Year	Type of organisation	Grading	Finding Text	Company Number
2016	Commercial Sponsor	Other	The TMF room contained a number of safes, some which were dedicated to live TMFs for active studies and some were dedicated to the Archivist for storage of TMF boxes before being sent to archive. The keys for all safes were accessible through the same lock box in the room so anyone with access to this room had access to the files secured for archive.	1
2016	Commercial Sponsor	Other	The contract with [redacted] did not specify that once boxes were accepted into the archive facility that they would be kept in a specified location. Therefore there is the potential that they could be moved to another UK or overseas site that had not been audited or approved by [redacted]	1
2016	Commercial Sponsor	Other	The inspector was told that while boxes were being prepared for archive the project manager would assess if any missing documentation was essential for the trial and needed to be escalated to senior management to confirm if a file note would suffice to document the missing information. SOP [redacted] 8 Nov 2014 did not describe what action should be taken in the event that key essential documents were missing when the TMF was being prepared for archive. Therefore the process for dealing with missing documentation was dependent on project managers, meaning that once they leave the organisation, that it may not be possible to reconstruct what review process was undertaken.	1
2016	Commercial Sponsor	Other	The eTMF filling plan [redacted] 28 Aug 2015 did not contain sufficient detail on how the eTMF would be delivered to [redacted] specifically in relation to file and folder structure and the format of the disks.	1
2016	Commercial Sponsor	Other	The contract with [redacted] for the [redacted] study did not contain details on the process for archiving the eTMF once the trial was complete. This is of importance as the eTMF structure being used is owned by [redacted]	1
2016	Commercial Sponsor	Other	There was no process in place for the future proofing of documents that have been archived on CDs in an electronic format. This includes the [redacted] spreadsheets and [redacted] data files from the [redacted] study which had been archived.	1
2016	Commercial Sponsor	Other	In the [redacted] trial TMF management plan there was no process detailing how the TMF would be archived following completion of the study as per the archiving SOP [redacted] 19 Dec 2014.	2

2016	Commercial Sponsor	Other	The [redacted] trial had been archived however number of documents necessary for the reconstruction of the trial were missing from the TMF. Examples included: - Interactive Voice Recognition System (IVRS) confirmation email reports confirming the receipt of IMP kits at sites. It was explained to the inspectors that this was due to this not being a required item on the accession forms used to archive TMFs. - Documentation attached to the database lock checklist confirming approval of eCRF pages from sites that had not been approved prior to database lock. These were located in the e-Room which was not part of TMF. The SOP [redacted] 5 Jul 2012 stated that documents stored in the e-Room should be removed within one year of the Clinical Study Report (CSR) production and before archiving. - The Interactive Response Technology (IRT) activation emails were not filed in the [redacted] study TMF and did not form part of the accession form for archiving.	3
2016	Commercial Sponsor	Other	At the time of the inspection, there was no process for electronic archiving of the TMF. Whilst there was a procedure to change user access to read only one year after CSR production, this did not include ensuring the eTMF was truly archived and access controlled through the archivist (e.g. tracking of any changes to the eTMF). As there was no eTMF audit trail extractable at the time of the inspection, any changes to the eTMF following a change to access rights would not be identifiable (e.g. if read only access was required to be amended in order to add/delete/replace documents etc.).	3
2016	Commercial Sponsor	Other	The [redacted] eTMF status was not changed to read only within one year of CSR approval as required by [redacted] 27 Jul 2015.	3

2016	Commercial Sponsor	Major	TMFs for the [redacted] and [redacted] trials had been archived within a storage area (converted barn) on the same business complex as the sponsor site, which was owned by [redacted] (the farm management group). Archiving was not robustly controlled because:• The storage area was used since 2014 for the [redacted] trial with no documented assessment of suitability for the archive prior to or during the storage period.• Access to the storage area and TMFs was not restricted to [redacted] staff only. Other businesses within the business centre also had access to and used the storage area and the TMFs boxes were not sealed to prevent any tampering.• There was no process in place to track documents which were placed in and removed from the archive.• There was no ongoing oversight of documents held within the archive to check that all documents were retained and preserved.Whilst the archive facility could not be visited during the inspection, it was identified by [redacted] prior to the inspection that the storage area was not a suitable archive and that an alternative vendor was being explored. TMFs would be retained within [redacted] offices in a locked secure room, temporarily, until an alternative archive was identified.	4
2016	Commercial Sponsor	Major	At the time of the inspection, there was no named archivist within the organisation and the role had not been formalised within a job description.	4
2016	Commercial Sponsor	Major	There was no process in place for the management of electronic archiving of documents, data and systems held electronically, including those held by a third party contractor (e.g. electronic clinical trial databases, Interactive Response Technology (IRT) systems etc. as per finding 1.1.2). There was no requirement to perform any back-ups of data held electronically or perform a test restore to ensure that documentation could be retrieved (e.g. from the virtual data room used by [redacted] to exchange documents with contractors/ third parties).	4

2016	Commercial Sponsor	Major	There were no requirements for archiving specified in the contracts with GP sites in the [redacted] trial. The retention period was not specified nor any requirements to retain the documents in a suitable archive/storage facility for sites 30 ([redacted] and 26 ([redacted] . Protocol version [redacted] 07 Feb 2014 stated: 'Essential documents should be retained until at least 2 years after the last approval of a marketing application in an ICH region and until there are no pending or contemplated marketing applications in an ICH region or at least 2 years have elapsed since the final discontinuation of clinical development of the investigational product. These documents should be retained for a longer period, however, if required by the applicable regulatory requirements or by an agreement with the sponsor. It is the responsibility of the sponsor to inform the investigator/institution as to when these documents no longer need to be retained.' However, no further instructions were provided to investigator sites regarding the archive retention periods relating to their trial records. As a result, during the investigator site inspection of [redacted] site [redacted] the Principal Investigator (PI) confirmed that he was not aware of what the retention period was for [redacted] trial documents. .It was acknowledged that whilst the close out visit report dated 11 Jun 2014 demonstrated that the site monitor had reviewed the archive/ storage area for the site, there was no documentation available to confirm if the retention period had been discussed (nor were these discussed at the site initiation visit on 30 Oct 2013).	4
2016	Commercial Sponsor	Major	There was no process in place for the archiving of electronic systems that were identified as repositories which were part of the Trial Master File (TMF). For example: The [redacted] TMF system was not archived at the end of the study (the inspector was able to access documents within [redacted] for the [redacted] study which published its CSR in September 2011). The [redacted] system for this study contained documents with modified dates of 08 August 2015 (e.g. document [redacted] . It was therefore not clear how access to the TMF had been managed to control the removal/addition of documents.	5
2016	Commercial Sponsor	Major	There was no process in place for assessing the suitability of electronic systems as an archive. Criteria for system suitability for long term archiving of documents/data was not defined, and no assessment of suitability for this was conducted. A number of systems (including [redacted] lacked functionality to "lock" TMF documents at the point of archive, therefore they may not be suitable for this purpose.	5

2016	Commercial Sponsor	Major	There was no documentation in place to identify the named archivist(s) for paper and electronic records, or whether the requirements of the UK regulations were recognised in Archiving processes and individual job requirements/descriptions.	5
2016	Commercial Sponsor	Major	The supplied document [redacted] Version [redacted] effective 22 November 2012 [redacted] was not clear how this procedure managed the requirements for archiving of vendor documents as it did not reference archiving.	5
2016	Commercial Sponsor	Included as one aspect of a wider record keeping / essential documents critical finding	There were issues observed with other systems holding TMF documentation. [redacted] (Doc No [redacted]_version [redacted] were used to assess the use and suitability of electronic systems. The documents reviewed did not adequately assess the systems' use as a TMF, how direct access by inspectors would be granted, or how archiving of clinical trial information would be considered. For example: - [redacted] contained no assessment of use as a TMF or how information would be archived, although reference was made that the system was used for storage of drug and patient safety information. Retention of documentation was referenced without discussion of ability to archive. - [redacted] did not consider GCP requirements and the use of the system as a part of the [redacted] TMF. - [redacted] assessment did not assess how electronic SOPs would be archived. - [redacted] was referred to as being used for clinical trials, but did not record that it would need to consider archiving arrangements. - [redacted] contained no assessment of use as a TMF or how information would be archived, although reference was made that the system was used as a document management environment. - [redacted] contained no assessment of use as a TMF or how information would be archived.	5
2016	Commercial Sponsor	Other	There was no named individual appointed within the organisation as the person responsible for archiving the documents which are, or have been, contained in the TMF, as required by Regulation 31A (9) of UK Statutory Instrument 2004/1031 (as amended).	6

2016	Commercial Sponsor	Major	There was no process or formal documentation to demonstrate the control and approval of archived data which had been placed in or retrieved from the [redacted] archive. For example, when the inspector requested documentation to support the approval and subsequent removal of records of the [redacted] trial from the archive situated in the USA, all that could be provided were chain of custody forms betweer [redacted] and the courier [redacted]	7
2016	Commercial Sponsor	Major	The named archivist was only responsible for the archiving of non-interventional trials in the UK. Therefore there was no named archivist(s) responsible for the archiving of clinical trial documents and electronic data for interventional trials.	7
2016	Commercial Sponsor	Major	Archived data from the [redacted] database was stored in pdf format and only included patient data and associated audit trails. This data was not dynamic and therefore would prove to be difficult to use to verify study conduct. In addition data relating to system audit trails were not collated with this information. It was recognised that [redacted] databases used on [redacted] rials remained on [redacted] servers and would provide access to study data and audit trails. However agreements with [redacted] did not specify the fate of this data should the contract with [redacted] end, and it could be possible for the data to therefore be deleted.	7
2016	Commercial Sponsor	Other	There was no formal arrangement with [redacted] for long term access to trial specific helpdesk tickets for the IRT system (although it was noted that this could be provided on ad-hoc basis).	8
2016	Commercial Sponsor	Other	There was no named archivist until 22 Sep 2016 prior to the inspection. It is acknowledge no trials have yet been archived.	9
2016	Commercial Sponsor	Other	The timeline for when trials were to be archived following completion was not defined or formalised within the quality system. No archiving activity had been planned or considered for the [redacted] trial despite completing in Jan 15.	9
2016	Commercial Sponsor	Other	There is no process for the archiving of electronic documents.	9
2016	Commercial Sponsor	Other	The SOP on archiving, [redacted] effective 30 Nov 2013 doesn't state how archiving is performed or detail any processes that should be followed in order to ensure the integrity of the documents held in archive.	9

2016	Commercial Sponsor	Other	No transmittal forms were available for the transfer of original documents between the UK and USA for the [redacted] and [redacted] trials.	9
2016	Commercial Sponsor	Major	There were no processes in place to ensure the archiving of the eTMF [redacted] and associated systems identified within relevant TMF Plans)	10
2016	Commercial Sponsor	Major	There was no documentation that describe the content of the Data Bases that were returned to [redacted] by CROs at the end of the studies and formalised procedure to assess their completeness. It was therefore not clear if [redacted] would receive complete data sets including audit trails to support any verification activities and if the data bases could be recommissioned in the future.	10
2016	Commercial Sponsor	Major	The named archivist was not documented in any [redacted] Policy or SOP.	10
2016	Commercial Sponsor	Other	There was no archiving process in place at the time of the [redacted] and [redacted] trials with the SOP describing the archiving process not being introduced until December 2016 (SOP [redacted] effective 15 December 2016). It was noted that documents were able to be retrieved but [redacted] had required retrieval of documentation from [redacted] to support the inspection.	11
2016	Commercial Sponsor	Other	The contract with [redacted] dated 10 May 2016) permitted [redacted] to transfer and store records at any [redacted] location therefore records could be moved and stored in locations which had not been subject to audit/assessment by [redacted] The contract stated 'The supplier reserves the right to determine, at its sole discretion, the manner in which the services are provided, including (without limitation) the route, location and area where goods shall be carried and stored. The supplier shall also be entitled to interchange goods between vehicles and storage premises at any time'. [redacted] should ensure that either records are not moved or are only moved with [redacted] approval.	11
2016	Investigator Site	Other	Medical files for deceased patients are required to be returned to [redacted] for retention. As a result, the historic paper medical records for subject [redacted] in study [redacted] (who passed away in November 2014) were no longer available at the site and efforts to retrieve these have so far been unsuccessful. UK Statutory Instrument 2004/1031 (as amended), Regulation 31A (8) requires that the sponsor and the Principal Investigator shall ensure that medical files of trial subjects are retained for at least five years.	12

2016	Investigator Site	Other	The site archive consisted of the loft space of the premises and was found to be at capacity with many storage boxes having been crushed or collapsed. There were no documented checks of humidity, pest control or condition of trial documents. The Principal Investigator should consider whether the existing archive area is appropriate for the long term retention of clinical trial documentation.	12
2016	Investigator Site	Other	Trial [redacted] was unable to be reviewed as part of the inspection due to the site master file being unable to be provided from archive. The site and [redacted] are to ascertain whether these records still exist and why they were not able to be retrieved for review. This information should be included in the response.	12
2017	Commercial Sponsor	Other	The archiving process was deficient in that it did not ensure that the TMF was complete and reconciled by [redacted] prior to archiving as the signed checklists did not include checks made of reconciled vendor documents and electronic components such as biometric [redacted] files programs etc. No checks were in place to ensure that the vendor documents that were provided were complete and as expected.	13
2017	Commercial Sponsor	Other	No processes were in place for archiving electronic media to ensure it was available, accessible and readable over time.	13
2017	Commercial Sponsor	Other	The role and responsibilities under regulation SI 2006/1928 31A for archiving were not clearly reflected in the Job Description for the Clinical Document Management Specialist or Clinical Document Manager.	14
2017	Commercial Sponsor	Other	There was no process in place for long term archiving of the eTMFs once they were returned from [redacted] to [redacted]	14
2017	Commercial Sponsor	Other	When electronic media was received and added to older 8-folder structured paper TMFs such as for the [redacted] trial there was no requirement to confirm that the media was readable and contained the relevant data. This was, however, a requirement for 11-folder structure TMFs, but the check was not formally documented. Issues were found with the [redacted] TMF provided for the [redacted] trial as the meta data files contained on CDs were not in a readable format that allowed for the data to be reviewed or understood.	15

2017	Commercial Sponsor	Other	There was an inadequate process in maintaining investigator control of access to the Investigator Site File (ISF) when archived on their behalf by [redacted]. SOP [redacted]" Version [redacted] (effective 29OCT16) only stated that ISF records must not be accessed by the sponsor, [redacted] but contained no detailed process of how investigator approval was required to access the records and how the records would be delivered to the investigator site and not to [redacted] etc.	15
2017	Commercial Sponsor	Other	There was no Sponsor appointed archivist with agreed and documented responsibilities as required by UK SI 2006/1928 for paper records and associated Quality System documentation (i.e. SOPs, training records etc). It was stated that a vendor, [redacted] at [redacted], was responsible for archiving however the job description provided did not clearly stipulate that they had taken on these legal responsibilities from [redacted]	16
2017	Commercial Sponsor	Other	There was no company named archivist, as required by Regulation 31A(9) (UK SI 2004/1031) as amended to ensure that a named individual took responsibility as per the regulations to ensure adequate archiving of clinical trials records.	17
2017	Investigator Site	Other	There was no clear process described in SOPs [redacted] dated February 2016 or [redacted] dated March 2016 to ensure the integrity of all types of electronic media/data such as ediary data held CD ROM's over time. It did not cover all other types of electronic source data required to be archived as part of the Investigator Site File (ISF). There were no controls in place to ensure electronic data was complete and readable prior to archiving and over the archival period; there was also no consideration for ensuring both software and hardware was available over time for readability of the data.	18
	Investigator Site	Other	There was no documented assessment of suitability for long term clinical trial record storage at the external archive vendor.	18
2017	Investigator Site	Other	The site Investigator Site Files (ISFs) had been agreed to be stored at an external facility organised by the site according to the Close-out visit report however at the time of inspection this had not been done even though a year had passed from this close out visit.	19

2018	Commercial Sponsor	Other	There was no documentation in place to identify the named archivist(s) for paper and electronic records (as required by regulations), or whether the requirements of the UK regulations were recognised in Archiving processes.	20
2018	Commercial Sponsor	Other	The archivist group were not clearly responsible for all relevant clinical trial documentation, the archiving procedures and job descriptions only covered eTMF and did not cover associated clinical trial documentation such as quality system documents and training records which were held and managed outside the eTMF system.	20
2018	Commercial Sponsor	Other	The retention requirement was stipulated as 6 years for training records and 10 years for procedural documents (unclear if best practices and other levels of supporting docs included in this). The timeframe for retaining these documents should be associated with trial retention periods as these documents may be required to support how trials were conducted.	20
2018	Commercial Sponsor	Other	[redacted] receive trial TMFs from CROs for archiving at the end of a study, these are received on disks as flat files (i.e. the TMFs are not formally archived with the same system they were maintained in during the live phase of the trial). There was no defined requirement (either in the quality system or in trial specific agreements) for ensuring eTMF system audit trails and document associated meta data were provided with the eTMFs for archiving to ensure the eTMF and how the eTMF was maintained during the live phase of the trial could be reconstructed.	21
2018	Commercial Sponsor	Other	There was no formalised plan/process for electronic archiving of trial databases/documents and management of media and software redundancy.	22

2018	Commercial Sponsor	Major	In the Policy [redacted] 02SEP15 and in SOP [redacted] 17OCT18, the procedures related to the archiving of essential documents are described. The RMA (records management and archiving group) was responsible for the archiving of electronic data in the [redacted] TMF and [redacted] system. [redacted] had appointed a named individual responsible for archiving via their Job Description, but these individuals' responsibilities were restricted to [redacted] TMF and [redacted] and paper systems as part of the RMA group and they had no oversight of archiving from other electronic systems that [redacted] had defined as TMF systems, therefore this arrangement did not meet the requirements of the legislation. It was acknowledged that [redacted] stated that these systems have been assessed as suitable for long term retention of TMF content and had suitable control processes and business system owners assigned, but there was no-one with overall responsibility for TMF essential documents and clinical trial data archiving.	23
2018	Commercial Sponsor	Major	The inspectors were informed that there was no formal procedure in the quality system for electronic archiving to ensure that archived files would continue to be accessible through the retention period and not be subject to software redundancy such that the data would become unreadable. Such issues affect all forms of trial archived files that could be data (e.g. [redacted] or electronic documents (e.g. [redacted] or PDFs).	23
2018	Investigator Site	Other	It was unclear how the trial file would be archived at the end of the trial to ensure all investigator and support services trial file data would be archived (e.g. together or separately and if separately how it would be identified and defined for the trial), as the trust R&D SOP [redacted] August 18) did not provide sufficient detail to cover this. This SOP also did not have any detail on how to cover electronic archiving should the trial contain any electronic documentation.	24
2019	Commercial Sponsor	Major	The named archivists (2 persons) had responsibility only for the [redacted] system containing essential documents. Other electronic systems were being used as set out in Finding 2.3.1, but there was no oversight of these to ensure all documents/data in these systems would be archived at the same time, therefore ensuring the complete TMF would be archived and that the necessary subsequent oversight of maintenance and retrieval from the archive would be in place. Therefore, this arrangement did not meet the requirements of the legislation	25

2019	Commercial Sponsor	Major	There had been no detailed assessment of the systems used for essential documents that were not [redacted] in terms of how the system would be locked at archive, the format of data/files retained & maintenance of readability and how access would be controlled in accordance with the legislation under control of the named archivist (see 2.1.1). Whilst it was stated in [redacted] MAY 2019 (not a quality system document) that archiving was undertaken according to the systems own procedures, there was not an overall procedure in the quality system for overseeing the TMF archiving as it was fragmented and not all systems appear to be addressed. It was stated that the [redacted] Global Retention and Disposal (GRAD) schedule would be followed, but it was not clear whether essential documents/data are retained as part of the Enterprise Archiving System.	25
2019	Commercial Sponsor	Other	There was no formalised plan/process for electronic archiving of trial databases/documents and management of media and software redundancy.	26
2020	Commercial Sponsor	Major	A named individual was responsible for archiving but only of the primary TMF maintained in the [redacted] or [redacted] systems. The archivist had no oversight of archiving from other electronic systems to ensure that they were archived appropriately and at the same time as the primary TMF. Therefore this arrangement did not meet the requirements of the legislation as stated above.	27
2020	Commercial Sponsor	Major	A named individual was responsible for archiving, but only for the primary [redacted] TMF. However, they had no oversight of archiving from other electronic systems to ensure that these were archived appropriately and at the same time as the primary TMF essential documents and that the necessary subsequent oversight of maintenance and retrieval from the archive would be in place. Therefore, this arrangement did not meet the requirements of the legislation.	28

2020	Commercial Sponsor	Other	The current arrangements for archiving and retention were not consistent across the laboratories being used with different retention periods being stated in the summary provided in response to document request [redacted] 'confirm the archiving and retention arrangements with each laboratory'. The archiving arrangements in place with [redacted] did not meet the UK Clinical Trials Regulations requirement for retention of essential documents for at least 5 years after the conclusion of the trial. The response to document request [redacted] stated 'Paper records and documentation are kept for 6 months by [redacted] after which time they will be disposed of confidentially. Electronic data, including scans of request forms, copies of lab books, scanned spot counts and the results spreadsheet, is kept for 1 year, after which time it is deleted, unless otherwise requested by the customer'. There was also the potential that records archived by [redacted] could be destroyed before the required duration had been met as the response stated 'Data are archived for 5 years' but did not state that this was from the conclusion of the trial.	29
2020	Commercial Sponsor	Other	The sponsor had no formal process in place to prepare for the archive of the TMF following the closure of the trial in order to ensure essential documentation from all aspects of the trial would be retained in accordance with the UK legislation.	29
2021	Investigator Site	Other	The retention period for archiving of records necessary to support the analysis of clinical trial related samples were not described within the [redacted] quality systems reviewed at each site, only that records would be retained.	30
2021	Investigator Site	Other	When trial documentation was held outside of the paper ISF or PF, this was not documented or signposted. There was a risk that at the time of trial closure, these documents would not be archived appropriately:- Records held by the [redacted] team relating to recruitment and screening were not available during the inspection and there was no plan to detail how these would be archived when the trial closed. -There was also no plan in place to ensure that any email correspondence stored in the shared trial inbox would be archived.	31

2021	Investigator Site	Other	The current hospital retention policy for the investigator site detailed in the Clinical Records Management Policy dated 21 June 2017 (expired 21 June 2020) was not reflective of the current retention and storage of clinical data for patients. To further detail: - The policy had stated under section 12 Retention of Records, that adult records were retained for 8 years only after conclusion of treatment of death, however it was confirmed by the RN/R&D - The policy did not cover archiving details of clinical trial data held in the electronic systems such as the DXA/radiograph scans. It was noted that work was currently ongoing to update the Clinical Records Management policy to reflect clinical trial requirements for record retention. The site are required to provide a timeline for completion of this update.	32
2021	Commercial Sponsor	Other	A named individual was responsible for archiving, but only for the primary [redacted] eTMF. They had no oversight of archiving from other electronic systems, including [redacted] eCRF data/metadata, data snapshots generated for IDMC meetings and statistical programs from the 'clinical reporting environment' to ensure that these were archived appropriately and at the same time as the primary TMF essential documents and that the necessary subsequent oversight of maintenance and retrieval from the archive would be in place. The IT department managed these systems, therefore, this arrangement did not meet the requirements of the legislation.	33
2021	Commercial Sponsor	Other	It was described at interview that the Clinical Document Control Administrator was the [redacted] named archivist. However, this was not described in their job description until 04 January 2023 despite their start date being 10 January 2022.	34
2022	Commercial Sponsor	Other	At Investigator Site [redacted] archiving of the ISF and Pharmacy File was only planned for 15 years (as per both versions of the Clinical Trial Agreement dated 03 December 2015 and 13 April 2016). Correspondence was in the ISF from the current CRA asking for 30 years, as required for Advanced Therapy Investigational Medicinal Products (ATIMPs), (in response to an email in August 2022 asking if the files could be archived) but this could not be accommodated due to the details in the contract so the CRA agreed to 15 years on 12 August 2022.	34

2023	Commercial Sponsor	Major	There was no current named archivist within the organisation specified in the QMS and as required by regulation 31A 2004/1031. It was also noted that there had been formal archiving completed to date (for the closed [redacted] trial). It was acknowledged that [redacted] had recently appointed a TMF Operations associate direct to be the designated archivist as of 12 June 2023, however it was also noted that 'named archivist' was not stipulated in their job description.	35
2023	Commercial Sponsor	Major	There was no formal retention policy or process within the departments in [redacted] to ensure that all the documents would be retained as required by the regulations (Regulation 31A). The TMF for the closed [redacted] trial was currently archived in [redacted] area, however there were no procedures governing the retention times of the TMF. The [redacted] area also held other key pertinent data such as SMT minutes, Quality Check documentation, Quality Investigations documentation.	35
2023	Commercial Sponsor	Major	There was no formal retention policy or process within the departments in [redacted] to ensure that all the documents would be retained as required by the regulations (Regulation 31A). SOP [redacted] dated 18 April 2023 did not detail the retention policy of such documents. It was noted that SOP [redacted] which did detail retention timelines) was still in draft form.	36
2023	Commercial Sponsor	Other	It was confirmed via document request (response to [redacted] that the Senior Clinical Trials Assistant was the [redacted] named archivist. However, this was not described in their job description until 18 January 2023 despite their start date being 01 April 2022. It was noted that prior to this there was no named clinical archivist within the organisation. It was acknowledged that there had been no formal archiving to date.	36

2023	Commercial Sponsor	Other	It was confirmed via document request (response to [redacted] that the Clinical Trials Assistant (CTA) was the [redacted] named archivist. However, this was not described in the CTA job description. It was also noted that SOP [redacted] dated 06 September 2022 stipulated the Clinical Operations Study Lead (COSL) as the person responsible for archiving (although it was also noted that this activity could be delegated). The named archivist is a legal requirement as per regulation 31A 2004/1031 and therefore also holds regulatory/legal responsibilities which should be agreed to by the individual/s and listed within their relevant contracts and job descriptions.	37
2023	Investigator Site	Other	There was an inadequate process in place to control the archive of electronic records produced as part of the trial: - There was no process for the archival of electronic data from the [redacted] instrument and data was left on the instrument. - Printed paper examples of spreadsheets were seen in the laboratory files provided for the inspection but these lacked the electronic functionality of the spreadsheet and key information such as the headers, page numbers etc.	38
2023	Investigator Site	Other	Laboratory SOP [redacted] dated 14 July 2023 made reference to the protocol for retention of essential records (documents and data) as it stated 'all electronic and paper data/files are stored and discarded as per trial protocol'. This made no reference to relevant [redacted] SOPs (including [redacted] dated January 2023 and [redacted] dated January 2022) and may be in conflict with the Laboratory [redacted] dated December 2019 which required retention of clinical trial records for 25 years. The protocol for the [redacted] trial required retention for 25 years, but this may not always be the case. It was seen that some paper records had already been destroyed, not complying with the trial protocol, as the samples had not been analysed as clinical trial samples (see finding 4.1). Additionally, electronic raw data (.raw files) in [redacted] were not subject to archiving.	39