CASE STUDY

Cerevel Tx

Finding a forward-thinking eTMF archiving solution

Arkivum

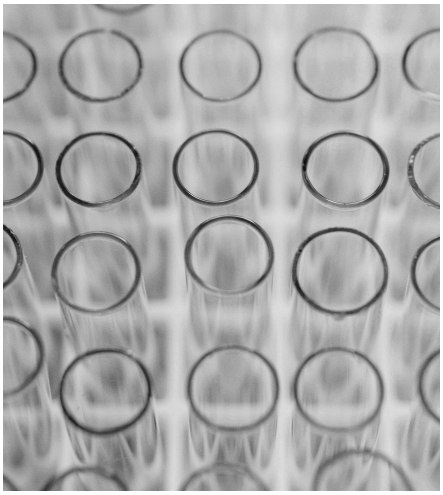
Cerevel: Finding a forward-thinking eTMF archiving solution

As a partnership between Pfizer and Bain Capital, Cerevel Therapeutics was established in 2018 with the mission to push boundaries, develop solutions, and transform lives of people living with some of the most devastating neuroscience diseases, including schizophrenia, Parkinson's, and epilepsy. The biotechnology company is based in Cambridge, Massachusetts, USA and employs more than 340 staff.

Building on the foundation of Pfizer research, Cerevel intends to become the premier neuroscience company. Currently, they have three ongoing Phase 3 trials and an open-label extension trial for tavapadon in Parkinson's, two ongoing Phase 2 trials and an open-label extension trial for emraclidine in schizophrenia and an ongoing Phase 2 proof-of-concept trial and an open-label extension trial for darigabat in focal epilepsy.

These trials have and will continue to produce high volumes of valuable digital records and data. A large proportion of these records and data are managed through Veeva, their live electronic Trial Master File (eTMF) solution. While this system is an effective solution for the management of the live trial data, Cerevel is aware of the limitations of using this system for the archival of their records.

In addition to clinical trial data, Cerevel holds other essential digital records including legacy data, Form FDA 1572s, and standard operating procedures (SOPs); all of which needs to be archived and preserved.



In 2021, given the progress of their trials, the organisation began to develop their plans for archiving and preservation of the trial data to ensure that they were well prepared when the trials near conclusion.

A ‘forward thinking’ approach to digital archiving

In planning for the long-term archival of their data, Cerevel encountered several areas that needed to be assessed and overcome to find the most suitable solution.

Given Cerevel’s focus on revolutionising research and drug development, they want this focus to be reflected in every aspect of their organisation. As such, they actively seek forward-thinking approaches for which their choice of solution for archiving their clinical data needed to align with.

First, Cerevel places Good Documentation Practice (or GDocP) at the forefront of their long-term data management strategy and actively seeks out innovative and effective tools to support this approach.

Part of this commitment to GDocP included alignment with the ALCOA++ principles. Embracing these principles is designed to ensure that the data remains accurate, trustworthy, reliable, and complete, all of which help achieve as close as possible to 100% data integrity.

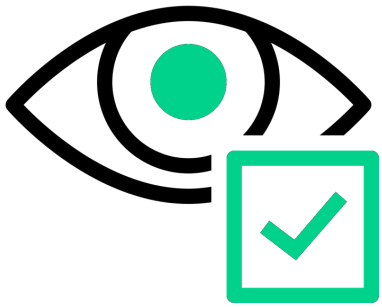
Therefore, a key criterion for the organisation was to find an approach which would support them in aligning to these principles for the entire time that these records needed to be retained.

As a newly established organisation, they were able to learn from historical good and bad practices in the field of digital preservation, and this was a key driver in their desire to align with ALCOA++.

It was also important for Cerevel to comply with EU clinical trial regulation (i.e., EU Regulation 536/2014) around data retention, despite being located within the U.S. This relatively recent update (came in effect in January 2022) to EU regulation stipulates more stringent retention requirements and in turn, has become to be seen by many as a gold standard to adhere to.

Some of these requirements include the provision of a dedicated digital archive and retaining clinical trial records in an accessible and readable state for a minimum of 25 years.

In defining these criteria, **Cerevel** was aware of the risks around retaining data for long periods of time, and needed a solution that ensures:



- Data is safeguarded against corruption and loss
- Records are preserved in usable and readable formats
- Data remains readily accessible throughout the retention period
- User access is controlled, managed and auditable

Organisations often leave archiving considerations too late and are left uncertain about where and how best to archive data at the conclusion of the trial. This case study provides a great example of a best practice approach to planning for and preparing your organisation for the long-term retention of clinical records and data.

Selecting a preservation partner

Across the management team, there was a shared consensus that not only was a digital archive necessary and crucial for the organisation but that they wanted a solution that was 'ahead of the game'. This tied in closely with Cerevel's goal to be forward thinking and revolutionise the clinical trial development process.

First, Cerevel considered building a digital archive internally. However, as a recently established organisation, it was felt that there was a need for external digital preservation expertise to support building a solution and supporting processes from scratch. This led Cerevel to decide to look for an external provider.

At the outset of the selection process, Cerevel established clear expectations and criteria for choosing a vendor. These included:

- Adherence with the ALCOA++ principles,
- Compliance with EU clinical trial regulations,
- A user-friendly solution that the team could manage themselves, and
- Most importantly, expert knowledge of digital archiving and preservation.

To help choose the best provider, Cerevel sought guidance and recommendations from various groups, including the HSRAA (Health Sciences Records and Archives Association), PRIMO (Pharmaceutical Records and Information Management Organisation) and the Avoca Group.

As a result, they shortlisted three vendors for comparison, including Arkivum.

At this stage, Cerevel conducted several meetings and review sessions with the various vendors including having each provider demo their system.

An important element of this process was to ensure that there were representatives from across the organisation at each of these sessions. Although the project was led by the records management team, multiple functions would be users of the solution in some form, and their input into the process was necessary to ensure that the selected solution would meet their often department specific requirements. These included members from quality, IT, clinical, the laboratory and senior management.

After an extensive review of each solution, Arkivum was selected. This was for various reasons including:

- User-friendly navigation and use of the platform.
- Easily access data as and when needed, which can assist for audit purposes.
- Industry knowledge and high-level expertise.
- Available and easy to contact to answer all questions.

Cerevel felt that the Arkivum solution's capabilities went beyond what their current organisational needs were but that they would be a partner who would be able to meet their preservation requirements not only now, but in the future.

Preparing for long-term preservation

As of writing, Cerevel is planning the upload of their first data into the Arkivum solution. There has been a lot of work and preparation to ensure that they are ready and well prepared for when trials conclude, and data is ready to be moved into the archive.

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This section will outline the process that Cerevel have gone through to date, and plans for their long-term data management.

One of the first onboarding steps for Cerevel was for all relevant users to undertake fundamentals training – this was a combination of online training videos and sessions with the Arkivum team to teach Cerevel staff how to use the system and prepare the data to uploaded into the archive. Through this process the Arkivum team can help with any questions that arise.

This training has been designed to be understood and relevant for all potential users of the system, regardless of a background in records management – this includes breaking down key terminology and cutting through any unnecessary jargon.

In the next step, Cerevel are working with Arkivum to plan the migration of their data from their live system into the archive.

During this data migration planning stage, it includes a step calling “mapping”. This consists of the Arkivum team analysing and organising the metadata to reflect the eTMF structure while also identifying any gaps in the data to be fixed. Therefore, when data is moved into the archive, it will not only be findable and accessible (i.e., inspection ready), Cerevel will also be confident that it is complete.

Data migration is and can be a daunting task, with vast amounts of data involved. In working with Arkivum, the Cerevel team have grown in confidence around the data migration process and feel well prepared for the future transfer from live system to archive.

As mentioned at the beginning of this section, Cerevel are yet to upload data into the Arkivum platform but are undergoing the planning and prior onboarding processes. Once the clinical trials have been concluded, and the data is ready for migration, Cerevel will undergo a training refresh of any areas needed. Once confident in the process and with the help of the Arkivum team, the data will be migrated into the solution and secured for archiving and preservation. Thereby, these valuable assets remain accessible, readable, and usable for 25 years and more.

Looking ahead, Cerevel plans to continue with archiving clinical trial data and documents with Arkivum. This includes future clinical trials and internal documentation such as SOPs and legacy data. We hope to be able to bring you future updates on this exciting collaboration between Arkivum and Cerevel.