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Revolutionising eTMF Archiving and Preservation

Ashley Avery – Cerevel Therapeutics

Antonia Witten – Arkivum

Meet the Speakers

Ashley Avery

Title: Senior Specialist, Quality Documents and Archival

Organization: Cerevel Therapeutics

Ashley Avery is the Senior Specialist, Quality Documents and Archival for Cerevel Therapeutics. She first entered the Clinical Research Industry as an In-House Clinical Research Associate with a focus on regulatory start-up. In that role, she heavily focused on proper TMF maintenance to ensure audit ready deliverables for phase 1-3 trials. Her dedication to providing quality documentation led her to transition from a CRA to a quality specialist where she successfully led an all system TMF transition.



Antonia Witten

Title: Customer Delivery Manager

Organization: Arkivum

Antonia Witten works as a Customer Delivery Manager at digital archiving and preservation provider, Arkivum. Within her time at Arkivum, Antonia has built a successful track record of onboarding new clients onto the solution. This is achieved through the use of structured onboarding sessions and helping customers to successfully migrate data, overcoming various obstacles presented in the migration process. .





Disclaimer and Disclosures

- *The views and opinions expressed in this presentation are those of the author(s) and do not necessarily reflect the official policy or position of CDISC.*



Agenda

1. Planning for archive
2. Selecting an archival provider
3. Digital archiving proficient practice
4. Sustainable archiving
5. Archiving to GCP and ALCOA++
6. EU regulations
7. Cerevel's digital provider process
8. Where are we now
9. Archiving end of study migration tips



When did Cerevel start planning for archival?

- Cerevel was established in 2018 with a mission to develop solutions for the devastating effects of neuroscience diseases including schizophrenia, Parkinson's, and epilepsy.
- By 2021, with the given progress of their trials, they began the archiving and preservation plans,
- Cerevel believes in a forward-thinking approach from the beginning

Dedication To Selecting An Archival Provider

Why not keep data in-house?

Cerevel is committed to data integrity. Keeping paper documents in-house compromises that integrity. Instead of relying on resources to keep a department to ensure documents aren't at risk of destruction, Cerevel opted to be digitally innovative in its archival solution approach.

Physical record challenges include but not limited to:

- Lack of organization
- Difficult document search
- Missing documents
- Document visibility diminishing or illegible
- Increase manual needs for retention



Archival Provider Continued

Why not choose other electronic options such as SharePoint, Microsoft 365, Box, etc?

- Higher data integrity and security risks/breach
- Lack of compliant data retention guidance
- Difficult or lagging internet connections
- Lack of organizational tools for report building
- Constant application updates
- While Cerevel strives to be a front runner for technological innovations and updates, we opt for consistency, system validation documentation, and vendor communication prior to the updates to be well prepared for an efficient system update

Digital archiving proficient practice

- Address the risks and challenges that come with using digital records
- Successful retention requires tech, organisation & resource
- Strive for a single long-term repository which is easier to manage over the long-term
- Leverage good practice –
 - HSRAA (Health Sciences Records & Archives Association)
 - Primo (Pharmaceutical Records and Information Management Organization)
 - DPC (Digital Preservation Coalition)
 - NDSA (National Digital Stewardship Association)
- Safeguard your data
- Preserve your data



Sustainable archiving requirements

- Cerevel participates in practices that aim to be environmentally sustainable, this includes digital archiving, which reduces paper usage.



Sustainable long-term data preservation

- Utilizing Infrastructure as a service (IaaS) from cloud providers and their green credentials, including data centres powered by renewable energy
- Auto scaling the compute resources depending on the data being handled- using computer resources when needed
- Using resources in the cloud that would otherwise be left idle (eg: Spot Instances)



Sustainable long-term data preservation continued

- No paper required
- Address the variables- volume of data, processing type, where and when processing is done, tools used, how it is stored
- Accurately tracking the carbon footprint of each activity within the archive (ingest, export, fixity checks, replication of data)
- Deep archive (cold storage) for infrequent accessed data



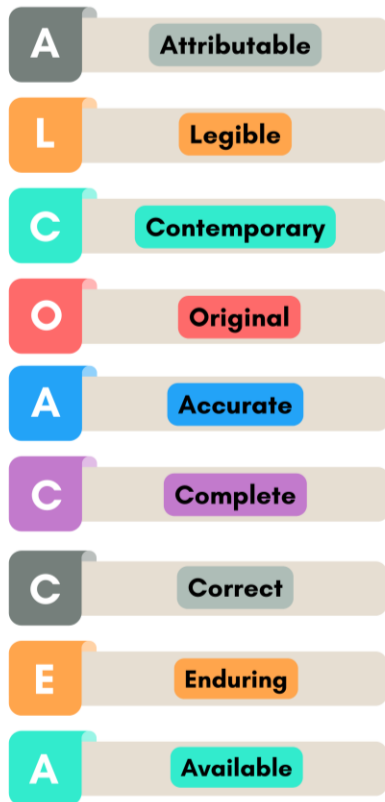
Aligning the Cerevel archiving strategy with Good Documentation Practice (GDocP) & ALCOA++

- GDocP is at the forefront of their alignment principles
- We seek to achieve 100% data integrity by embracing the ALCOA++ principles
- We perform continuous reviews of SOPs and data to ensure GDocP compliance
- We utilize industry experts to provide feedback to ensure unbiased reviews of SOPs to maintain data integrity



ALCOA++ requirements in depth - Enduring

ALCOA+ Principles



“Enduring includes preventing data corruption or loss using appropriate Storage, Integrity checks and Control.”

But what does this mean in practice? Are you doing all the below in your archive?*

- Verifying integrity information when moving or copying content.
- Replacing or repairing corrupted content as necessary.
- Have at least three copies in geographic locations, each with a different disaster threat.
- Have a plan and execute actions to address obsolescence of storage hardware, software, and media.
- Maintaining logs and identify the human and software agents that performed actions on content.
- Performing periodic review of actions/access logs.

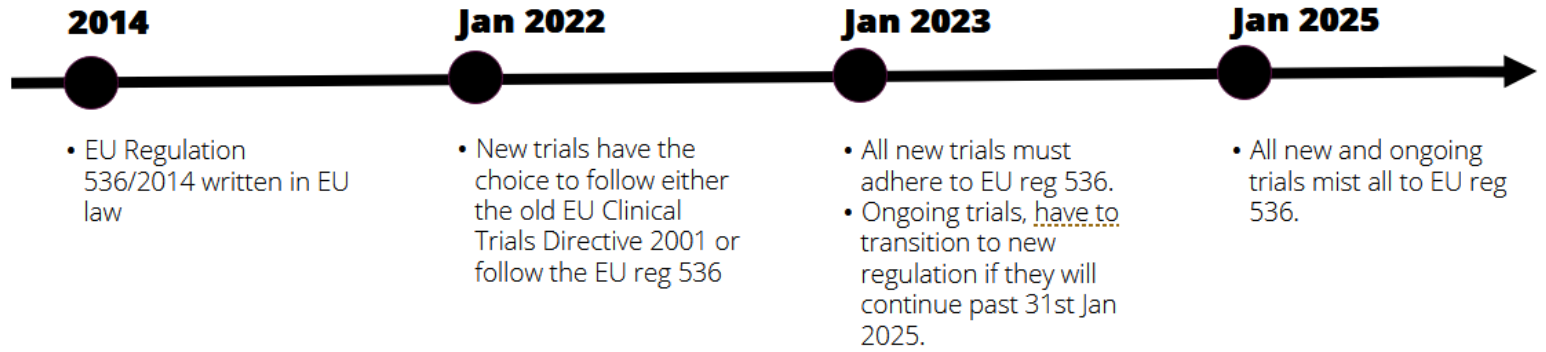
Enduring requires long-term digital archiving and safeguarding.

Cerevel aimed to align with EU regulation 536/2014

- It's been noted the EU regulation provides a more stringent retention requirement which better aligns with Cerevel's mission of maintaining documents with 100% data integrity
- EU requires preservation for a standard of 25 years versus 15 years in the US per ICH GCP.



EU Regulation 536/2014 timeline





EU regulations – retention highlights

- Data Integrity and Quality Management
- Source Data
- Archiving of essential documents
- Retention periods (at least 25 years)
- Storage and security
- Access to archived data
- Data transfer and migration
- Data privacy and confidentiality
- Audit trails

Selecting the right archiving partner for us



EU based company set to meet EU CTR requirements for data retention



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

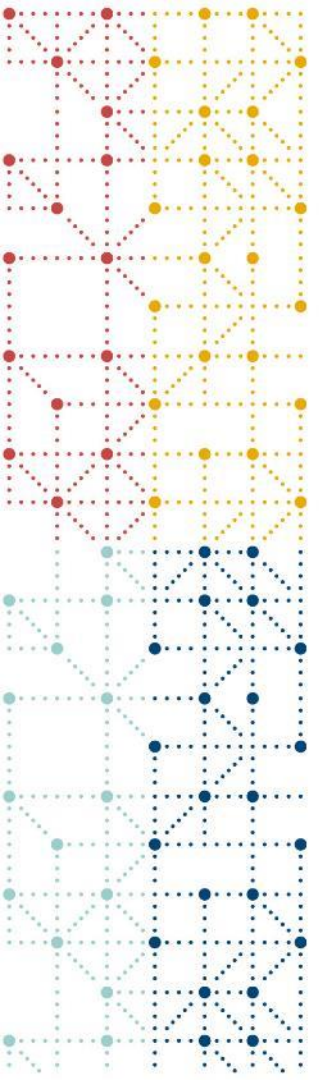


Anticipation of future needs with periodic release updates to stay forward-thinking within the industry



Cerevel's digital provider process

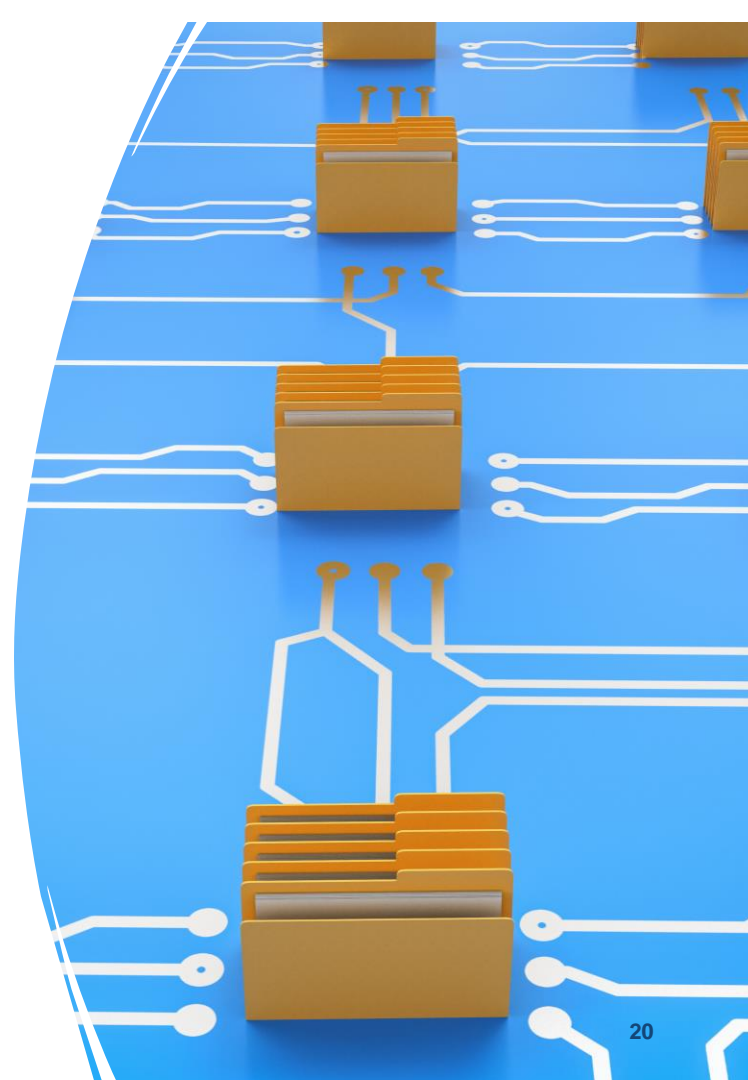
- Cerevel sought multiple demos from digital preservation providers seeking a supplier that was equally innovative in their technological approaches.
- They included members of various departments internally to represent archiving needs from the entire company with varying levels of expertise
- They received guidance from the following groups:
 - HSRAA (Health Science Records and Archives Associations)
 - PRIMO (Pharmaceutical Records and Information Management Organization)
 - Avoca Group



Where we are now...

Cerevel working towards data migration process

- Proactive archiving vs reactive archiving
- Ensures data integrity when not rushing into a post study decision
- Reduces cost
- Ensures quality checks are maintained throughout the study



Cerevel Data Transfer Plan



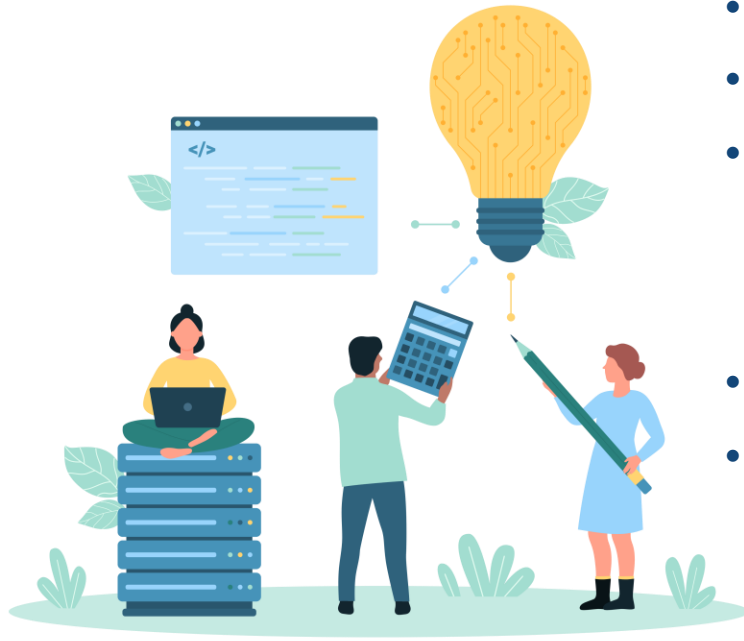
- Involved entities include:
- Business System Owner
- eTMF Vault Owner
- Transfer/Migration Lead
- IT Lead
- Subject Matter Expert
- Develop a transfer plan
- Identified entities utilize an internal Data Transfer Plan to determine a system methodology for data migration

Data Transfer Plan Continued, Vendor Requirements

- Identifying vendor procedures and systems used
- Zip files, usb, etc.
- System access
- Data export
- Checksum performed prior



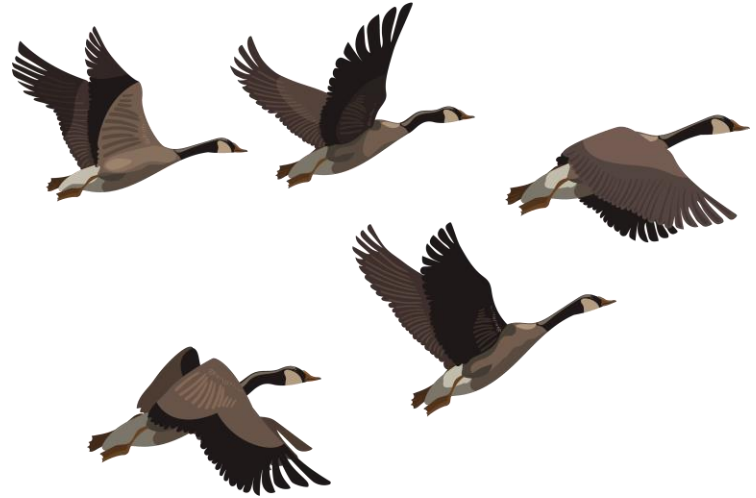
Data Transfer Plan Continued

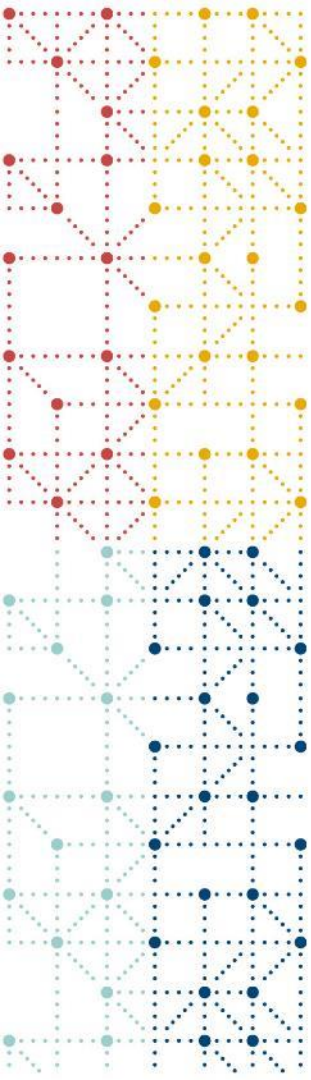


- Transfer testing
- Cerevel sampling performed
- Sampling Procedures and Tables for Inspection Attributes, ASQ/ANSI A1.4-2003 (R2018) utilized to identify business criticality and verification requirements
- Checksum
- Audit Trail

Archiving End of study migration tips

- Plan migration timeline - where, when, who and how
- Know your data
- Testing
- Think long term
- Quality check
- Tidy up





Thank You!

Questions?

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