HSRAA24 CONFERENCE

24-26 SEPTEMBER | EDINBURGH

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Bringing archived data to life

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PROGRAMME

PROGRAMME

TUESDAY 24TH SEPTEMBER - WORKSHOPS 13:00-17:00

GxP-Regulated Archives and the GxP Archivist

Presented by: Neil Gow, UCB & Bob Thompson, TauRx

The "GxP-Regulated Archives and the GxP Archivist" workshop is a detailed and current training workshop that focuses on the key aspects of GxP-regulated archiving, with these main areas of focus:

- GxP Regulations: The workshop will delve into the regulations that impact GxP archives.
- Role of the Archivist: It will cover the role of the archivist in the operation of the archive.
- Archive Design, Operation, and Management: The requirements for the design, operation, and management of an archive will be discussed.
- Archiving Electronic Records: The workshop will provide an overview of how the principles apply to the archiving of electronic records.

This workshop is suitable for archivists who have recently joined the profession or wish to refresh their knowledge of good archiving practice. The principles of archiving covered in this workshop are also relevant for any research or scientific archive.

Data Dynamics: Mastering GxP Migration in the Pharma Industry

Presented by: Pawel Rucki & Frederik Sorensen, Base Life Science

Come to our hands-on workshop where we'll explore the basics of data science and how it's used in GxP data migration for the pharma industry. We've carefully crafted this workshop to give you a solid understanding of data science and GxP data migration principles.

You'll get practical experience with techniques for analyzing, cleaning, and enriching data, which will help you improve your data's quality and usefulness. Our experts will guide you through the key strategies for a successful data migration, taking into account important aspects like budget and timing.

We'll also share key insights on how to choose the best migration vendors, giving you the criteria and questions you need to make smart choices. If you want to make your data migration smoother or ensure it meets all standards, this workshop will provide you with the necessary tools and knowledge to succeed in the fast-changing world of GxP data.

EDINBURGH CITY TOUR & NETWORKING **18:30-21:30**

WEDNESDAY 25TH SEPTEMBER

SESSION ONE - WELCOME, AGM & KEYNOTE **09:00-10:15**

Annual General Meeting of Scientific Archivists Group Limited (Operating as HSRAA)

The Annual General Meeting of the Health Sciences Records and Archives Association (HSRAA) will take place at the start of HSRAA24.

Keynote TBC

Presented by: TBC

BREAK **10:15-10:45**

PROGRAMME

SESSION TWO - INDUSTRY UPDATES — 10:45-12:15

Digital Health Technologies (DHTs) & the Impact to Records & Retention

Presented by: Jamie Toth, BeiGene

An overview of DHTs including FDA Guidance on DHTS and discussion on the impact to records and retention. Patients using DHTs will also be discussed.

Digital Records: A new era in clinical records management

Presented by: Paul Fenton, Montrium Inc.

Many of the interactions we have on a daily basis are now digital and within the realms of clinical trials, we are also starting to see a similar shift. Records management within clinical trials has traditionally been very document-centric, however, that is starting to shift as more and more records are digitized and as we start to move towards a more interoperable data driven approach. This presentation will discuss the concepts and principles of Born Digital Records and how broader initiatives such as ICH M11 or Digital Data Flow will enable a more data driven approach to records management in clinical trials. Finally we will discuss the benefits and opportunities of digital records and considerations for records management and retention.

CDISC TMF Reference Model Risk Management Project

Presented by: Marion Mays, Jerion Consulting Group & Sarah Hitching, Hedian Records Management

We will discuss current activities associated with the CDISC Risk Based TMF Management initiative.

We will cover the various components of the risk-based initiative being led by CDISC volunteers. This will include information about the whitepaper, tools that will support the risk assessment process, and training that will also be part of the deliverables.

The goal is to provide a condensed view of what the initiative is and what kind of deliverables can be expected. We will share the current timeline for the initiative.

LUNCH — 12:15-13:15

SESSION THREE - TECHNOLOGY — 13:15-15:00

Engage in Conversation with a Records Retention Schedule!

Presented by: Stephane Wulc, SANOFI

I have developed a chatbot capable of answering questions based on elements from the Sanofi Retention Schedule.

Questions like: "I have a map of a building, what category of document is that?", "Can I destroy a SOP?", "What is the difference between records related to 'personnel qualification' and 'training'?", "I have a photo of the CEO, should it be kept as a record?", etc

My objective is to provide an enhanced user experience, sparing people the effort of manually searching for the most relevant records type or retention guidelines in an Excel sheet.

The chatbot utilizes Conversational Generative AI and Natural Language Processing techniques. The challenge was to integrate Retention Schedule elements for analysis and responses by Artificial Intelligence.

"A Quiet Place:" Mitigating Risks during GxP Transfers and Migrations

Presented by: Angel Ramos, BeiGene

With last summer's frightening "A Quiet Place" horror films, what better time to discuss risks to your eTMF data? When moving from one location to another—compliance with health authority regulations is a major matter. We plan for an interactive session with real-world scenarios, and hope to make them less frightening. Shh! Let's take in lessons learned and industry best practices during eTMF transfers, internal migrations and archival projects. What deliverables should you expect? How can you ensure data integrity and safe journeys through your "Quiet Place?" What if your data does not step along the path of the CDISC TMF Reference Models? What if it's missing metadata? What if you cannot follow the audit trails? We will look at how to blaze a safe path eTMF transfers for you. We will discuss setting expectations and training transfer project teams, navigate cross-walks between systems, ensure we know what to look for in our new and legacy data, have the necessary tools and playbooks to protect our received data, assess data-in-motion and data-at-rest for long-term integrity, and address any incidents long the way.

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Digital Innovations in Archiving Technology for Regulatory Compliance

Presented by: Ashley Avery, Cerevel Therapuetics | Angel Ramos, BeiGene & Tom Lynam, Arkivum

This panel will delve into the intersection of technology advancement, archiving, and regulatory requirements, focusing on the EU and US standards. 1. Data Archiving Essentials: Archiving involves organizing vast volumes of information into secure storage systems. 2. Emerging Trends and Technologies: To address these challenges, archiving and TMF providers are turning to innovative solutions. 3. Regulatory Compliance: Compliance with regulatory bodies such as the FDA, EMA, MHRA, and ICH is critical. 4. Looking Ahead: As technology continues to evolve, we anticipate further advancements in records archiving.

BREAK **15:00-15:30**

SESSION FOUR - REGULATIONS **15:30-17:00**

The State of Clinical Research in the UK

Presented by: Karen Roy, CDISC

With the UK no longer being part of the EU, the clinical trials landscape has changed and a huge focus has been placed on increasing the number of commercial clinical trials in the UK. As the Chair of the Institute of Clinical Research, I will be looking at the influencing factors on clinical research: the Lord O'Shaughnessy report, the MHRA role with ICH, the standardisation brought about by the NIHR and how partnering organisations such as ICR and HSRAA can bring strength to the clinical trial space.

The EU CTR and its Impact on the Records

Presented by: Karla Navera-Andersen, Ascendis Pharma A/S

The EU CTR was implemented to "increase transparency and restore the EU's clinical research competitiveness by reducing administrative requisites and streamlining workflows" but does it have the same effect on the TMF process? This presentation is about how Ascendis Pharma implemented the new documentation requirements brought upon the new regulation into its budding TMF processes. It will describe how processes were updated due to redactions, required documents, and the Clinical Trials Application System (CTIS). At first glance, we did not realize just how much EU CTR would affect the TMF process at Ascendis. After all, the TMF is only mentioned briefly in two articles of the regulation, articles 57 and 58 - which is not a lot when you consider that the regulation is 84 pages long. And what is mentioned is nothing really all that groundbreaking and frankly, it looks pretty harmless. However, the regulation doesn't give any details on how to do any of these things practically. This is where many of us run into challenges. Because what does the change under the EU CTR really mean on a practical, tangible level? This presentation will outline how and how much the EU CTR affected the eTMF processes in Ascendis Pharma. The EU CTR "forced" us to reevaluate our maybe not so solid processes and create new once that were very much needed. This presentation will mainly look at the documents related to submitting a Clinical Trials Application in the CTIS.

Implementing Risk-Based Approach to Records Management in Compliance with R3 Regulation: A Strategic Perspective

Presented by: Marion Mays, Jerion Consulting Group

In today's rapidly evolving regulatory landscape, organizations are increasingly expected to adopt risk-based approaches to managing information and records. The R3 regulation, a comprehensive framework that focuses on risk assessment, resilience, and recovery in various aspects of trial management, presents a unique opportunity for organizations to enhance their records management practices to better safeguard critical information assets leveraging data and employing risk-based processes. This presentation provides insights into the implementation of a risk-based approach to records management in compliance with the R3 regulation. It explores the strategic implications of integrating risk management principles into records management processes, offering a proactive and systematic methodology to identify, assess, and mitigate information-related risks.

DRINKS RECEPTION & CONFERENCE DINNER **19:30-23:00**

sponsored by cencora PharmaLex

PROGRAMME

THURSDAY 26TH SEPTEMBER

SESSION FIVE - ARCHIVING BEST PRACTICES — 09:00-10:45

Selecting an eArchive Vendor

Presented by: Ashley Avery, Cerevel Therapuetics

This presentation will explore the archive selection process.

1. Building an internal team of cross-functional subject matter experts to collaborate on archiving needs.
2. Determining the optimal time to identify your archiving needs.
3. Aligning your company's needs with regulatory compliance and vendor offerings.
4. System Validation.
5. Defining the archival process: • Data Transfer Plan. • ALCOA++ principles.

Summary: The archive vendor selection process will be delineated through internal team collaboration, proactive timelines, creation of SOPs, and vendor cooperation.

Digital Archiving in Business Continuity Planning

Presented by: Justine Han, Red Nucleus

As the need for digital archiving solutions expands, continuity planning increases in complexity. What are some effective strategies for business continuity planning, and what role do digital archives play? In today's working environment, our daily operational processes not only generate business-critical records but also form the foundational layer of an effective continuity plan. They provide the basis for building an effective framework that takes into account the scenarios that trigger the execution of a continuity plan, controlled documentation in effect, and the stakeholders involved. Our archives, in turn, serve as the source of truth of what actually happened, making them a crucial component of the continuity planning process.

TBC - Panel

BREAK — 10:45-11:15

SESSION SIX - ARCHIVING & BEYOND — 11:15-12:45

A unified approach to requirements specification, qualification and validation of archiving and preservation solutions that makes everyone happy!

Presented by: Matthew Addis, Arkivum

When specifying and selecting a solution for long-term archiving and preservation of GxP regulated data, there are a multitude of stakeholders that need to be satisfied that their requirements will be met. This includes clinical, QA, regulatory affairs, internal IT and more. This is not always an easy task, especially when there are competing viewpoints on suitable solutions! Requirements include long-term GxP Data Integrity, computerised systems validation, information security and data privacy, archiving and records management, audit trails and inspection readiness, data migration and more. This talk will show how the diverse requirements from stakeholders in organisations such as Sponsors, CROs, Labs and Sites can be specified in a URS and how vendors can then show support for these requirements through a Validation Pack and in particular a Requirements Tracebility Matrix (RTM). By combining areas such as ALCOA++, 21 CFR 11, Info Sec and Long Term Digital Preservation good practice into a single URS and matching RTM, there is major utility that goes beyond the usual Computerised Systems Validation (CSV) process.

When to Say "That's a Wrap" to your Trial Master File (TMF)

Presented by: Jacqueline Petty, Cencora Pharmalex

The Trial Master File (TMF) is like the backstage crew of the clinical trial – it runs behind the scenes but plays a crucial role in the overall performance. It's already working away in the build-up to the show and is a hive of activity right up until the final act. So, when the show's over, when do you finally say "That's a Wrap!" to the TMF? This will take an insightful journey into the after-show activities of the TMF, exploring the 'when' and 'how' of closing down this crucial piece of the performance. We'll go behind the stage into the shadowy world of regulatory guidelines, the continuous quest for data completeness, and the dramatic consequences of calling time too early or too late. Bringing in real-world knowledge from time with the backstage crew, can we answer the question of whether there is a perfect ending for the TMF?

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Beyond Storage: Transforming Health Sciences Archives with AI, Machine Learning, and NLP for Advanced Data Classification and Interoperability

Presented by: Hans de Raad, OpenNovations

The expansion of data within the health sciences sector necessitates not just efficient storage solutions but intelligent systems capable of enhancing data utility and compliance. This presentation delves into the forefront of artificial intelligence (AI), machine learning (ML), and natural language processing (NLP) in revolutionizing the archiving and management of health sciences data. Specifically, it focuses on the innovative application of NLP for sophisticated data classification and labelling, a crucial step in ensuring data is accurately organized, searchable, and compliant with regulatory standards. Further, we explore how ML algorithms can be adeptly employed to analyze diverse datasets, significantly improving the semantic interoperability of datasets from varying sources. Through real-world examples and theoretical models, we will demonstrate how ML enables an in-depth analysis of datasets to ensure contextual compatibility and assess overall data quality. Such capabilities are paramount for organizations seeking to integrate and leverage historical and real-time data for comprehensive insights in research, development, and clinical trials. The session aims to illuminate the potential of AI and ML not only as tools for automation but as transformative technologies that can drive the future of health sciences archiving towards more intelligent, compliant, and interoperable systems.

LUNCH **12:45-13:45**

SESSION SEVEN - THE FUTURE OF RECORDS MANAGEMENT **13:45-15:15**

The Future of Records Management: Addressing Proprietary Data and the Retention-Archive Mystery

Presented by: Marcin Hernik & Erin Markle, Cencora PharmaLex

Technology is at the forefront of progress, often making our lives easier and ensuring efficiency and effectiveness in our tasks. However, while we embrace these advancements, we sometimes overlook potential future challenges. Proprietary data and long-term retention do not always go hand in hand; by design, some solutions and file types require the original software for access. This isn't an issue while actively using and paying for these solutions, but will that still be the case in the future? This presentation will explore the problems with proprietary data, the pros and cons of storing native files in the TMF, and the long-term impact of these file types. Is continuing to pay for the software the only answer? What considerations should we make before choosing specific solutions? And has Excel become a proprietary solution in how we use it?

Your New Best Friend, The System Record Assessment

Presented by: Lan Tran, Daiichi Sankyo Inc.

Computerized systems have become the norm for storing our records, but do we know what each system holds? Are we sure it's just what we think is in that system? Have we captured this information anywhere? When paper records were the only game in town, it was easier to know that a cabinet or section of a file room contained a specific kind of record. In the early days of electronic systems, they essentially emulated the paper-based organization with digital cabinets and folder structure. Modern systems have changed how our content is organized and allows us to integrate more information into them. We too need to evolve how we manage our information. How do we ensure that we understand what information is in which system? This is where a System Record Assessment can help reduce that ambiguity. In this session you will learn what it is, why it is needed, how it captures the way systems interact with our data, and how it can bring context to your information management landscape.

Records Management in 2025

Presented by: Reynold Leming, Informu Solutions Ltd

We live in a time of rapid change, where the flexible working revolution has been followed by the surge in use of artificial intelligence. All of this (and more) has huge implications for information management. This talk looks ahead to what will both influence and be the focal points of activity for records management in 2025. It will look across a range of legal, technical and ethical trends and considerations, assessing the impact on and vital role of records management.

CLOSE OF HSRAA24 **15:15-15:45**