

CASE STUDY

Neuraly

Helping a revolutionary clinical-stage
biotechnology company become
GCP compliant



Arkivum

Arkivum have been working with Neuraly - a clinical-stage biotech - to ensure and future-proof their eTMF requirements and protect their Quality documents. Neuraly was founded in 2016 to translate foundational research by world class neuroscientists into therapies for patients suffering from diseases such as Parkinson's disease (PD), Alzheimer's disease (AD), and other neurodegenerative disorders. Their mission is to develop revolutionary new drugs that can radically improve and prolong the lives of people suffering from these devastating diseases.

Ensuring GCP data compliance

As two of Neuraly's clinical studies are currently in Phase II (with three more in pre-clinical stages), the Quality function within the business sought to establish a Quality Management System (QMS). Part of this process included the outsourcing of the archival of the electronic trial master file (eTMF).

The storage of the eTMF within the archive must be compliant with the requirements set by Good Clinical Practice (GCP) but retaining the eTMF for an extended period of time creates a number of challenges, including:

Safeguarding the data to ensure that it is not lost or corrupted.

Archiving the data in such a way that it can be easily found if required.

Preserving the data so that the information can be read and used, regardless of the format or device that is used, however long into the future.

Audit trails must be recorded to show who has accessed the data and when.

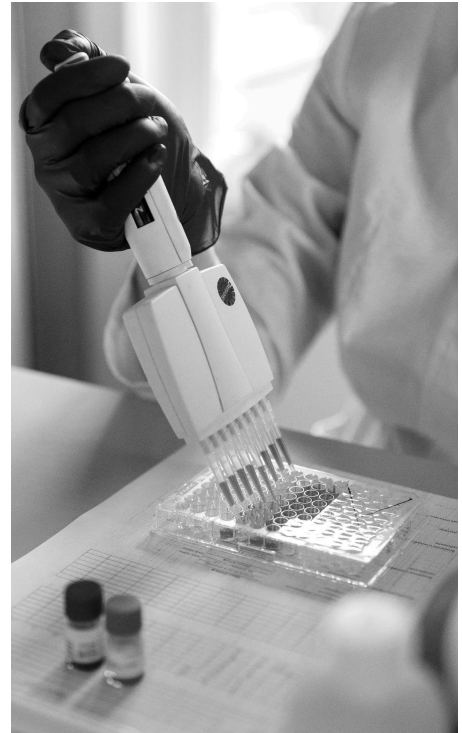
Secure access to be provided to approved stakeholders, including inspectors.

Adhering to these industry regulations and requirements primarily led to the decision by the business to outsource the archiving and preservation capability.

The road to compliance

Neuraly chose Arkivum's solution because they needed a reliable provider who could help them meet regulatory requirements and compliance in storing their eTMFs offsite.

Arkivum worked with Neuraly to identify and define the requirements needed from an eTMF to ensure they were compliant with GCP standards, FDA regulations and in alignment with ALCOA+ principles. It was important to Neuraly that the company they chose to preserve their data with provided a fully validated (CSV) solution and had a shared commitment to high standards of QMS.



As part of Arkivum's fully managed solution, Neuraly's data was uploaded via the industry recognised Exchange Mechanism Standard (EMS). During this upload to our system, we provided a number of automated processes to the data to ensure that it is safe, accessible and usable for as long as it is needed:

Each file was automatically checked on upload for any errors or issues. These checks will also continue on a regular basis throughout the retention period to identify any issues or errors with any of the files in order to identify and fix potential data corruption.

We assisted with the mapping of Neuraly's eTMF metadata in order to make it searchable (in alignment with the widely recognised TMF reference model).

In addition to archiving the original file, we created a copy which is automatically updated to one of our preservation formats so that all documents within the eTMF can be read and used by future devices.


Neuraly are able to view, manage and report on these processes via our online user dashboard. The dashboard also provides access to various compliance functionality including managing retention policies for the data and applying legal holds if required.

Benefits

By selecting Arkivum, Neuraly was easily and quickly provided with assurance that their quality and eTMF documents were secure, accessible and usable – now, and into the future.

They are now compliant with FDA guidelines on the effective storage of the eTMF and can easily demonstrate this compliance and provide access during any future inspections which may arise over the coming decades and beyond.

Neuraly can also demonstrate compliance with GCP standards and alignment to the ALCOA+ principles, as well as having been able to segregate their volumes of data in both physical and electronic formats to provide further storage and access security.



“Arkivum offered the best package for the solution we are looking for. Their team was knowledgeable, very helpful and responsive from beginning to end. We are looking forward to working with the team for subsequent eTMF archiving needs”

Celia Baula

Head of Quality and Director, R&D Program and Portfolio Management, Neuraly

About Arkivum

About Arkivum Arkivum is recognised internationally for its expertise in the archiving and digital preservation of valuable data and digitised assets in large volumes and multiple formats. The long-term security, integrity and accessibility of data is crucial for all Arkivum's clients and partners, who share a commitment to good practice in its stewardship and governance.

Arkivum's specialist software and services are chosen by major institutions and commercial organisations in a diversity of sectors, including life sciences, research (CERN), financial services, and organisations in higher education, culture and heritage. Confident in Arkivum's reputation and resources, they are in a position to maximise insight and discovery by deriving optimum long-term value from their data, collections and intellectual property.

Headquartered in the UK, with presence in the US, Arkivum advocates the use of the FAIR principles in data management: Findable, Accessible, Interoperable, Reusable. Arkivum is also certified in ISO 9001 and 27001.



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