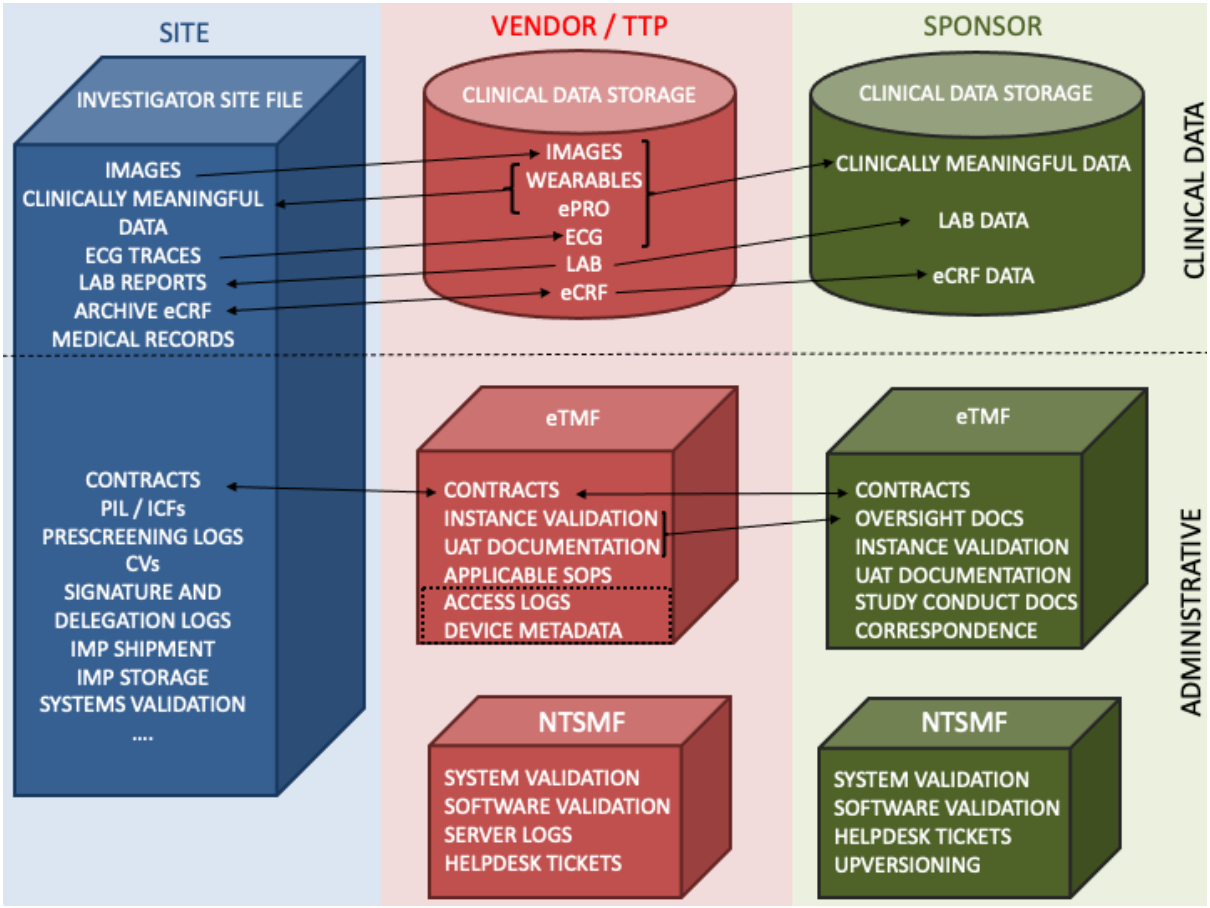

Figure 2 Typical Clinical Trial records and data, their expected location, ownership and custody. The diagram lists examples of documents only and is not meant to be a conclusive list. See the footnote for diagram specific acronym definitions.[3]

[3] ECG – Electrocardiogram
eCRF – electronic Case Report Forms
ePRO – electronic Patient Reported Outcomes
eTMF – electronic Trial Master File
ICF – Informed Consent Form
IMP – Investigational Medicinal Product
PIL – Patient Information Leaflet
TTP – Trusted Third Party
UAT – User Acceptance Test

Clinical trials involve the use of multiple computerised systems and many of these systems are rarely specific to one trial. Instead, they are shared between multiple trials, and in the case of vendor-supplied solutions, across multiple sponsors and contract research organisations (CROs). Software and system validation materials are then expected to have at least two components:

- the “base system” that is not trial-specific and is validated by the system vendor (usually part of the TMF held by the delegated party)
- trial- or sponsor-specific configurations, applied by the sponsor, a CRO or other sub-contractor (usually part of the sponsor’s Trial-specific Master File)

The location of validation materials must be known, and they should be managed and be available for review, no matter who has performed the validation or where the documents are archived. It is critical that all parties involved in documenting clinical trial activities (investigator, sponsor or their delegates), must understand and comply with the requirements set forth for regulated systems and processes, as predicated in ICH GCP E6 guidelines and other industry standards and guidance. All these parties should have clearly defined processes, roles and responsibilities for the initial creation of these essential documents and their maintenance for the duration of the clinical development activities, but also for their archiving and retention.

3 Definitions and Abbreviations

This section is provided for reference, to define the meaning of terms as they are applied in this position paper. Definitions that are inherited from other sources are noted using footnotes, refer to those sources for more detail.

- **ALCOA+:** Attributable, Legible, Contemporaneous, Original, and Accurate (ALCOA) plus Complete, Consistent, Enduring, and Available
- **Archive:** Long term, permanent retention of completed data and relevant metadata in its final form for the purposes of reconstruction of the process or activity.[4]
- **Archivist:** A role, individual or shared, held by one or more persons within an organisation with oversight of the contents of and access to the archive.[5]
- **Backward- (or Reverse-) Compatibility:** A property of a system, product, or technology that allows for interoperability with an older legacy system, or with input designed for such a system, especially in telecommunications and computing.[6]
- **Certified Copy:** A certified copy is a paper or electronic copy of the original document that has been verified (e.g., by a dated signature) or has been generated through a validated process to produce an exact copy having all the same information, including data that describe the context, content and structure, as the original.[7]
- **Dynamic Archive Formats:** File formats that allow the contents to be sorted, filtered and queried.
- **Essential Documents:** Documents which individually and collectively permit evaluation of the conduct of a study and the quality of the data produced.[8] For the purpose of this position paper the term "essential documents" is used to cover all records, data and documents retained in the TMF.
- **Investigational medicinal product (IMP):** Means a medicinal product which is being tested or used as a reference, including as a placebo, in a clinical trial.[9]
- **Internet of Medical Things (IoMT):** A means of integrating medical devices, sensors and wearables with healthcare information technology systems by using networking technologies.
- **Metadata:** Metadata refers to data that describe the attributes of other data and provide context and meaning. Typically, these are data that describe the structure, data elements, inter- relationships and other characteristics of data. Metadata also permit data to be attributable to an individual.[4] The Audit Trail is included in the metadata.

[4] MHRA GMP Data Integrity Definitions and Guidance for Industry, March 2015
[5] See section 4.6 for more information on the role and duties of an archivist
[6] Petersen, J.K. (2002), The Telecommunications Illustrated Dictionary (Second ed.), CRC Press, ISBN 9781420040678
[7] EMA/INS/GCP/856758/2018 Guideline on the content, management and archiving of the clinical trial master file (paper and/or electronic), December 2018
[8] Integrated Addendum to ICH GCP E6(R1): ICH Guideline for Good Clinical Practice E6(R2)
[9] REGULATION (EU) No 536/2014 on clinical trials on medicinal products for human use

- **Non-Essential Documents:** Information which would not routinely be prioritised for retention during sponsor or vendor risk assessments. Non-essential documents are not relevant for reconstructing GCP events for the full legal retention period.
- **Non-Trial Specific Master File (NTSMF):** Essential documents that are not trial specific and will usually apply to multiple trials, including trials being run by different sponsors and CROs.
- **Primary TMF:** Essential documents that are trial specific or IMP specific.
- **Signpost:** To give information or guidance about the location of essential documents that are in another part of the distributed TMF.
- **Trial Master File (TMF):** The collection of essential documents that is used by sponsors, CROs and investigators/institutions for the management of the trial and by monitors, auditors and inspectors to review and verify whether the sponsor and the investigators/institutions have conducted the trial in line with the applicable regulatory requirements and the principles and standards of GCP.[10]
- **Trusted Third Party (TTP):** A service provider that is a separate legal entity from the sponsor and from the investigator. A detailed contract should be in place defining the duties of the service provider, enabling the sponsor and/or investigator to transfer some of their tasks, but to retain control of their responsibilities.[11]

[10] EMA/INS/GCP/856758/2018 Guideline on the content, management and archiving of the clinical trial master file (paper and/or electronic), December 2018
[11] EMA/INS/GCP/454280/2010 Reflection paper on expectations for electronic source data and data transcribed to electronic data collection tools in clinical trials, 09 June 2010

4 Positions concerning the archiving of the TMF

4.1 Index of essential documents

The sponsor should define and implement the index of essential documents for their trial

Once the sponsor or their representative has determined which documents belong to the set of essential documents, it is not possible to define subsets of documents and allocate differing retention periods to them. According to law all essential documents must be retained for the full retention period.[12]

"*The sponsor and investigator/institution should maintain a record of the location(s) of their respective essential documents including source documents. The storage system used during the trial and for archiving (irrespective of the type of media used) should provide for document identification, version history, search, and retrieval*".[13]

The archiving of essential documents is a sponsor as well as an investigator responsibility. The sponsor, as the overall accountable party for the clinical trial, must ensure that investigators and third parties agree to maintain and archive the essential documents with this duty contained in contract with the trial sponsor.

The following items should be part of the index of essential documents:

- Details about the location of all archives at the sponsor, TTPs, investigators/institutions and the investigators' delegated parties with contact details to facilitate retrieval and identify the origin of the information. The pointers to these locations are referred to as "signposts" in this position paper.
- All items in the index shall be covered by risk assessments evaluating the ability to retain and retrieve the essential document for the required period. A risk assessment may cover more than one item in the index. Mitigations must be documented.
- Periodic evaluations of the ongoing viability of the formats (dynamic or static) of the essential documents retained should be undertaken, i.e., in what format do they need to be retained for the remaining retention period.

[12] Retention periods vary depending on locale, see relevant local laws and regulations for details, i.e., legal hold
[13] From ICH GCP E6

4.2 Distributed Responsibilities and the TMF

The same rules apply to all essential documents in the TMF for which the sponsor, investigators and vendors have distributed accountabilities

TMF creation, maintenance, integrity protection and archiving must be planned and executed throughout the trial lifetime. All essential documents must be accessible and readable during the trial and for the complete applicable retention period.

Mechanisms and sharing of responsibilities for TMF management shall be explicitly agreed before the start of a trial between the sponsor and all involved parties. These mechanisms will be detailed in written procedures, e.g., filing/archiving plan.

The accessibility of the TMF shall be confirmed by all contributing entities, whether acting as sponsor, investigators, inspectors, sponsor's partners, systems and/or service providers or archiving vendor.

There is no regulatory requirement to retain non-essential documents as these do not contribute to the evaluation of the conduct of the trial or the quality of the data produced. Instead, non-essential documents should be retained in accordance with standard industry practice for the type of document being considered. A risk assessment should be conducted and documented to assess the relevance of non-essential documents to define their retention accordingly. This risk assessment could cover multiple trials.

For example, some documents related to the trial computerised systems functioning and security may not be relevant from a clinical data integrity perspective. Examples are documents detailing the testing of backup power supplies, and computer hosting facility temperature logs. Some documents may be used in case of issue investigation during the course of the trial, without requiring retention after trial completion.

4.3 Contractual Agreements

It is the responsibility of the sponsor to ensure via contractual agreements with all parties that essential documents are readily available and accessible for audits and inspections during the retention period

"All parties" includes sponsors, investigators/institutions, CROs and any third party (e.g., Technology Provider) holding relevant data and documents. It is the sponsor's responsibility to confirm that all parties have processes to support audits and regulatory inspections. This shall be a mandatory requirement for the selection of Business partners supporting clinical trials. Given the long retention periods the agreements should include business continuity clauses covering change of ownership or discontinuation of business.

The investigator/institution is responsible for the documents they are to retain. The sponsor should check the storage arrangements the investigator/institution have for their essential documents before initiating the trial at that site.

4.4 Risk Assessments

Risk assessments and risk management plans covering essential document retention threats such as acquisitions, bankruptcies and technology obsolescence shall be performed, and mitigations shall be documented

Contingencies must be considered within such planning for discontinuities in the roles and responsibilities of all parties, e.g., going out of business or transfers of ownerships. Likewise, precautions must be taken to address technology obsolescence.

The responsibilities should be reflected in contracts. A succession plan should outline what will happen if vendors would go out of business and their archives disappear. A description of implemented mitigations shall be included. Technology obsolescence shall be addressed in the contracts as well.

A common situation is the acquisition of one company by another where the two have had differing principles for archiving. The use of differing archiving formats complicates the combination of the archiving responsibilities in the new combined company. This is a good justification for proposing a standard format for archiving of essential documents, for example CDISC ODM[14] for information from an EDC system.

Assurance shall be given that essential documents are readily retrievable at the request of the sponsor as specified in the contractual and confidentiality agreements.

[14] Clinical Data Interchange Standards Consortium Operational Data Model

4.5 Periodic Archive Check

There needs to be a periodic check of the essential documents held within the archives to confirm continued viability

The contents of the Trial Master File must remain complete, legible and easily retrievable throughout the retention period. Electronic archives will require logical access over the retention period. A documented periodic check of "archive continuity" (akin to business continuity) means that all of the archivists must verify that they can both confirm the physical/logical location of their essential documents as well as confirm their usability and readability in the computing environments current at that future time.

The periodic check should be a process triggered by all sponsor, CRO, investigator, and Trusted Third Party (TTP) TMF archive holders for media decay, and/or technology advances. Technology developments over time may render old file formats unreadable, alter context, or change access rights. This will trigger the need to transform the information to current technology. Care must be taken to preserve both the content (data) and the context (metadata) of the information. Diligence in this area will ensure the archive viability for the full retention period.

4.6 Archivist Role

There are archivist duties required within all organisations (sponsor, investigators/institutions, and trusted third parties) managing parts of the TMF

Each organisation involved in the archiving of the TMF should have one or more persons within their organisation with the archivist role, (however named, individual or shared). This is to ensure that one or more persons within the organisation will have oversight of the contents of the archive and ensure its continued suitability.

Their duties should include the following:

- Have documented processes in place to ingest, preserve, retrieve and ultimately destroy content.
- Maintain records of the archiving activities (storage, user management, retrieval).
- Have sufficient control of the information to the level needed to ensure long-time preservation.
- Preserve archived essential documents against all reasonable contingencies, including demise of the archive, over the retention period.
- Ensure the availability of essential documents to the designated community by periodically checking retrievability.
- Secure the archive and vet access requests for accountability and privacy.
- Enable checked out copies to be traceable to the original in the archive with evidence supporting authenticity (certified copies).
- Periodically report to the sponsor archivist of the continued availability and suitability of the essential documents as well as any change of ownership or demise of the archive.
- Provide a point of contact to the outside community for information about and logical access to the archives.

The sponsor archivist has the additional responsibility of maintaining a link down to each of the TMF holder archivist(s). This provides assurance that the sum of the parts of the whole TMF remain intact.

4.7 Investigator/Institution Archives with Trusted Third Parties

Investigators/Institutions may decide to use Trusted Third Parties (TTPs) to archive some / all essential documents

Investigators/institutions must plan for the archival of essential documents aligned with their local healthcare environment. Investigators/institutions without the structure and facilities to perform the archival duties may decide to use TTPs to provide such services. Issues may arise if an investigator/institution should cease to operate, or not be able to retrieve the archives in a reasonable timeframe upon inspection request in which case it should be mitigated.

The use of Archiving TTPs to maintain and manage archives on behalf of investigator/institution provides a reasonable solution to these issues. There shall be appropriate contractual agreements established between the TTP and the investigator/institution, to define the responsibilities, ensure compensation, and provide assurance that the investigator/institution will keep control of the essential documents, even if the sponsor reimburses the costs. This agreement should also define the conditions for granting any access to the archives, including the case of investigator/institution termination. The TTP's responsibility should go beyond just storing and should include maintaining the archived essential documents in a state ready for inspection, as defined in section 4.6.

The use of Archiving TTPs would reduce the risks and has the added benefit of a central source and common process to retrieve investigator/institution essential documents in a timely manner whenever these would be required.

5 Positions concerning the archiving of electronic data

5.1 Aggregated Data

Only the aggregated data that comes from IoMT need be retained as source

Devices that collect and store Electronic Clinical Outcome Assessment (eCOA) data should be defined in the protocol and all relevant collected data must be archived appropriately.

Devices that continuously collect data (wearables, patches, sensors, etc.), sometimes characterised as IoMT (Internet of Medical Things) devices, can collect huge amounts of raw data that are pre-processed within the device or vendor portal.

These are called aggregate data collectors, and they result in only cumulative or aggregate values being uploaded and retained – the raw data is used to generate the aggregate data.

The clinically meaningful measurement values, which are the aggregated results of the data collected, must be defined within the protocol so it is clearly understood what data are being uploaded, saved and archived. It is these aggregated values that are the source data.

5.2 Transient Data from Patient User Devices

Transient data from patient user devices becomes source when migrated to the clinical trial database

The data collected from devices used or worn by subjects in a clinical trial (including IoMT and ePRO devices) are classically deemed source data as discussed in regulations. It is essential to upload the collected data (and appropriate metadata) either continuously or as soon as possible after each logical session to limit the risks associated with loss of data related to session interruption or loss of locally stored data.

Examples of patient user devices include wearables, medical devices and mobile data collection units such as smartphones and tablets.

These devices are categorized as Transient Data Collectors, as the source data (and all appropriate metadata) are only temporarily stored on the individual devices during the data collection process. The data are subsequently uploaded to a durable electronic database where the data are securely captured for the first time which is considered the data source.

This view aligns with that of the FDA as written in "Guidance for Industry – Electronic Source Data in Clinical Investigations" from September, 2013[15,16].

Wherever these data are uploaded, it must be ensured that the investigator/institution retains access to and control over the data during the trial and continues to retain access to the archived data over the entire retention period.

[15] III.A.2.b – When a device or instrument is the data originator (e.g., blood pressure monitoring device or glucometer) and data are automatically transmitted directly to the eCRF, the eCRF is the source.
[16] III.A.2.e – When a PRO instrument is used by a subject to transmit data elements directly to the eCRF, the subject is the data originator and the eCRF is the source.

5.3 Essential Document Formats

Essential documents must be migrated into appropriate archive formats

Clinical trial data (and metadata) from investigators/institutions should be archived in *dynamic* formats that permit the data to be analysed or queried.

The sponsor is accountable for evaluating and selecting appropriate international standard formats (more than one, if required - see below). The sponsor is also responsible for ensuring data extraction methodologies comply with computerised systems validation principles. These requirements apply to all organisations archiving essential documents from the trial, including investigators/institutions.

The data extraction, which precedes the decommissioning of a trial or a computerised system, must be validated. Decommissioning cannot happen before having had proof of the appropriateness of the archiving format and the tools required to review the archiving datasets.

The sponsor is accountable for ensuring access (i.e., via data visualisation) of the entire essential document with its full audit trail, to allow auditing, monitoring, inspection and analysis of the data and metadata collected in the clinical trial. It is our recommendation that the audit trail be available in a dynamic format.

Open standards (e.g., ASCII, XML) as laid down by standard developing organisations (such as ISO, IEEE, ANSI, CEN, CDISC and DICOM) customarily establish domains of requirements on the proper usage, acceptable use cases and minimally required maintenance of the technologies, which they define. A common recurrent essential requirement in the development of these standards is reverse compatibility, which is aligned with the clinical research objectives for long retention periods.

At present CDISC ODM is a commonly used clinical trial archive format. As technology and international ICH and ISO standards evolve, interested parties will continue to define the format, version and specific domain and datatype structure for current and future clinical data. This will drive migration to robust and reverse-compatible standards as they become available (such as CDISC BRIDG).

Vendor-specific file formats (SAS, MS Excel XML, PDF, etc.) can also provide popular and validated methods of archiving, provided that the sponsor/CRO acknowledge that accessing the data and its metadata will often be associated with licensing costs. Sponsors remain ultimately accountable for clearly maintaining contracts and licenses needed to facilitate regulatory or other types of data access and review.

A significant risk reduction can be achieved by selecting more than one archive format for the clinical trial datasets.

Significant changes in open source or proprietary archive formats over the years should prompt immediate sponsor re-evaluation of the data integrity of the clinical trial data. Sponsors should follow developments of archive formats and contribute specific considerations associated with clinical trial data retention and integrity needs to the development of those archive formats.

5.4 Electronic Trial Systems

Electronic trial systems which are no longer being used in a trial are not required to be maintained in a (live) transactional state for the full retention period

By transactional state it is meant access to and dynamic interaction with the electronic system as it was used when active during the trial.

There is no expectation that clinical systems can be kept indefinitely in the transactional state, but some parties have alluded that such might be required, based on the assumption that electronic trial systems allow users to better interact with the electronic records.

When clinical trials reach the end of the legal retention period, very few of the computerised systems used are still operational and supported by vendors. Operating systems, databases and programming languages have all evolved over time. Entire technical solutions such as remote data hosting and access to data over the internet did not even exist 25 years ago. Systems were not interconnected then as they are today, and information security is also an entirely new sector. Older browsers, programming languages and operating systems have security issues that cannot be fixed. Information security issues alone would make it inadvisable to use a 25-year-old computerised system today – even if the system could be kept operational the information security issues alone would mean that any data in the system would not be secure and could not be trusted.

Attempting to retain data and metadata in live systems for the full retention period presents significant risks and a very questionable cost-benefit effectiveness. The Industry has therefore the following practical options:

- To retain the data in an electronic trial system by continuous migration of all required data/metadata into state-of-the-art electronic trial systems and/or
- The leveraging of appropriate archive formats for data retention (outside of electronic trial systems) throughout the retention period

These solutions depend upon the definition of the metadata required to be archived from the computerised system.

6 Conclusions

This position paper was authored by the EUCROF and eClinical Forum Joint Task Force on Archiving and Decommissioning.

You can contact the task force via the EUCROF and eClinical Forum websites (www.eucrof.eu and www.eclinicalforum.org) if you would like more information or if you have any comments on the contents of this position paper.

Although the Task Force was initiated as a joint effort by EUCROF and the eClinical Forum, team members representing the following organisations have also participated in the authoring of this position paper:

- ECRIN - https://ecrin.org/
- The ePRO Consortium - https://c-path.org/programs/eproc/
- Medicines for Europe - https://www.medicinesforeurope.com/
- RQA - https://www.therqa.com/

We would also like to thank the many organisations and individuals who reviewed and commented on this position paper before we released it.

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