JUNE 2013 VALUE £20/€30

Sagacity

Scientific Archivists Group

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Scientific Archivists Group

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Letter from the Editor

Russell Joyce

The overarching theme of both the Bristol and Edinburgh conferences -the challenges of records retention and digital preservation - seem all the more poignant given the news this month that Labour MEP Glenis Willmott's proposed changes to Directive 2001/20/EC have passed the first hurdle in the European Parliament.

Of particular significance to GCP Archivists and Records Managers is Amendment 60, which states: "The sponsor and the investigator shall archive the content of the clinical trial master file for an indefinite period of time after concluding the clinical trial. However, the medical files of subjects shall be archived in accordance with national legislation. If the sponsor is unable to archive the master file, it may be archived in the EU database."

Setting aside for one moment

- the naïveté of the suggestion that a single "EU database" could be used to store all documents for every study for every pharmaceutical company conducting clinical studies in the EU
- that it is doubtful that either Ms Wilmott or the MEPs approving the repeal fully comprehends the meaning of a TMF, the vast volume of records involved, or the variation in relevance, content and format of those records

there appears to be no consideration given to how to overcome the onerous and costly technological challenges of retaining those records (especially digital records) indefinitely. Had those MEPs attended the SAG conferences, I'm sure the viability of these requirements would have been more thoroughly researched and questioned.

Members with a vested interest in these changes might like to think about how best to exert influence when the matter is discussed in full parliamentary session in the coming months.

In the meantime, in this edition of Sagacity the theme of records retention continues with articles from Jon Tilbury on Tessella's digital preservation maturity model whilst James Lappin explores the options for preserving e-mail. Fiona Waddell also provides a comprehensive summary of the usefulness to archivists of the much-anticipated MHRA Silver Guide. On a lighter note, Gail Dams reviews the Edinburgh Conference in words and pictures, Claire Hope gives her first impressions of the conference and Reinhardt Schoebitz reveals all in his "Director Profile".

We hope these articles are enjoyable and informative. If you have suggestions as to topics you would like covered in future editions (topics that will capture the attention or imagination of members) or are willing to submit an article for inclusion in Sagacity, I shall be pleased to hear from you.

For the time being, enjoy the summer holidays. Looking forward to meeting with you all in York in October.

Russell

About The Scientific Archivists Group

The aims of SAG are:

- To develop a professional status for members.
- To advance the disciplines of archiving and records management.
- To ensure archives meet business, scientific and regulatory needs.
- To encourage a high profile with regulatory authorities.
- To keep abreast of trends & developments, particularly technological advances and regulatory updates.
- To encourage consistency across borders, particularly within the European Union.

To achieve these objectives the Group will:

- Promote training in the processes associated with archiving and records management, advance the professional competency of its members and promote co-operative relations with allied organisations.
- Promote standards in the profession of scientific archiving and records management.
- Publish relevant information on the activities of the group and subject matter.
- Organise meetings, congresses and symposia which allow exchange of information on the role of the Archivist and Records Manager.

The group hold bi-annual conferences to promote the exchange of information on the role of the archive and archivist within a changing scientific and regulatory environment. Papers are published in the group's biannual journal along with current awareness features and topical articles to enable members to keep abreast of developments within the industry.

Full membership is open to individuals with an interest in archiving scientific records.

For further information visit our website

www.sagroup.org.uk

Letter from the Chair

Chris Jones

Welcome to the summer edition of Sagacity. My thanks to Russell for his editing prowess. I hope you enjoy this edition!

In April, we had another successful conference in Edinburgh, where a mixture of familiar and new faces came together to participate in workshops, listen to presentations and network with each other. Feedback about the event from the delegates has been overwhelmingly positive. My thanks to Tim Stiles and Gail Dams for making it happen. Organising these events is a lot of work and -at times- quite stressful. We have them both to thank for making it a success. For those of you who have not been to a conference yet, I can promise you will learn a lot and enjoy yourself -hopefully you'll be able to make it to one in the future.

Over the next couple of months, the process of electing the group directors for the next two years will take place. The directors are responsible for the day to day running of the group. Being a director is an excellent way to meet new people, influence the group's direction and perhaps taking on a task outside of your normal day to day work. Being a director of this group is a very rewarding role. If you are interested, I hope that you will put your name forward when the nomination process begins. In the meantime, please do contact me if you are interested in learning more about what is involved.

Since the last edition of Sagacity, we've been learning more about the upgraded SAG website. Like all new technology, it has had a few wrinkles that have had to be ironed out, however we think that it is helping to raise the profile of the group, and provide more services for our members. I strongly encourage you to utilise the LinkedIn group; there have been some good discussions, but I want to see more! Please do take advantage of this service as a means to network with your fellow members outside of formal events, and to help you address any archiving related queries you may have. If you have any queries or suggestions regarding the website, please contact Neil Gow or myself.

So what else do we have planned for the rest of the year? There is the Autumn conference in York, currently in the planning stage; continued progress on the e-Archiving document; kicking off a revision of the GCP archiving booklet and a few other tasks aimed at further improving the quality and value of what we provide to our members. It is going to be a busy few months! I hope that you enjoy a warm, sunny, successful summer!

Chris

Members Pages

General Updates and Information

Welcome to our New Members

We give a warm welcome to new members who have joined SAG since the last Sagacity was published. Contact details for networking may be found in the Membership Directory which is issued twice each year to SAG members.

Name	Organization
Nicole Convery	Medical Research Council, UK
Rachel Keetley	Worldwide Clinical Trials, UK
Rhett Marshall	Qualogy Ltd, UK
Sian Meeking	Retroscreen Virology Ltd, UK
Sharon Lambert	Norgine Ltd, UK
Genevieve Fidele	Takeda Global Research & Development (Europe) Ltd, UK
Joanne McNeill	Warner Chilcott Pharmaceuticals, UK
Jayne Edmunds	Harlan Laboratories Ltd, UK
Hanspeter Huber	Harlan Laboratories Ltd, Switzerland
Helen Lovett-Turner	Health Protection Agency, UK
Caroline Spencer	Lonza Biologics, UK
Heather Hanger	Exco InTouch, UK
Claire Hope	Tribal, UK
Steven MacAllister	MedImmune UK, UK
Kim Hodder	AstraZeneca, UK

Members Pages

News for Retired & Newly Redundant Members

SAG is pleased to announce that it will introduce a new membership category, "Retired Member", for members who have retired from active employment but wish to remain members of the Group to maintain contact and to network with colleagues. The annual subscription for a "Retired Member" will be 50% of the full membership fee (i.e. £25 in 2014). The "Retired Member" category will be available from the 2014 subscription year.

From 2014 SAG will also offer support to members who have been made redundant and wish to remain members of SAG for networking opportunities whilst seeking new employment. At the discretion of the SAG board, SAG members who were fully-paid up members in the preceding membership year and are out of work through redundancy when their membership subscription becomes due, may be provided free SAG membership for a maximum period of one year only.

Administrative Matters

Changes to delegate packs at future conferences

One piece of feedback raised by delegates at several conferences is the value of hardcopy delegate packs containing conference materials, which are made available in electronic format via the SAG website shortly following each conference.

Use of delegate packs following the conference is limited and some attendees complain about having to transport heavy delegate packs back from the conference. Invariably there are also issues surrounding production of these delegate packs, specifically

- changes to presentations when the presenters arrive, compared to what has been provided, leading to a mismatch between the materials in the delegate pack and those being presented and
- presentations provided in advance are often provided very late, making the production of the physical pack a last minute (and stressful!) activity.

In addition, there are costs associated with printing and shipping of the paper delegate packs.

As a result of considering these issues, the SAG directors have agreed that from the Autumn Conference in York that a paper copy of the presentations will not be provided to conference delegates. Instead, the presentation materials will only be made available electronically on the SAG website (for members) or provided via email (to non-members).

Have You Been Working on an Interesting Project Recently?

Have you ever wondered about giving a presentation at one of our conferences but the thought of speaking for 45 minutes is a little daunting (or terrifying!)?

Then why not fill one of the four 15-minute slots that we are making available at our future conferences for any member that wishes to give a short presentation on any relevant topics of interest?

This could be used to provide an update on a project that you are working on or perhaps to raise awareness of a particular issue that you have come across.

If you would like to fill one of these slots then please contact either Eldin Rammell or Russell Joyce. Please also let them know if a colleague has a great subject to speak about. We always welcome new and exciting speakers!

Director Profile
Reinhard Schoebitz

In February 2013, we welcomed Reinhard Schoebitz to the SAG Board of Directors. Reinhard has been an active member of SAG since 2007 and for much of that time has been a "larger than life presence", a dynamic force within the group. Intrigued by his unique brand of infectious energy, we asked him to reveal a little more about himself.

How long have you been an archivist/records manager?

For almost 22½ years. Including my time as a part-time student at Bonn University, it's 26½ years.

How did you become an archivist?

Originally, I was studying to become a teacher. Then at Bonn University I was offered a student's job at the University Archives to earn my living. After a fortnight of working there, I knew I had found my profession.

> *"Reinhard has been an active member of SAG since 2007 and for much of that time has been a "larger than life presence", a dynamic force within the group."*

Which qualities make a good archivist?

I do not know if I am a good archivist, so I am not absolutely sure about the required qualities, apart from knowledge, training, or experience. But I would think that thoroughness, perseverance, curiosity, communication skills, and also the ability to work alone are requirements of the job. And Archivists are normally not job hoppers.

What is the most intriguing aspect of your work?

To support the work of internal customers and company projects by preserving, finding and making available records when and where they are needed.

Where do you see the profession in the future?

Records Management will become more and more an integral and vital part of a company's work and projects, and the increase in e-records -and correspondingly e-archiving- means a big challenge for us all. The Records Manager must be prepared to take over responsibilities for e-archiving as well.

What inspired you to apply for directorship of SAG?

The desire to support the Board in running S.A.G. as best I can.

I could not make it through the weekend without…

- … my Sunday newspaper, "Welt am Sonntag", and a good Scotch Single Malt Whisky.

The clichéd English view of Germans is of a people driven by efficiency and a lack of humour. Is that a fair characterisation?

No, like every cliché it is too generalised. I know English colleagues much more efficient than myself, and I know very humorous and funny Germans. And by the way, English cooking is very good!

German is famed for its ability to express complex meanings in a single word as in 'schadenfreude' & 'drachenfutter'. Which aspects of the English language do you enjoy most?

My impression is that the English language is often more precise than the German. For example, when we wrote the book "Herzschläge -50 Jahr Schwarz Pharma" ("Heartbeats - 50 Years Schwarz Pharma"), the English text after translation was much shorter than the German original and thus we could add additional photographs to fill the book. Since my school days I've loved idiomatic phrases like "Once bitten, twice shy", or "Water under the bridge" (indicating, that what happened cannot be reversed).

I believe you love to run.

I do. I love running. In the early 1980s I spent a year as a Foreign Language Assistant in Barking and Dagenham. Thanks to the connection of my headmaster (himself a former international mid-distance runner) with Chris Brasher (the initiator and organizer of the London Marathon), I was among the 7,747 fortunate runners whose application was accepted to run in the very first London Marathon on 29th March 1981. I remember it was raining that day but it was a wonderful and memorable experience. I was among the 6,255 finishers together with my friends Frank Heigh and David "Alf" Orton with a finishing time of 3hrs 23mins 09sec. I still run today …but on my own and purely for personal pleasure.

Reinhard is wearing number 7253

Your epitaph? Or a pearl of consummate wisdom you would hand down? Or an inheritance track? Maybe all three!

My epitaph? One of my favourite hymns, originally a poem by the German protestant theologian Dietrich Bonnhoeffer (which he wrote in a concentration camp shortly before being murdered by the Nazis): "Von guten Mächten wunderbar geborgen / erwarten wir getrost, was kommen mag. / Gott ist bei uns am Abend und am Morgen / und ganz gewiß an jedem neuen Tag." ("By loving forces wonderfully sheltered, / we are awaiting fearlessly what comes. / God is with us at dusk and in the morning / and most assuredly on ev'ry day.")

> *"Since my school days I've loved idiomatic phrases like "Once bitten, twice shy", or "Water under the bridge" (indicating, that what happened cannot be reversed)."*

My wisdom? For everyday working life: "The situation is hopeless, but not earnest!" For life as such, I heard it some time ago from a protestant priest that "You cannot fall lower than into God's hand."

My inheritance track? I cannot think of anything specific. I love all kinds of music because it goes straight to the heart.

Schadenfreude noun

To take delight pleasure in the misfortunes of others

Drachenfutter noun

A husband's gift to his wife for misdemeanours

GLP Consultative Committee Update

Richard Pennicard

Andrew Gray, the head of the Good Laboratory Practice Monitoring Authority has written to SAG, and other stakeholders to inform us of changes to the way the GLP, GCP and GPvP consultative committees will operate. This is what he said:

"One of the strategic objectives of the MHRA is to provide accurate, timely and authoritative information to stakeholders. One of the ways in which the Inspectorate meets this objective is to actively engage with stakeholders through meetings, symposia and consultative committees.

Consultative committees have been running in the GLP, GCP and GPvP areas for a number of years with the aim of providing advice to interested parties on each technical area and their associated inspection programme. These have proved a valuable means by which the Inspectorate has been able to directly discuss issues and topics with various groups and organisations.

It is felt, however, that the time has come to review the current structure of these committees and to pilot a new approach to the meetings. As such, a meeting will be held on 25th October 2013 from 13:30 at our main office in central London.

This meeting will be split into 2 parts. The first part of the meeting will be a joint GLP, GCP and GPvP session in which topics relevant to the MHRA as a whole and/or all technical areas will be discussed. The meeting will then split into 3 streams to allow discussion of topics relevant to each technical area. […]

The aims of this new structure are as follows:

- *To streamline the process and reduce the administrative burden*
- *To provide consistent information and advice across the 3 groups*
- *To provide a forum to encourage discussion of relevant issues across the 3 disciplines*

As stated above, engaging with stakeholders is an important component of the work of the Inspectorate. […] If you have any questions in relation to the new structure then please do not hesitate to get in touch.

Andrew J Gray BSc PhD

Head GLPMA (or electronic)"

If anyone has any questions (technical or policy) to put to the inspectors about the way that GCP, GPvP and GLP is inspected and enforced in the UK, please e-mail Richard at *treasurer@sagroup.org.uk*, and he will pass them on (anonymised if desired).

About the Author:
Richard Pennicard is the QA Controller at Selcia

How useful is the Silver Guide to Archivists?

Fiona Waddell

Archivists have floundered in the wilderness without instruction or direction for many years which is very surprising when you think that they hold the key to the final audit trail of all clinical trials, laboratory work, animal testing, the manufacturing process and much, much more.

If you wanted to find out how to archive clinical trial documents and consulted the MHRA website in order to find this information you will be directed to a GLP archiving document. This is useful but many parts are only relevant for the laboratories for which it is intended. Commercial archives use British Standard BS 5454: 2000 Recommendations for the storage and exhibition of archival documents but this is not always enough when considering scientific documentation and materials and the regulations/requirements pertaining to them.

However, the MHRA must have heard your cries of frustration because, in a collaboration between the Clinical Trials and Statistics Units of the MHRA Licensing Division and the HRA (via NRES) they have come up with the Silver Guide (also known as the Grey Guide) and this does give archivists useful direction and guidance even if it's only in the field of GCP.

The Silver Guide is a practical and pragmatic guide for those involved in any aspect of clinical trials including archiving. It gives lots of examples and provides information on what is in the regulations and what is standard practice or MHRA expectation in the UK.

The Silver Guide clears up confusion e.g. it states that a requirement is to be in compliance with the EU Regulations, Directives and UK Statutory Instruments (the word 'must' is associated with a requirement); guidance has the word 'should' associated with it and good practice has the words 'recommended' or 'suggested' associated with it.There are 14 chapters in the Silver Guide but Chapters 2 -5, 9, 12 and 13 have no mention of archiving so, unless you are interested in other aspects of clinical trials as well as archiving then I suggest you flick over these. This leaves you with 6 chapters to read and, specifically, Chapter 10 gives you the real archiving meat.

So, what does The Silver Guide say about archiving?

Chapter 1: Sponsor Oversight

Keep a TMF to hold all documents relating to that trial and appoint a named individual (s) responsible for archiving the trial essential documents. This also includes having sponsor oversight of a vendor archive.

Chapter 6: IMPs

The requirements for the retention of IMP documentation are defined in Article 9 of Directive 2003/94/EC (GMP Directive).

Chapter 7: Monitoring

Gives details of suggested monitoring activities at the various trial periods to include 'Complete and archive the investigator site file' and 'All support department files are present, complete and archived with the investigator site file'. It also says that the archive facilities for the ISF should be reviewed by the sponsor.

Chapter 8: Data Management

Contains a section on comparison of paper and electronic CRFs and states '...there is no consideration given to the long-term access to the data on the disc (eg if software becomes obsolete) or to backing up the data'.

Chapter 10: TMF and Archiving

This chapter says it is essential to have a suitable indexing system in place in the TMF. Vendor involvement in the TMF allows the vendor to retain and archive internal vendor records. All essential documents listed in Chapter 8 in ICH GCP and Chapter 3 of the TMF guidance document are the basic minimum that must be retained.

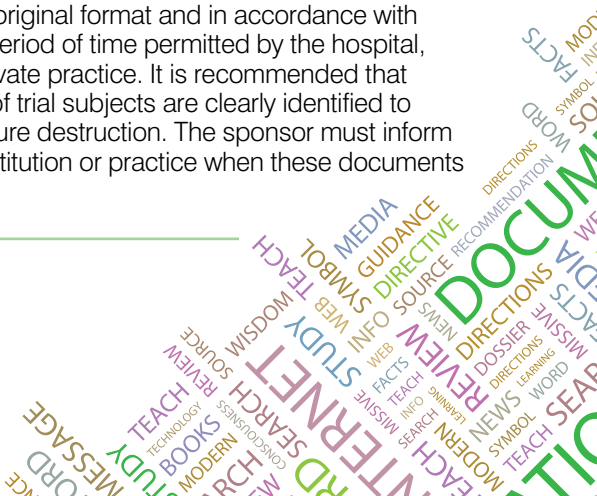
Chapter 10: TMF and Archiving (e-Mails)

The thorny question of what you do with emails is answered: e-mails must be kept. However, those of no value may be discarded but there should be a formal process to assist individuals in their evaluation.

Chapter 10: TMF and Archiving (Document Retention)

Retention of the documents within the TMF and the medical records of trial subjects is a legal requirement and must be retained for at least 5 years after the conclusion of the trial. If the data is to support a marketing authorisation it must be retained for at least 15 years after completion or discontinuation of the trial or at least 2 years after the granting of the last marketing authorisation in the EC or at least 2 years after formal discontinuation of clinical development of the IMP. Additionally, the sponsor or other owner of the data must retain all other documentation pertaining to the trial as long as the product is authorised. Additionally, the final clinical study report shall be retained by the sponsor or subsequent owner, for 5 years after the medicinal product is no longer authorised. Retention periods must be documented in the clinical trial protocol. It is a sponsor responsibility to ensure that all trial records are available to the MHRA throughout the retention period, in particular for documentation held by vendors.

Trial subjects' medical files must be retained for at least 5 years in their original format and in accordance with the maximum period of time permitted by the hospital, institution or private practice. It is recommended that medical notes of trial subjects are clearly identified to prevent premature destruction. The sponsor must inform the hospital, institution or practice when these documents



no longer need to be retained. The sponsor should notify investigators in writing when their trial records can be destroyed.

Advanced therapy IMP trials have a longer retention period of 30 years after the expiry date of the product or longer if required by the clinical trial authorisation.

Archiving requirements for paediatric trials should meet the requirements of Directive 2003/63/EC.

Records relating to written procedures, staff training records or maintenance and calibration records for equipment used in the trial must also be retained and archived.

Chapter 10: TMF and Archiving (Named Individuals Responsible for Archiving)

It is a legal requirement that the sponsor appoints a named individual within the organisation to be responsible for archiving the documents which are, or have been, contained in the TMF, and that access to these documents must be restricted to those appointed individuals and auditors or inspectors. This can be undertaken either by having a specific archivist role or by combining the archiving duties with another role, but in either case there must be clear documentation to support the appointment and appropriate training provided. The named individual responsible for archiving must have a clear legal link to the sponsor, in that they are the sponsor themselves or employed or contracted by the sponsor. Although an investigator site institution is not required to have a named individual responsible for archiving (unless they are a sponsor in their own right), it is recommended that, where an organisation has many trials, there is a person responsible for this activity.

Chapter 10: TMF and Archiving (Ownership of documentation)

Where there is a change of ownership of data or documents connected with the clinical trial, eg, transfer of a marketing authorisation to another organisation, then the sponsor must record the transfer and the new owner must be responsible for data retention and archiving.

Chapter 10: TMF and Archiving (Review of TMF Prior to Archiving)

Before the TMF is archived, it is recommended that it is checked to ensure that it is complete and that all necessary documentation has been filed.

Before archiving it is important to weed out duplicates and those documents that may be subject to rapid deterioration or need special requirements in order for them to be retained, such as needing to be transferred to other media.

The investigator must locate any trial-related files eg pharmacy IMP files and combine them with the investigator site file. Alternatively, if pharmacy retains and archives its own files then the process and documentation should be assessed by the sponsor.

Chapter 10: TMF and Archiving (Tracking of archived documentation)

Removal of the records from the archive is anticipated to be a relatively rare occurrence and the records should track transfer of documentation to and from the archive facility (particularly where contract archives are being used) and, where appropriate, such as for large organisations, location of the documentation on site when it is temporarily removed from the archive. The process should be controlled or overseen by the named individual responsible for archiving. For TMFs that are returned to the archive it is recommended that the contents are checked to ensure all the originally archived records are still present.

Chapter 10: TMF and Archiving (Sponsor Archiving on behalf of the Investigator)

The investigator should retain control of the documentation contained in the investigator site file. The investigator site file should never be sent to the sponsor organisation except where the sponsor and investigator are essentially the same.

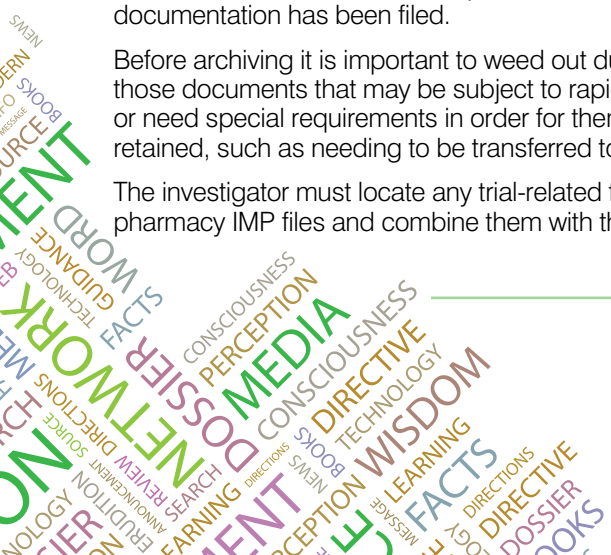
This does not mean that an external sponsor cannot arrange archiving on behalf of the investigator; this is acceptable, subject to the following being implemented:

- The archive arrangements are formally agreed and documented between the sponsor and investigator or host institution
- A formal procedure is in place such that the documents are only released from the external archive with the approval of the investigator or host institution. It is recommended that this is tested for robustness. Permission from the investigator or host institution should also be required to permit access to the contents of investigator site archived materials at the archive facility
- The records go directly between the investigator site and an archive facility independent of the sponsor, thereby ensuring that the sponsor does not have uncontrolled access to the investigator files.

Chapter 10: TMF and Archiving (Contracting out archive facilities)

The storage of the sponsor's or investigator's documentation may be transferred to a vendor eg a commercial archive, but the ultimate responsibility for the quality, integrity, confidentiality and retrieval of the documents resides with the sponsor and investigator respectively. It is strongly recommended that the sponsor/ investigator assesses the facility (eg by audit) for suitability

(...continued)



How useful is the Silver Guide to Archivists?

(continued)

prior to use and that consideration is given to ongoing assessment. There should be a formal contract in place between the sponsor/investigator institution and the archive company. It is recommended that the sponsor/investigator makes sure it is made aware of the storage location of its TMFs if the archive company has more than one storage facility.

Chapter 10: TMF and Archiving (Storage Areas -Section 10.7.8)

The storage area for the TMF records must be appropriate to maintain the documents such that they remain complete and legible throughout the required period of retention and can be made available to the competent authorities upon request. This may be assessed on a risk-adapted approach. Some areas to be considered when performing such a risk assessment include:

- Security
- Location
- Size
- Environmental
- Pests

British Standard BS 5454:2000 Recommendations for the storage and exhibition of archival documents is a standard for commercial archive facilities and this may be considered in maintaining purpose-built archive facilities as well as for the assessment of potential contract archiving companies. It is essential that the sponsor makes a documented assessment of the storage conditions at the investigator site for the investigator site file, and that the investigator provides this information.

Chapter 10: TMF and Archiving (Electronic Archiving -Section 10.7.9)

The use of electronic systems for such activities as data management, statistical analysis, reporting, trial management systems and eTMFs means that electronic documentation and data are likely to need to be retained. The data may be on a server or on transportable media (eg USB drives, CDs, tapes). It is recommended that more than one copy of the data is retained: eg back up if stored on a server (back up stored in a different location). Consideration may be given to storing the data in different formats on different types of media or even on the same media from different manufacturers.

Access to archived data must be suitably restricted by user access levels to the archive area of a server or by controls to access the storage area where the media are retained (as for paper). Additionally, the electronic documents or data that have been archived must be protected from unauthorised changes to maintain authenticity.

It is important that future access to records and data is maintained. This could include maintaining the system (hardware and software) to access the data in its original format, or the use of a new system to emulate the old software or migration of the data into a new format to ensure continual access with new software. This issue should be addressed by the organisation via written procedures.

Media used to store the data may potentially deteriorate or become obsolete e.g. floppy discs. The transfer of data to new media as technology advances would need to be considered by the organisation. It is also recommended that periodic test retrieval or restores are undertaken to confirm that on-going availability of the data is being maintained.

Where data have to be migrated to a new media or a new format, then the transfer should be validated and fully documented, so that it can be subject to audit, to ensure and demonstrate that there has been no loss, change or corruption to the data or metadata and that authenticity is maintained.

Chapter 13: Clinical Trial Samples

If a laboratory is contracted by the sponsor to retain source data, they must be stored in a way that ensures their integrity and security. Retention times should be agreed with the sponsor prior to the initiation of the work and will usually form part of the agreement between the laboratory and the sponsor. It is important that information relation to retention is known generally and not just by one person in case they leave and take the information with them.

Chapter 14: Quality Systems

Although no mention is made of archiving in this section it is recommended that all archivists read this in order to ensure compliance with their own QMS.

So, is the Silver Guide useful to Archivists?

Yes, it is but it doesn't go far enough. There is a section at the beginning of the Silver Guide that is an invitation to comment on the content of the guide. This is a golden opportunity (or maybe a silver one!) to give your archiving-specific comments and make this a truly comprehensive guide to all activities involved in clinical trials.

Fiona Waddell

Fiona Waddell is the managing director of 3D Clinical Research, a virtual CRO consultancy in Edinburgh. She is also a Director of Tower Mains Ltd (TMQA and Tower Mains Training) and The Learning Principals (a soft skills training organisation). Her qualifications for writing this article are that she has been involved in life sciences for more than 30 years at all levels and in many therapeutic areas across the full range of phases of clinical trials.

Did You Know?

Has Expanded Further and Opened Another New Archive Facility

Outsource your Archiving

- **Independent secure storage for your ISF & TMF**
- **Separate locations for back up data**

Freeing up Internal office space

- **Regulatory Compliant**
- **Personalised Service**
- **Cost effective**

If you require further information on any of the services offered please contact:

The Archivist
Qualogy Ltd
PO Box 6255
Thrapston
Northamptonshire
NN14 4ZL

Telephone: +44 (0)1933 357953
Email: archives@qualogy.co.uk
Web Address: www.qualogy.co.uk

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Preserving e-Mail – Records Management Perspectives

James Lappin

On 29th July 2011, the Digital Preservation Coalition event "Preserving e-Mail: Directions and Perspectives"[1] brought together records managers, archivists, cultural heritage institutions and digital preservation experts to discuss the problems of preserving e-mails (Chris Prom's Practical e-records blog[2] provides a detailed summary of the event). In this article I shall give some thoughts on the records management perspectives raised at that event.

Three Approaches to Managing e-Mail

Stephen Howard gave his take on the three different approaches records managers could take to e-mail:

- **The message-by-message approach** – where users are encouraged to move significant e-mails out of their e-mail client and put them together with other documents arising from the same work (this is the traditional records management approach).
- **The e-mail account by e-mail account approach** – where some individuals within the organisation are selected as having particularly important roles, and their entire e-mail account is preserved.
- **The whole e-mail system approach** – where the organisation treats its entire e-mail system as one aggregation and applies one retention or preservation rule to the entire system.

In his current organisation Stephen is thinking of applying the in-box by in-box approach. It would be relatively easy to identify people in key roles whose e-mail was worth preserving. Those individuals could be told of the organisation's intention to preserve the contents of their e-mail account after they had left. They could be given ways of filtering out personal e-mail so that the personal stuff did not enter the archive.

Earlier in the day Stephen had given a presentation[3] in which he reflected candidly on advice he had given back in 2005 to a local authority he worked for at the time. The head of IT in the authority was concerned about the e-mail servers, and their lack of resilience in the face of mounting volumes of traffic and e-mail storage. They wanted to buy an e-mail archiving tool, to remove stored e-mails from the production e-mail servers. Stephen at the time advised them not to.

The authority decided against an e-mail archive. Instead they adopted the intention of implementing an electronic document and management system (EDRMS) to manage records in all formats, including e-mail. In the meantime they used an array of methods to encourage colleagues to adopt better e-mail practice.

The authority:

- asked colleagues to save significant e-mails into shared drive folders
- put quotas on e-mail in-box sizes to encourage staff to weed out ephemeral e-mails
- encouraged people to avoid sending attachments where alternatives existed
- gave advice and training on good use of e-mail

None of these measures did any harm, but the overall approach did not work. Few colleagues saved e-mails into the shared drives. The bottom fell out of the EDRM market and the EDRM never came. Stephen wondered whether the IT manager was right after all – maybe the e-mail archiving tool would have been the least-worse option.

Records Management Concerns about e-Mail Archiving Tools

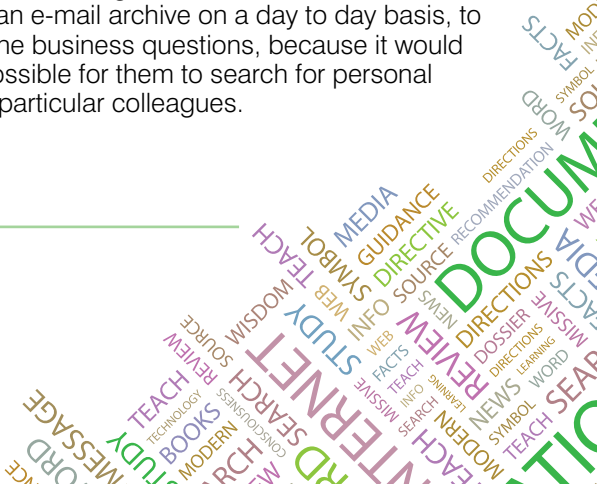
Records managers have had philosophical concerns about e-mail archiving tools. A standard definition of a record is that it consists of all documentation regardless of format needed as evidence of a piece of work. The idea of treating one set of documentation (e-mail) differently purely because of its format was anathema to us records managers.

There are practical as well as philosophical concerns. In particular the concern that an e-mail archive operates as a 'black hole'. Such an archive may well have a great search engine, but how could the organisation allow people to use that search engine given the vast amounts of personal information buried in every e-mail account? The fundamental problem is that a typical e-mail account makes no differentiation between innocuous e-mails, and e-mails containing sensitive personal information about the e-mail account holder or the people they correspond with.

In practice an organisation could allow:

- individuals to access e-mails in the archive that were sent to or received by themselves
- central administrators to search the entire archive for e-mails that fall within the scope of a legitimate e-discovery request, data protection subject access request or Freedom of Information request

But I don't see how an organisation could allow staff to search across an e-mail archive on a day to day basis, to answer mundane business questions, because it would then also be possible for them to search for personal information on particular colleagues.



Yes, you could tell staff that if they send or receive e-mails containing sensitive personal information about themselves or third parties then they should delete it from the e-mail archive, or flag it up with an access restriction. But could you ever be confident enough that this has been acted upon to widen up access to the e-mail archive?

The access permission problem means that organisations will not want to give up totally on the idea of having e-mails aggregated in some ways, other than simply lumped together in an e-mail archive divided into individual e-mail accounts. One of the aims of Customer Relations Management CRM) implementations is to ensure that e-mails to/from customers are aggregated by customer rather than by the e-mail accounts of the members of staff that sent/received them. An EDRMS implementation aims at aggregating e-mails and other documentation according to the piece of work that they arose from. Both approaches offer the advantage that access permissions can be ascribed that fit the nature of those e-mails.

We need to have our cake and eat it. The advantage of e-mail archiving tools is that they give you the security of knowing that you have a record of everything that has come in or out. But what we also need is the ability to apply frameworks that enable those e-mails to be understood, managed and accessed according to different criteria than the name of the individual who sent or received them.

What Impact will MoReq 2010 have on the e-Mail Archiving Tool Market?

Until recently the records management world treated the existence of multiple applications within an organisation (e-mail clients, line of business applications, CRM systems, an HR system etc.) as a problem that could best be mitigated by implementing a single electronic records management system and endeavouring to get all documents or e-mails needed as records saved into it.

The recent MoReq2010 specification takes a different approach. It attempts to boil down a core set of records management requirements with a view to making it feasible for any and every business application to have enough records management functionality to manage its own records, and to export those records and accompanying metadata, rules and classifications at the end of the useful life of the application. This is hugely ambitious, as line of business application developers and vendors rarely take notice of records management specifications.

The first output of MoReq2010 – the **"Core Services and Plug-in Modules"**[4] published in June 2011, does not specifically mention e-mail. This is because the core services cover only that minimum set of requirements that every records system should possess, and it is possible to envisage a records systems that is not intended to hold e-mails. But an extension module of MoReq2010 is planned, to specifically outline MoReq 2010 records management requirements for e-mail.

It will be interesting to see what effect that MoReq2010 e-mail module, when it appears, will have on the e-mail archiving tool market. A MoReq 2010 compliant e-mail archiving system would be an interesting proposition for records managers: I wonder if any of the big players in the market will rise to the challenge.

The 2009 Gartner **"Magic Quadrant Report"**[5] on e-mail active archiving tools shows that many such tools are branching out from simply archiving e-mails and now claim to be able to archive and manage material in shared drives and in SharePoint sites. All the more reason for such products to go for MoReq 2010 certification.

Whether they do go for it depends in part upon their willingness to re-architect the way their systems maintain metadata and event histories. MoReq 2010 is much more prescriptive on these fronts than previous standards, and established players with set architectures may be reluctant to change.

James Lappin

James Lappin is the Founder and Director of "Thinking Records Ltd" and currently co-chairs the Information and Records Management Society's London Group. After obtaining his MA in Archives and Records Management at UCL in 1994, James was RM at The National Archives, London Borough of Hammersmith and Fulham, and the Wellcome Trust before becoming an RM consultant and trainer for TFPL in 2004. Since then, James has had the privilege of advising high-calibre clients including the International Committee of the Red Cross, the UK National Air Traffic Service, and the Houses of Parliament and for five years provided RM training to the European Commission. James was lead researcher for Northumbria University's 'Investigation into the use of SharePoint in UK Higher Education' and now regularly presents on the conference circuit, specialising in the impact of SharePoint and on the rise of Web 2 on RM practices.

This article first appeared as a blog at *http://thinkingrecords.co.uk/* is kindly reproduced by permission of the author.

1 *http://www.dpconline.org/events/details/32-preserving-email-directions-and-perspectives*
2 *http://e-records.chrisprom.com/preserving-email-the-nature-of-the-problem/*
3 *http://e-records.chrisprom.com/why-preserving-email-is-harder-than-it-sounds-steven-howard/*
4 *http://moreq2010.eu/pdf/moreq2010_vol1_v1_1_en.pdf*
5 *http://www.gartner.com/technology/media-products/reprints/commvault/article1/article1.html*

Digital Archiving Maturity Model

Jon Tilbury

Organisations are realising that it is business critical to archive digital information for several years. Ensuring archived information can be accessed when the need arises is key, as is creating value from assets that are archived.

The term **"Digital Archive"** is however used to cover many different types of solution for this problem. This paper provides a way of categorising these different approaches to enable organisations to understand the differences and to select the best solution for them.

Why a "Maturity Model"?

The term Maturity Model is used to imply layers of sophistication in processes, the first of which must be complete before graduating to the next. This is true for Digital Archiving – there is no point having a clever information management system if you do not have secure storage.

Key Components

The Digital Archiving Maturity Model has two main sections:

Durable Storage

Layers 1-3 provide increasing levels of sophistication in the safety and security of the storage of the raw bits used to hold information. By the time you have a Level 3 compliant system you can be confident your information will not be lost and that it has not been tampered with.

Information Management

Layers 4-6 ensure that the preserved raw bits can be found and interpreted correctly now and in the future. With a Level 6 system your information is organised and searchable, the processes are automated and you can use it as you wish.

Level 1: Safe Storage

The simplest layer incorporates simple bit-level storage on magnetic or optical storage with some level of reassurance that the bits are protected against simple storage failure. This includes storage on protected spinning disks using RAID techniques, optical media with long-term storage and managed locations, or long-life tape storage.

Level 2: Storage Management

At level 2 we add active storage management which moves the bits to the most appropriate location. The decision on which bits are located where may be done on the basis of storage durability, cost reduction, or performance. The criteria are flexible to balance all of these drivers.

Level 3: Storage Validation

The final storage sophistication adds multiple object storage plus fixity checking to validate storage durability. Object fixity is checked on storage, access and at regular intervals to confirm objects have not been tampered with. If bit failure is identified, self-healing from an alternative copy will occur.

The Best Storage System

A level 3 Storage System appropriate to Digital Archiving will combine intelligent storage virtualisation with the digital object assurance. This will make sure it is possible to store the information efficiently and retrieve it as required, sure in the knowledge that it has not been tampered with during this process.

Level 4: Information Organisation

The first level of information management incorporates information hierarchy organisation, descriptive data management, and simple processes for uploading, locating and downloading information. Basic information security is also included.

Level 5: Information Processes

The next level of sophistication adds efficient and flexible business processes to automate the activities associated with information management. These include interfaces to the information sources and dissemination to information consumers using flexible workflows and programmer interfaces. They also include high-throughput capabilities and integration with a third party identity management system. Non-archiving processes such as object versioning, should be excluded.

Level 6: Information Preservation

The most advance Digital Archiving systems add capabilities to ensure that the information stored is usable when it is needed by the audience that requests it. This turns out to be highly complex as file formats and the applications that can read them are short lived and fragile. A level 6 solution contains a variety of strategies to ensure the information is accessible for as long as it is needed – which may be forever. These could include file format identification, characterisation, validation, and migration to multiple alternative formats with different purposes. Alternatively it could include ways of using the original file long into the future by emulating the original software and/or hardware.

The Best Digital Archive System

A level 6 Digital Archive system is built on level 3 Storage and incorporates all of the features of levels 4-6. Systems that incorporate full Information Preservation are very rare in this emerging discipline.

What do I Need?

A key question to ask is what level of sophistication do I need? If it is raw storage you are looking for levels 2-3 might be good enough. If you just need to keep information for a couple of years but need to be able to find it quickly level 4 might be sufficient. If you have high volumes of information and few staff you will need a level 5 System If you are concerned about being able to find information and to be able to use it more than 5-7 years after it was created you need a level 6 System.

Jon Tilbury

Jon has led Tessella's Archiving Solution business from its inception. Under his leadership our archiving capability has grown from a research project, to a productised archiving platform (SDB) in use by national libraries and archives on four continents, and more recently to the creation of cloud based Software as a Service offering (Preservica). Jon is now able to concentrate all of his time to developing the archiving division and plans to significantly expand the business.

Jon joined Tessella in 1986, after a degree in Materials Science from Oxford and has worked in many roles within the company including programming, system design, project management, technical management and business development across multiple industry sectors. He completed his Institute of Directors Certificate in Company Direction in 2000.

Spring Conference 2013

Gail Dams

As I looked through the photographs from the Spring Conference in Edinburgh I was once again reminded how well it went. I hope you enjoy seeing them yourself.

The workshops on the first day as always proved very popular. We attempted to cover as much of the aspects of archiving as possible in the time available, and I think even those more experienced delegates came away with nuggets of new information. The content and presentations of the speakers on the Friday sessions received good reviews.

Some of the positive feedback received about the conference included comments on the informality of the conference, the ability to mingle and network, the structured presentations being presented without the pressure of feeling that they needed to 'know everything' and that everyone was at the event to learn. Delegates from 'newbies' to those that have more experience were able to swap information and ideas in a friendly environment. I'd like to extend our grateful thanks to those who led the workshops and presentations.

Gail Dams

Presenters & Delegates
At Work and Play Photo Gallery

First Impressions (Conference Attendee Experience)

Claire Hope, Reckitt Benckiser

I am Claire Hope. I have worked as the Archive and Library Assistant for Tribal at Reckitt Benckiser in Hull since March 2010.

Firstly, thank you to the Scientific Archivists Group for a great two day conference at the George Hotel in Edinburgh. I honestly enjoyed it and really learnt a lot as I am quite new to the world of archiving and this was my first SAG conference. I found that both the organisers and other attendees were very approachable; I was made to feel very welcome by everyone involved. The staff at the hotel where extremely kind and helpful, even though we could not check into our rooms upon arrival the hotel was kind enough to let us leave our bags in a locked room until the afternoon workshops had finished.

On day one I attended the workshop The Role of The Clinical Archivist/Records Manager which was delivered by Russell Joyce of Heath Barrowcliff Consulting. This was the workshop which I thought was most beneficial to me as clinical archiving is a big part of my day to day work. My colleague and I then attended the second workshop which was TMF workshop delivered by Liz Hooper from Plexglobal. This workshop was interesting as I have always wanted to learn more about what a trial master file contains and how it is used.

After checking in and finding my room there was time to relax before heading to the conference dinner. The food was very nice (as was the wine!) and it was great to get to know other members of SAG, their archiving backgrounds, what organisation they work with and where they have travelled from, including some general chit chat.

Day two included a lovely breakfast. The day was a little busier starting bright and early and getting straight into it with a presentation on digital archiving and preservation by Jon Tilbury from Tessella. Even though the company that I work with does not yet have a digital archive, I still wanted to take back as much information to share with my colleagues. With my new digital archiving knowledge I have seen how so much more modern this way of archiving is. It would be really great to implement this within Reckitt Benckiser.

After our mid-morning coffee and a cream scone the next presentation was "Challenges and Solutions to Long-term Records Retention and Access" delivered by Matthew Addis from Arkivum. This was another presentation that I found very interesting and upon my return to Hull I relayed my new found knowledge on retention policies to the rest of my team and we are implementing a more regimented policy.

Next was a presentation on the archving of electronic records and documents by Tim Stiles followed by lunch, which was yet another lovely meal!

After lunch there was a regulatory update and run through the MHRA Good Clinical Practice Guide (now called the "The Silver Guide" as opposed to "The Grey Guide" because of the unintended association another bestseller with "Grey" in the title!) from Fiona Waddell of Tower Mains in Edinburgh. This was a very informative update and concluded the afternoon. It was then time to find the train station which some people did faster than others!

Thank you for a very interesting two days, I feel my archiving knowledge has really grown as a consequence of attending the conference. I really enjoyed the two days and look forward to the next one in the beautiful city of York in October. See you there.

Claire

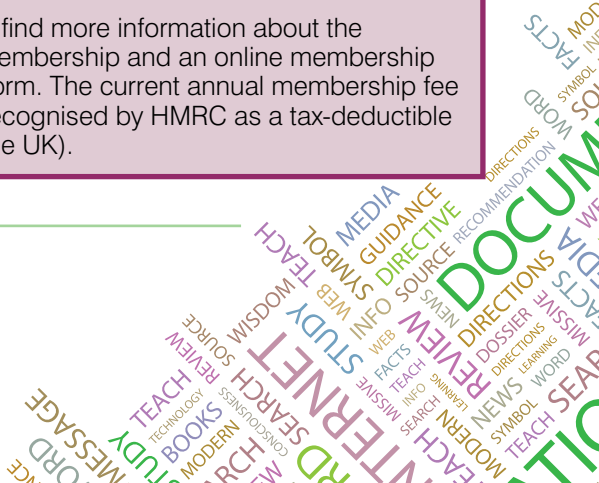
Call for Articles

Should you like to submit an article on a topic you feel would be of interest to our members, please contact the editor Eldin Rammell by e-mail ***sagacity@sagroup.org.uk***. Equally, if you have seen an item of news that you think would be of interest to SAG members, please let us know and we may include it in the next Sagacity.

Considering Membership?

If you have enjoyed the content of this publication and think that membership would be of benefit, please go to our website at ***http://www.sagroup.org.uk*** and navigate to the Membership page.

Here you will find more information about the benefits of membership and an online membership registration form. The current annual membership fee is just £50 (recognised by HMRC as a tax-deductible expense in the UK).



Date for your Diary – Autumn Conference

17th & 18th October 2013 The Marriott Hotel, York (GB)

The Autumn conference will take place at the Marriott Hotel in York on the 17th and 18th October 2013.

The title for this conference will be **'The Records Lifecycle Revisited'**. We aim to look at each aspect of the record lifecycle to take a fresh look at some of the basic concepts and challenge some of the long-held views on topics such as record classification, retention and disaster recovery, together with understanding some of the recent developments such as cloud computing and digital signatures. As always we are very happy to hear from anyone that would like to contribute to our conferences with presentations or suggestions.

We shall be pricing this event at the same as the Spring conference, which represents excellent value for money.

The conferences are an ideal opportunity to share thoughts and ideas with like-minded professionals in an informal environment and an event not to be missed. I really hope that you will be able to attend.

To date we have confirmed speakers on the following topics:

- Records Classification
- The Consolidation of Disparate Archive Holdings
- The Competing Drivers of Regulatory, Legal and Business Imperatives

Don't forget! If you would like to give presenting a go, please contact Eldin Rammell, Gail Dams, Reinhard Schoebitz or Richard Pennicard.

Further the most current information on the forthcoming Autumn Conference, please visit our website *www.sagroup.org.uk*

For other conference-related queries, please e-mail *conferences@sagroup.org.uk*

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SAG Conference Grant

The SAG Conference Grant was agreed by members at the AGM in October 2000 and is now available as follows. The purpose of the Grant is to provide financial assistance to SAG members who, through redundancy or some other circumstance beyond their control, would otherwise be unable to attend conferences organized by the group.

An amount to be set aside will be reviewed and decided upon by the Directors on an annual basis. The fund will be used on the basis of a written request from individual members a minimum of 2 months prior to the conference. The request must be sent to the Group Secretary and the Chairperson. The Directors will discuss each case on its merit and, if justified, will allocate a sum from the fund, based on an amount to cover an individual's conference fees only.

Once the monies set aside for any one year are used up no further requests will be considered until the following year. All applications will be treated in confidence.

Scientific Archivists Group

Promoting excellence in records management

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