CASE STUDY

Aspire Pharma

Complying with EU Reg 536 Retention Requirements

Arkivum

Aspire Pharma: Complying with EU Reg 536 Retention Requirements

Aspire Pharma Limited (APL) is a medium size pharmaceutical company, based in the UK. Incorporated in 2009, APL is committed to making a valuable difference to patients, healthcare professionals and the NHS through their range of medicines and medical devices.

As part of the licensing and development of their products, APL are required to conduct clinical trials. These trials are generally small bioequivalence trials in healthy patients, so the data sets produced are consequently small. Previously, 1 to 2 clinical trials have been sponsored each year by APL, who act solely as a remote sponsor. The activities of the clinical trial are carried out by specialised contract research organisations, of which APL retains oversight. As a result of being within a heavily regulated industry, APL require a solution to store clinical trial data that ensures GxP and regulatory compliance over a long period.

Ensuring GCP and Regulatory Compliance

Previously, APL's data for the live trials has been stored on a secure server. However, APL recognised that this method does not preserve or protect the data for the long-term. In fact, using this solution as an archive created several challenges that prompted the company's search for a viable solution.

Complying with EU Regulation 536/2014

A significant proportion of the challenges faced by APL, were driven by the introduction of the new European Regulation 536/2014. One of the key changes this regulation brought in was requiring sponsors to archive the Trial Master File (TMF), the collection of essential documents detailing how the trial was run, for a minimum of 25 years.

Therefore, APL required a solution which could ensure:

The records would remain legible; preserved in long-term formats so the records could be opened and read up to and, possibly beyond, the 25-year retention period.

The records would also be secure, readily available, and accessible to authorised personal; APL needed a solution that would be easy to navigate, and that records would be immediately findable and accessible only to authorised individuals (e.g. during an inspection).

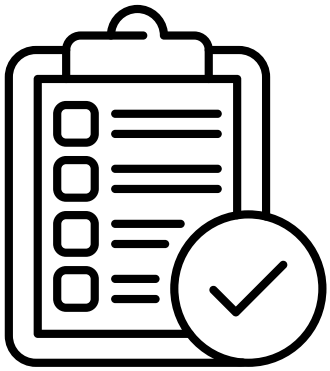
Accurate and detailed audit trails are captured; EU Regulation 536/2014 also states that "any alteration to the content of the [TMF] shall be traceable" and so capturing audit trails of those who accessed the archive was critical.

For APL, these requirements meant finding a solution which aligned to both Good Clinical Practice (GCP) and the ALCOA+ principles.

Given the volume of records involved (and potentially further generated in future), it was not feasible to manually maintain integrity in line with the above requirements throughout the whole retention period, and hence, Aspire began a search for an automated preservation solution.

Validation reducing onboarding effort

Another challenge was due to the sensitive and valuable nature of the data and the industry, it was important that any new system had been validated in line with **GAMP5 requirements.**



Thereby, APL wanted to source a solution that had already been validated by an external party. This would significantly reduce the cost and effort required to onboard a new digital archiving solution (i.e. if they chose not to select a validated solution, they would have incurred significant cost themselves validating the new software).

Finding a long-term cost-effective solution

Lastly, the company has strict budget requirements, due to clinical trials representing a comparatively small section of the overall company activities. Due to the typically less complex nature of their trials, APL required a solution which would be more cost-effective compared to retaining the data within an eTMF solution, which considering APL's role as a remote sponsor, would be unnecessarily expensive and burdensome.

Overall, APL's main criteria for exploring a solution included ensuring that:

- Data is safeguarded against corruption and loss for a minimum of 25 years.
- Data remains accessible through this retention period.
- User access is controlled, managed, and captured within an audit trail.
- The system selected has been validated in line with GAMP5.
- A more cost-effective solution than retaining the data within an eTMF solution.

"The working relationship with Arkivum has been brilliant. The Arkivum operations team have always been available to talk through any technical aspects and the support and expertise on offer has been outstanding. The solution provided by Arkivum will ensure our clinical trial data is kept secure and accessible over the archiving lifespan and allows confidence that it will be available in the event of a future authority inspection."

Selecting Arkivum

Aspire had several options available when assessing their options for where and how to retain their TMF records. This included:

> Store the records within the Microsoft Office suite of applications, hosted on APLs own servers. Given this option included no automated digital preservation it would have meant APL staff would have had to manually maintain records in long-term formats at great time and cost to the business.

> Invest in a full eTMF software package with archiving function, at considerable cost. Given the low complexity of APL's current trial portfolio and their position as a remote sponsor, this level of financial commitment was considered disproportional.

Therefore, APL took the decision to outsource their digital archiving and preservation to a specialist third party.

Selecting the Arkivum solution proved to be a relatively simple choice, as it precisely met the identified requirement. Working with Arkivum ensures that their TMF data is correctly archived, maintaining data integrity for 25+ years in line with the new legislation. In addition to this, the pricing structure aligned well with their budget requirements, without any hidden or extra costs for additional features.

"Creating a business case was a fairly informal process given the focus on complying with the relatively new regulatory requirements of EU Regulation 536/2014."

A Seamless Solution to Long-term Data Integrity

Once APL had finalised their selection process, the Arkivum onboarding and migration process began. One of the initial steps in the onboarding process is fundamentals training, whereby APL underwent video training and attended online sessions with the Arkivum team. Through this process, we help all potential users of the solution to understand the system with the use of simple terminology and jargon-free discussions.

"The migration process was well managed by Arkivum, there was lots of communication at every stage."

As one of APLs requirements was that records remain easily searchable in the event of an inspection by the competent authority, having meaningful metadata was key. An initial step in migrating data into the system is called “mapping”. Here, the Arkivum team assessed and organised all metadata to reflect the structure of the TMF while also identifying gaps to be recovered. Through organised and complete metadata, documents remain easy to access. During this stage, the Arkivum staff provided extensive expertise and assistance both with the technical aspects and with inspection readiness.

Throughout the migration process, communication between parties was critical. The Arkivum team remained available to answer all questions (big and small) that arose throughout process.

As of writing, APL have now ingested their first study into the Arkivum solution.

Accessible long-term TMF records with minimal effort

Since uploading their first study into the Arkivum solution, APL have found the online dashboard simple and intuitive to use. Due to the focus placed on assigning useful metadata to each record it has meant that records can be easily found both now and in the future.

While the obvious benefit of this means come inspection time, they have the confidence that records can be easily located by inspectors, APL believe it may also be useful to look back at previous similar studies when designing a new trial.

Aside from this, APL have found that using the Arkivum solution has meant that their retained TMF records are compliant with EU regulation 536 with crucially minimal requirement on staff time. It is a key benefit for APL that the data is preserved over the 25+ year retention period without need for additional maintenance or check by APL staff.

Looking ahead, as APL conducts more trials, more data will be migrated into the archive. As their metadata requirements are relatively simple and repeatable across their datasets, Arkivum are now helping to create a template to allow them to do this independently. Moreover, APL plans to continue working with Arkivum to ensure they can create their own metadata files in house to be able to manage this migration processes end to end.

Ensure you consider how you want to be able to use your data 'on the other side'. In Aspire's case, the data must be easily navigable in the event of an inspection and how we archive our data has a strong baring on that process.

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