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Scientific Archivists Group

Inside this issue

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Letter from the Chair

Eldin Rammell

As I write this, we are approaching Christmas and the end of another year. So it is tradition to look back over the year and make a few comments of reflection. Here goes!

In terms of changes to regulations that affect us as records managers and archivists, we have not seen huge changes over the past year. There were two important highlights however. The MHRA published draft guidance on data integrity for GxP-regulated records in July 2016, asking for industry to provide comment and feedback. We have yet to see the MHRA's response to the public consultation in a final guidance document. My impression was that the underlying principles contained within the document are welcomed but it lacked clarity in several areas and I am hoping that the ambiguity is resolved in the final published version. I am also concerned that industry and regulatory inspectors take disproportionate action with regards to data integrity; efforts should be focussed on high risk data.

2016 also saw the finalisation of the revision/addendum to the International Conference on Harmonisation (ICH) guidelines on good clinical practice (GCP). The changes will have a significant impact on the conduct of clinical trials but there were also changes that impact management of trial records. A small but significant change for me was the inclusion of a precise definition of "certified copy" that allows for production of acceptable copies through a validated scanning process, thereby removing the need to verify and certify each individual copy.

Hardly a month seemed to go by without our news including reports of a significant data breach, Yahoo! being the latest as I write. The prevalence of hacking activity reinforces the need for good information governance, including appropriate information security. On a personal level, we all need to take our own personal data seriously and ensure that we "practice what we preach" by using multiple, strong passwords for each of the different online systems that we use.

And no different from other years we have seen various company mergers and acquisitions, and rumours of mergers and acquisitions! These often have a direct impact on our own members and so we are mindful of those who have faced redundancy this past year or major changes to their own jobs as a result of corporate changes. Change seems to be a constant theme in our industry, impressing on us the need to keep up-to-date with latest developments in the records management and regulatory areas so that we are better equipped to respond to these changes. This leads me on to my next thought.

This past year, the GCP Special Interest Group within SAG developed and launched a new training course: TMF Essentials. The inaugural course had ten attendees and received extremely positive feedback. In addition, we ran a "Managing Electronic Records" workshop on two occasions, a "GLP Archivist" training day on two occasions and a "GCP Archivist" training day on two occasions. We also presented at the ICR Ethics and GCP Forum. And this was in addition to our usual annual conference held in Birmingham in April. So we have been successful as an industry association in helping to keep our members and industry up-to-date with their knowledge and education. We have plans to further develop our training offering and you will hear more about this in 2017.

For the Scientific Archivists Group, we also saw changes to our Committee this past year. We offer our thanks to Jody Salisbury, Gail Dams, Leigh Tate, Reinhard Schoebitz and Svetla Churchman-Zlatkova who all left the Committee over the last 12 months. We welcomed Sarah Curno, Carolyn Fitzpatrick, Alex Dingenouts and Jamie Toth to the Committee and look forward to their contribution to the operation of the association. It is important for us to ensure we keep pace with changes in the external environment and remain a modern, active association. I hope that as the New Year approaches, we continue to drive this group forward as a dynamic association that really helps and supports its members.

So that just leaves me to wish you all health, happiness and success for 2017. This is YOUR professional association so we would love to hear from you this coming year. Get in touch!

Eldin

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 £60 (recognised by HMRC as a tax-deductible expense in the UK).

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Letter from the Editor

Russell Joyce

As a hobbyist (and sometimes hired) musician, the Christmas period is always perilously hectic, far from the idyll of relaxation that most perceive it to be. Despite the immense pleasure I gain from music-making, there is nonetheless an exasperation to be had from playing even the beautifully transcendent "O Magnum Mysterium" so many times. Indeed, after such an intense period of performing, I am inclined to sympathise with the Emperor Joseph II who (when appraising Mozart's "The Abduction from the Seraglio" in the film "Amadeus") opined that there were "too many notes": that's how my Christmas feels! So as the festive season draws to a close and a New Year dawns, I look forward to returning to normality and the earthly world of records management. What a year it promises to be.

In this edition

- Eldin Rammell takes a look at the MHRA Data Integrity Guidelines and the newly published Revision/ Addendum to the ICH Guidelines on Good Clinical Practice;
- Oliver Herrmann considers a process- and risk-based approach to data integrity;
- Karen Roy provides an update on developments with the TMF Reference Model, a project that continues to make a major contribution to clinical research;
- Richard Pennicard summarises discussions at the GLP Consultative Committee;
- SAG Special Interest Group Leads provide updates on progress with their projects; and
- Heather Hanger extols the benefits of her experience as a Special Interest Group contributor and encourages others to "join the party".

These topics will all be the focus of discussion, exploration and analysis at the SAG Conference in Manchester in April 2017 (details on page 25) at which I hope to see many of you.

In the meantime SAG continues to evolve. In this issue, we welcome one new appointment to the SAG Board (Carolyn Fitzpatrick, Treasurer) and three new members to the SAG Operations Committee (Alex Dingenouts, Jamie Toth and Sarah Curno). We also bid fond farewells (Jody Salisbury and Leigh Tate).

Overwhelmed with the duality of my SAG role (Conference Organiser and Publications Coordinator), I am hoping this will be my last edition as Editor. If you feel you would like to take the reins, co-edit Sagacity, or even simply contribute an article or suggestions for articles for the next edition, I shall be delighted to hear from you.

In the meantime, my sincerest thanks all who have generously given of their time to submit articles for this edition. My very best wishes to all professionally and personally throughout 2017. Enjoy Sagacity. Enjoy life.

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 holds 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 the management and archiving of scientific records.

For further information visit our website ***www.sagroup.org.uk***

Members Pages

New Membership Year

Alex Dingenouts

A polite reminder that SAG is moving from a fixed calendar year subscription model to one in which the membership renewal date will be the anniversary of the member's joining date. Two months before the subscription expires, members will receive a renewal notification. Payment must be made before the expiry date otherwise membership will automatically expire and it will be necessary to contact the Membership Coordinator (membership@sagroup.org.uk) to reactivate membership. Allowance will not be made for delays caused by company finance systems or any extraordinary processes.

The quickest and easiest way to pay is by credit/debit card through the SAG website. This is the recommended method. To make payment

- click on "Your Profile" then "Subscription History"
- check the contact information is correct and amend if necessary
- click "Renew".
- request an invoice from the Membership Coordinator if paying by company cheque or BACS.

It is essential that payment reaches SAG a week before the expiry date to allow time to trace the payment and allocate it to the appropriate membership.

Remember: if the subscription payment is not received by SAG and credited to membership before the expiry date (28th February for most members) membership will automatically expire. Any member who allows their membership to lapse will not be able to log in to make a payment without first contacting the Membership Coordinator.

Farewell and Fare Well - Jody Salisbury & Leigh Tate

As some of you may already know, Jody Salisbury and Leigh Tate have recently announced their retirement from the SAG Board.

Leigh has been a SAG member since 2009, was co-opted to the SAG Board in 2014, and since 2015 has served as the SAG Membership Secretary a role that she has tackled diligently and that means (of course) that Leigh will be well-known to members. Leigh doesn't step down fully from SAG duties because she will continue to administer the GLP and GCP Archivist Training Courses on behalf of SAG. So, though we shall miss her contributions at operational executive committee meetings we are pleased that our relationship is set to continue into the future. On the plus-side, I'm sure Leigh will be looking forward to having more time to spend walking in the Lake District, playing in her local ladies cricket team, and maybe even horse riding again, having ridden professionally until 2003.

Jody has been a SAG member since 2005 and became Treasurer/Social Media Coordinator in 2015, a sometimes arduous undertaking but one that Jody has carried out with good grace and without complaint. In her New Director Profile Jody commented "my epitaph is for others to write"; so though Jody is still very much alive and well, I suppose I shall have to leave it there. Suffice to say that Jody is now free to enjoy her grand-daughter Lydia and her many hobbies, which include gardening, politics (looks like a busy year, Jody!), reading, and deplenishing (and replenishing?) the new wine cellar in her home.

Jody and Leigh's commitment, integrity and dedication to the continuing success of SAG have been constant, their relative perspectives and experiences making important contributions to myriad committee and directors' discussions in recent years, helping to deliver a balanced approach to ensure that SAG evolves in line with its aims to remain relevant to all its members.

On behalf of all SAG members, a huge thank you to Jody and Leigh for their support and dedication. We wish them every happiness and success in the (ad)ventures that lay ahead for them (whatever, wherever, and with whomsoever they may be). We look forward to catching up at future conferences.

New Members

We extend a warm welcome to new members who have joined SAG since Sagacity was last published. Contact details for networking may be found in the Membership Directory.

Andrew Fulford	Covance Laboratories Ltd
Ellie Barnett	Johnson & Johnson Medical Ltd
Emma Hawkins	Arysta LifeScience
Jo Smith	Keele University
Kaye Eames	Quotient Clinical
Linda Legrand	MeiraGTx UK II Ltd
Lisa Simpson	Jurox Pty Limited
Lorna Morrison	Edingburgh Pharmaceutical Processes Ltd (EPP Ltd)
Marc Webb	Quintiles
Marion Mays	Quintiles
Poh Quai Chan	Mitsubishi Pharma Europe Ltd
Richard Haslop	St Stephens Clinical Research
Shirley Kung	Mitsubishi Tanabe Pharma Europe Ltd

Retired Memberships

A reminder to retired members that SAG has introduced the category of Retired Member, which enables retired members to keep in touch with colleagues and with developments at a lower cost. Please apply to the Membership Secretary if this affects you *(membership@sagroup.org.uk)*.

Redundancy

If any members have been made redundant during the last 12 months and are still without employment, remember that the SAG Board (at its discretion) may grant a subscription-free membership to enable the redundant member to stay in touch whilst looking for a new job.
Please apply to the Membership Secretary if this affects you *(membership@sagroup.org.uk)*.

Caption Competition

In the last issue of Sagacity we asked you to submit a caption for these images. Congratulations to the winner, Neil Gow of UCB, who sent in the following caption:

"Resign before the Manchester conference? No way, Gail!".

SAG Special Interest Groups

Chris Jones

Earlier this year, a survey of SAG members indicated interest in forming Special Interest Groups (SIGs) within SAG, to focus on specific topics and areas of expertise. Some working principles for SIGs have been developed and are published in the document library in the members' area of the SAG website. The intent of SIGs is that they will

- act as autonomous groups within SAG, respecting and abiding by the rules of the parent organisation
- provide a forum for the exchange of experiences and the advancement of all aspects of records management pertaining to their area of focus
- encourage the maintenance and development of professional standards in all aspects of their area of focus
- communicate regulatory and technology updates, issues to members of SAG via publications and meetings.

The first step for setting up a SIG is to identify a Lead. Without a volunteer to lead a SIG, that SIG will not be formed. Two SIGs have already been formed, GCP and Electronic Records (summaries of their activities to date follow). However, SAG is actively looking for SIGs for a number of topics including, but not limited to, GLP, GMP, and Professional Development.

If you are interested in setting up a SIG, please contact (*chairman@sagroup.org.uk*).

SAG eRecords Special Interest Group **Hugh O'Neill**

The SAG Electronic Records Special Interest Group (eRecords SIG) is pleased to have recently published its second guidance document: "The Role and Use of PDF in Records Retention". This guidance is available free-of-charge and can be found in the publications tab on the SAG website. The guidance is a reasonably extensive review that

- covers the history, features and standards of the PDF file format; and
- provides carefully considered advice on the use of PDF for archiving purposes.

The guidance was reviewed by technical experts from the PDF Association whose feedback was complimentary regarding its usefulness and quality. Indeed the PDF Association will reference it via a link on their own website.

The eRecords SIG has now begun on a new series of meetings on a new list of topics. In the coming months we shall primarily consider the topic of electronic signatures. There will also be smaller projects that will consider the topics of

- VeraPDF (a free, open-source tool for validating PDF/A documents); and
- data integrity (looking specifically at the implications from a records management perspective)

If you have experience or a particular interest in these topics, the eRecords SIG will welcome your input.

In any event the eRecords SIG is always interested in considering suggestions for topics, either by expanding on existing projects or addressing new ones. If you are interested in becoming a member, have a topic that you would like us to consider, or would simply like to become involved, please let me know. You don't need to be an expert, just have a willingness and enthusiasm to contribute through research, co-authoring, or reviewing drafts of guidance documents.

The eRecords SIG comprises 10 SAG members with a shared interest in the archiving of electronic records. We meet by teleconference every month for approximately an hour although much of the work is done off-line, sharing thoughts and outputs via e-mail and a dedicated OneDrive repository.

In this edition of Sagacity, Heather Hanger has kindly written an article on her experience of being a member of the eRecords SIG, which I hope will encourage anyone who is interested (but may be unsure) to become involved. We look forward to having you on board!

Hugh O'Neill
eRecords SIG Lead
Hugh.oneill@croftdata.co.uk

SAG Good Clinical Practice Special Interest Group **Alex Dingenouts**

Last June, leadership of the Good Clinical Practice (GCP) Special Interest Group (SIG) group transferred from Eldin Rammell and Russell Joyce to Alex Dingenouts (Chair), Jamie Toth, Rose Faulkner-Coxon and Martin Thorley. The group currently has 18 members and meets monthly by telephone conference. Membership of the Group is open to any SAG member with an active interest in GCP records management. If you would like to participate in discussions and work streams in this area, please contact me (Alex Dingenouts) to join.

This coming year (2017), the Group is planning to organise its first UK Face-to-Face meeting on 24th and 25th April in Nottingham. The meeting will be hosted on site by Rose Faulkner-Coxon of PAREXEL. PARAEXEL has kindly to offer its meeting rooms free of charge meaning delegates will be required to meet only their own travel and accommodation costs. There will be a wide range of discussions and presentations on current and relevant hot topics with plenty of opportunities for networking with colleagues both during the interactive discussion sessions and at evening social events.

This year, the GCP SIG worked on multiple work streams. Below is a brief status update on each of these work streams.

Document Digitisation Guidance

This working group, led by Russell Joyce, has produced a guidance document to assist companies concerned to ensure that their scanning processes and systems support the generation of “certified copies” (or “true copies”) as required by regulatory agencies. The paper also provides advice to determine whether or not original hard-copy documents may be destroyed. This document is currently under review by the SAG Board.

eTMF Selection Guidance

This working group, led by Jamie Toth, has finalized its work and drafted a guidance document. The team has reached out to the TMF Reference Model Steering Committee and has worked jointly with the Pocket EDMS initiative. Plans are underway to publish in early 2017 in collaboration with the TMF Reference Model and Pocket EDMS. Watch this space!

TMF Essentials Training Course

- This one-day training SAG course was developed by Eldin Rammell, Russell Joyce and Liz Hooper supported by the rest of the GCP SIG members. It is deigned to be suitable for anyone with responsibility for establishing or maintaining trial master files. The course covers some of the underlying records management principles (e.g. record definitions and records lifecycle) and covers the regulatory requirements for trial master files including creation, maintenance and long-term retention.
- The first course (held at Heathrow on 7th September 2016) was facilitated by Russell Joyce and Liz Hooper and received good feedback. The next course is scheduled for Tuesday 11th Apr 2017 in Parsippany, New Jersey, USA and will be facilitated by Jamie Toth. Additional dates for the UK are set for 9th May 2017 and 12th September 2017 at Heathrow. Registration for all courses can be made online via the SAG website.

GLP Consultative Committee

Richard Pennicard

The UK GLP consultative committee met on 8th September 2016. It is a forum for discussion of GLP issues between the GLP inspectors, regulatory authorities such as the HSE, MHRA and FSA, and industry bodies such as ABPI, RQA and SAG. I attended as the representative from SAG. The GLPMA's official minutes should be posted on the MHRA website.

As well as GLP, the inspection group covers stand-alone GCP laboratories and GMP QC Laboratories. This report covers items of particular interest to Archivists and Records Managers.

Data Integrity

The MHRA has issued draft guidance on data integrity covering all disciplines. The document can be found on the MHRA website at http://bit.ly/2aloqm1. This is issued for consultation. All responses (positive or negative from individuals and groups) were sent in by 31st October 2016. There was a presentation on the document at the MHRA GLP / Laboratories Symposium in Birmingham on 22nd September 2016. When the document is finalised, the current GMP data integrity guidance document will be withdrawn.

The content of the document is driven by technology and the increasing complexity of studies. The principles underlying the guidance have not changed. It fits with new OECD guidance on computerised systems and with a global emphasis on the importance of data integrity and good data governance. WHO have also published a document on the topic.

During the discussion, the MHRA inspector emphasised that its inspectors would adopt a pragmatic approach i.e. is an organisation committed to implementing the principles? Inspectors would not penalise an organisation that is trying to do the right thing. There is not a fixed date by which an organisation must implement the guidance: certainly the MHRA does not expect all the elements of the guidance to be implemented as soon as the guidance is formally issued. On the other hand the MHRA expects organisations not to wait until an inspection before starting implementation.

The key elements of the guidance are:

- A more precise definition of what is raw data (the 'first printed copy' is unlikely to be acceptable).
- More emphasis on the role of QA in assuring data integrity. QA should demonstrate that they are monitoring data integrity effectively
- New technical considerations e.g. comparison between data held in flat files vs relational databases and dynamic vs static data formats.

Three questions were submitted on the subject of data integrity:

Question 1

What are the minimum requirements for the archiving of QA records? (Submitted by RQA)

Answer - QA records are needed to reconstruct a study and therefore need to be retained. The exact details on

what records are needed will depend on a company's procedures. MHRA would want companies to show that QA activities took place, especially when something has gone wrong and that QA oversight was effective. They do not want to be prescriptive about the precise records to be kept, but suggested that audit and review reports were almost certain to be needed, but checklists and marked up reports probably not. The MHRA suggested that there was scope for the industry bodies to draw up guidelines themselves.

Question 2

How can a test facility archive data in compliance with the guidance on data integrity when there is no guarantee that there will be the technology to allow it to do so? (Submitted by SAG)

The presentation and guidance made it clear that in most cases paper print-outs or other static formats would no longer be accepted as true copies of dynamic raw data that had been generated and stored in electronic systems. For GLP this implies that the data will need to be archived in a dynamic format and be available in such a format throughout its retention period. The problem is that there is no definite retention period for GLP data so effectively test facilities are being required to retain the data in its native or equivalent dynamic format indefinitely and for it to retain full readability throughout this time.

The problem is that this will rely on the necessary technology being available for an indefinite period. This is not guaranteed. Niche systems are particularly vulnerable to obsolescence and it can easily happen that it becomes uneconomic either to maintain support for an electronic data handling system or to provide a new system that data and metadata can be migrated to while retaining full integrity.

There is a problem affecting CROs. Normal contracts allow CROs to transfer raw data to sponsors for permanent archiving. However for electronic data this will require the sponsor to have the data systems to read the data in its native format. This will normally be impractical so the CRO will be forced to maintain the data itself indefinitely. What will happen if that CRO goes out of business?

Answer - This is an issue around retention times, which are not addressed in GLP principles. It is the sponsor's responsibility to ensure that records are retained so as to permit any requested product registration; therefore, the preservation of dynamic data should be discussed and agreed between sponsor and test facility before the start of a study. As far as retention times are concerned, it would be the sponsor's responsibility to perform a risk assessment. The major risk is that the MHRA is asked to perform a study audit by a registration authority and the test facility is unable to produce the raw data or an acceptable copy. In practice, such study audits nearly always happen within 5 years of the study being completed and it is almost unknown for one to be requested more than 10 years after completion.

Question 3

Is it acceptable for a pathologist to be sent scanned images of microscope slides for review rather than the originals? (Submitted by ABPI)

Answer - The MHRA would insist on there being a clear chain of custody in the scanning process to ensure that the copies were of the correct slides. The quality of the scan is a scientific issue but it would be advisable to validate the scanning process to ensure that the scans are of acceptable quality for review.

International Regulatory Updates

Mostly this was of little (if any) interest to SAG members. One change that may be relevant is that because the issuing of consensus documents has become impractical, the two categories of guidance documents (consensus and advisory) will be merged. The process for issuing new documents will be that they will be issued as drafts for public consultation before being published in their final form. Alongside this, more guidance will be issued as FAQs, which should create a more streamlined process.

The FDA has issued draft revised GLP regulations. There is some movement towards them becoming more consistent with OECD principles, particularly with regards to multi-site studies and archiving timescales. The MHRA emphasised that there would be no direct effect on GLP compliance in the UK but that UK test facilities may find that expectations of US sponsors may change.

MHRA Updates

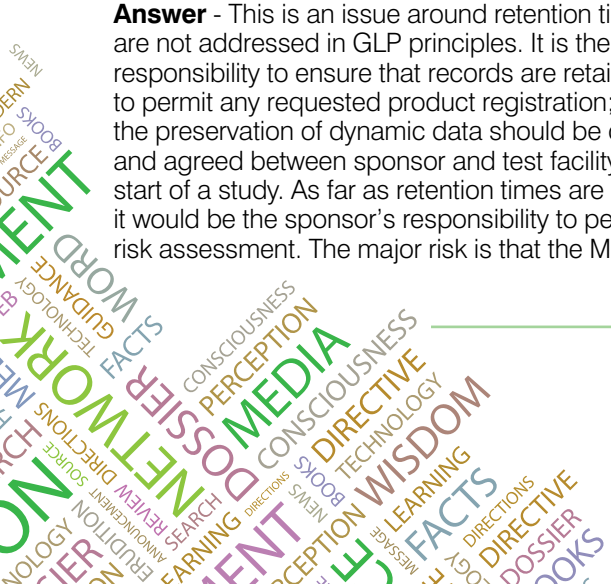
Due to lack of time, inspection metrics were not presented. They will be published in November 2016; excerpts will be presented at the MHRA symposium in Birmingham on 22nd September 2016. Answers to questions raised at the symposium will be published in the MHRA inspectors' blog.

Technical Questions

Technical questions submitted before the planned meeting in March 2016 have been answered as GLP Q&As

About the author:

Richard Pennicard is the QA Manager at Selcia Ltd and former Director of the Scientific Archivists Group. *Richard.pennicard@selcia.com*



New SAG Committee Member Profile

Alex Dingenouts

Senior Manager, Astellas Pharma Europe BV

What do you see as the greatest challenges and opportunities in clinical records management?

One of the challenges in records management is the harmonization of records management practices in a global organization. The biggest challenge with innovation is organization culture or internal politics or business groups that have no will to change.

The opportunities are enormous these days as technology evolves quickly that can support the business to align and move forward more easily.

What is / are the most interesting / intriguing aspect(s) of your work?

One of the interesting parts of my job is to work collaboratively in a global environment with creativity to innovate and solve business problems, with the mutual objective to focus on the creation of valuable products for our patients.

What are you most passionate about personally?

A passion of mine would be travelling, discovering and learning new cultures.

My last trip was to Tokyo. This was one the best travels so far. Tokyo is a medley of culture, old and new, that you can explore when wandering around in this ultra-modern city. Normally I do like to learn some words of new language as well. But Japanese is too much of a challenge so I gave up after a few days.

If you could have chosen any other job, what would it be?

I think I would have been a home designer. I love to think about redesigning spaces, to create new environments that best fit your needs. I would have studied architecture and by now, would be a famous Dutch architect….

What made you apply to become an Executive Member / Director of SAG?

I have been working with some know board members in other association, the recently wounded GCP-Records Managers association. It will be a pleasure to work with people who are dedicated to the area they work in. It is interesting to be part of this so we can help the SAG organization forward. Additionally in a board role, you can get exposure to different items than the one you get to know in your current job. This variance will provide opportunity to develop your skills, experience and competencies.

I couldn't make it through the weekend without…

A good breakfast that includes a croissant with fresh orange juice will always help me making a good start of the weekend. Together with a newspaper and some Blendle articles on my iPad.

The clichéd English view of the Dutch is of a friendly, generous, multi-lingual people bicycling through an endless flat but idyllic countryside full of picturesque flat tulip fields, canals, dykes and windmills. Is that a fair characterisation? How do the Dutch see the English

We all do like cycling but not only through idyllic places. We also go through boring industrial areas and have a lot of places without canals, dykes, and for the windmills; they are becoming more and more rare.

Many Dutch words are similar to English e.g. appel (apple), bier (beer), groen (green), nieuws (news), but there are many false friends too e.g. glad (slippery), rooster (grid), mug (mosquito), trap (stairs). Are there any words or phrases in English that amuse or confuse?

Yes there are many words that do amuse and confuse me!

- Oxter, to me it seems something like a Hipster, but I believe it is an outdated term for "armpit."
- Whippersnapper, I believe this has nothing to do with whips or snaps; it seems to be a young and inexperienced person considered to be presumptuous or overconfident.
- Poppycock has nothing to do with poppies or cock (male bird). It seems a nonsense word to me!

It is said that every Dutchman keeps at least three bicycles. How many bicycles do you own?

I now have only 2! One bike for in Amsterdam and one bike for in Leiden. The bike in Leiden I use to cycle from the train station to the Astellas site. I even have no car; I do the weekly shopping by bike. A bike bag is a very handy gadget for shopping in Amsterdam.

The English expression "to go Dutch" means "to share the bill equally", perhaps a reference to a Dutch tendency to being careful with money although the Dutch are universally seen as a generous nation. Do the Dutch have any expressions that allude to English characteristics?

I don't know a lot of expressions that allude to English characteristics.

But, I do know some funny Dutch Expressions that are nonsense in English language;

- Dutch don't only feel great…they feel 'Chickendelicious' (Kiplekker).
- Dutch people don't get goosebumps when they are cold…they get 'chickenskin' (Kippenvel).

Holland or Netherlands? There's a difference, right?

I would not recommend saying Holland when you are actually trying to refer to The Netherlands. As it refers to one of the two provinces we have in the Netherlands; North Holland and South Holland. The Netherlands, meaning "The Low Lands" is the official name for the country. The major cities (Amsterdam, Rotterdam and The Hague) are located in these two provinces. So if you have ever been to The Netherlands, the chance is big that you have also been to Holland.

Edam or Gouda? Both? Or neither? Why?

I would recommend trying them both. They are both very tasty and can be well accompanied with a good glass of wine.

New SAG Director Profile

Carolyn Fitzpatrick

Consultant, CACaD Services Ltd

How did you come to be involved in Records Management / Archiving?

It was my husband's fault. I was housekeeper for the Glaxo hostel. After I married my husband wasn't keen on me living in several nights a week and so I took on a filing role in Regulatory Affairs; this allowed me to go home each night even though it became increasingly late at night as my career progressed!

How long have you been involved in Records Management / Archiving?

Over 30 years! My filing role soon lead to me becoming manager of a centralised filing and archive area for the whole of Regulatory Affairs. During this time we moved from filing paper, to managing microfilm, and then to electronic records. After 20 years in Regulatory Affairs I changed companies and moved to an R&D role focussing on Clinical Records.

What are the most interesting aspects of your work?

For me variety and evolution are the most interesting things about the role / function. It certainly isn't for someone who dislikes change! I found the role more interesting as we increased the use of electronic systems to manage our records.

Your most memorable or amusing working anecdote?

I am not sure if this is amusing or depressing but like many working in this function, I have found my fill of Christmas decorations, stationery items, heaters and a gym kit in archive boxes labelled 'Miscellaneous'!

If you could have chosen any other job, what would it be?

An accountant! I really enjoyed this module both at school and in further education. I think this is why I signed up a Treasurer for a number of charities and associations. I thought I wanted to be a baker like my grandad but found I preferred baking occasionally rather than regularly to a schedule.

What made you apply to become a Director of SAG?

As I have had the opportunity to step back from a full-time career I thought it was time to give back to the group that supported me so much throughout my career

"Strictly Come Dancing" or "The X Factor"? Both? Or neither? Why?

Has to be "Strictly". Apart from the fact I prefer dancing to singing, there is no Simon Cowell on "Strictly"!

You grew up in the countryside but now live in suburbia. Has it been easy to adapt to town life?

The Devon countryside in which I was brought up holds many fond memories. However, I have found that I do like street lights at night; I have too much of a vivid imagination for a totally black night!

Who has proved an inspiration to you in your personal life?

It would have to be my mother; she is the real matriarch of our family. Even at her grand age she is still on the ball and able to provide the right balance of help without interfering. As we grew up she managed a career, 3 children copious cousins, extended family members, a large scale DIY husband, and holidays across most countries in Europe.

I believe you enjoy cooking and have been known to fundraise by baking cakes. What has been your most successful gastronomic creation?

I have a preference for individual cakes and go through a cycle of favourites; these have included simple butter whirls, cookies, Viennese whirls, Poppy Day cupcakes, 3D snowman, and reindeer Curly Whirly cupcakes!

So are you an avid fan of "Great British Bake Off"?

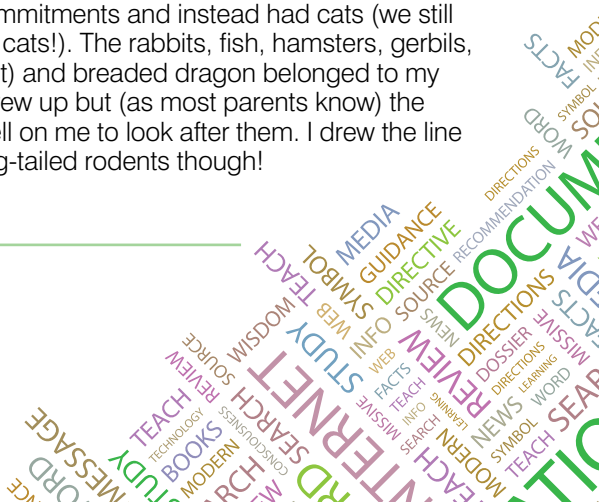
Despite my love of baking, I actually prefer "MasterChef" (especially the Australian one).

A one-time avid reader, which genre would you choose given the choice of any?

It would have to be a historical novel based on fact. I really enjoyed "The Autobiography of Henry VIII: With Notes by His Fool, Will Somers" by Margaret George. The Tudor era is my most favourite.

You've had have a veritable cornucopia of pets over the years including dogs, cats, rabbits, children, and bearded dragons. Which (if any) was the most pleasurable to own and why?

In theory I asked for the dog but my husband ended up choosing him which was OK as it helped sway the decision to get a dog. He is a lovely black Labrador-Collie cross and is my favourite. We had put off getting a dog due to work commitments and instead had cats (we still have two black cats!). The rabbits, fish, hamsters, gerbils, degus (a rodent) and breaded dragon belonged to my boys as they grew up but (as most parents know) the responsibility fell on me to look after them. I drew the line at handling long-tailed rodents though!



New SAG Committee Member Profile

Jamie Marie Toth

Director, TMF Operations, Daiichi Sankyo Inc

How did you come to be involved in Records Management / Archiving?

I inherited records management aspects at my previous company (a CRO) when I launched the eTMF project back in December 2010. I recall needing to be aware of aspects of records management due to the nature of the TMF and its importance with converting paper to electronic and storing the records for some period of time…back then almost forever! Records managment always intrigued me and I was happy to become part of such an important niche area.

How did your previous IT-related role inform your view of records management?

I started my career in big pharma in IT, and actually my undergrad degree is in IT, so records and documentation and following SOPs in the GCP space were always part of my background and I feel prepared me well for records management responsibilities.

If you could have chosen any other job, what would it be?

An Event Planner! I love to organize parties at my house with friends, from wine dinners to themed parties and just love tying a theme together to party favours and food and setting the stage for a day/night which is a break from the everyday work life. For one night or day…we are "in Hawaii" or "wearing ugly sweaters", it's a nice break once in a while.

What most excites you about the contribution you can make to SAG?

I think I can bring some American practicalism and humour to SAG, as well as experience that I have gathered over the past 6 years working at a CRO and now at a sponsor.

I couldn't make it through the weekend without…

Snuggling up with my Labrador retriever, Daisy; she is 13 and about 75lbs, of sweetness!

Reasons to be cheerful include…

My family! I have a wonderful husband of 22½ years, as well as a 21 year old son, and a 7 year old son both of whom keep me and my husband, Rich, very balanced!

What is your ideal book and why?

I enjoy Christian literature especially the Amish novels by Beverly Lewis because they are a sharp contrast to the entitlement and indulgence of everyday life.

You have a Pinterest page dedicated to your love of making things with cork. How did you discover this talent?

My husband and I enjoy wine. Once we started to accumulate enough corks, I wondered what I could do with them. Here's a picture of ornaments I made for Christmas. It's recycling at its best!

I believe you love to cook, especially with your husband as "sous-chef". Is your style more Rachel Ray (30 Minute Meals) or Gordon Ramsay (Hell's Kitchen)?

I do both! During the week, it's Rachel Ray about twice a week. My husband cooks as well and we really enjoy when we can get all Gordon Ramsay and make a fantastic eclectic meal together.

Thanks Giving or Christmas? Or both? Or neither? Why?

For Thanks Giving I hosted a party for 15 people and for Christmas I hosted a dinner party for 12 people. I love both holidays and family time and just being together and playing games. Our new favourite game is "Pie Face"! …

New SAG Committee Member Profile

Sarah Curno

RM Consultant, Hedian Ltd

How did you come to be involved in Records Management / Archiving?

I worked for a family run small CRO as a Senior Clinical Research Associate (SCRA) and was then promoted to Project Manager (PM) and subsequently a Manager guiding a team of PMs, CRAs and Clinical Trials Administrators (CTAs). On returning from maternity leave, I also became responsible for the CTA who looked after the Trial Master Files (TMFs). As the business grew into a medium sized CRO, it was clear that a separate Records Management Department was required. I took up the challenge to set up the new department, putting processes, systems and people in place to support all the operational departments. I have been involved in developing an eTMF, on several occasions, moving a TMF Room from one location to another and numerous audits and inspections.

What do you see as the greatest challenges and opportunities in clinical records management?

My experience is that Records Management, and in particular the TMF, is not given its rightful level of importance in organisations. All operational departments have documents that need to be in the TMF, but usually the task of keeping the TMF contemporaneous falls to the bottom of the 'To Do' list. My view is that making the task easier, more instant and less onerous to enable contributors to focus on the important aspects of the TMF, like quality of the documents, are challenges that need to be considered and solved.

What are you most passionate about professionally?

Honesty, integrity and timeliness! I would also like to see Records Management truly represented at the highest levels in organisations as I see this as the route to successful Records Management for companies.

Cats or dogs? Both? Or neither? Why?

I like all animals and, as a child, kept hamsters, guinea pigs and rabbits at different times. As an adult I had an infamous rabbit called Charlie. He lived in the garden, but spent much time inside the house pretending that he was a lap cat. With such an intelligent and charismatic pet as Charlie, I never felt the need for a cat or a dog.

If you could meet any person (contemporary or from the past) who would it be?

I would love to have met Emmeline Pankhurst, the political activist and leader of the British suffragette movement. What determination, shrewdness and bravery she must have had to enable her to help get the vote for women in Britain. I feel sure that I would have admired her greatly.

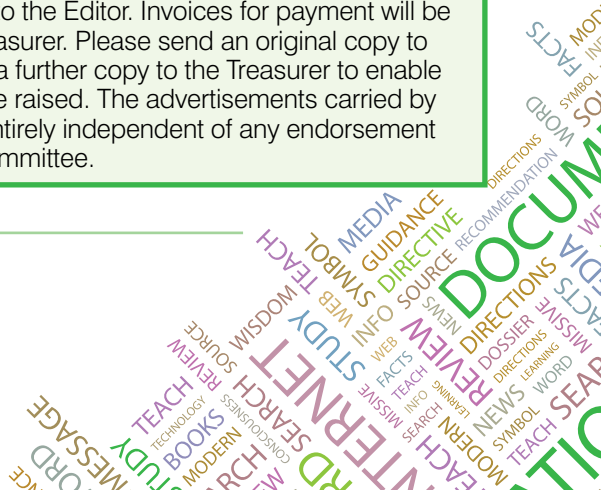
There's nothing I enjoy more than….

…going for an run. I am a strong believer that being fit helps with physical health and mental well-being. Running needs very little equipment: only running shoes and comfortable clothes, plus the time and the will to get out there. I come from a family of runners and I regularly take part in my local Parkrun, a free 5K run organised every Saturday at 9am.

I also like to spend time with my family. It is a tough but rewarding job giving your children a guiding hand as they grow and develop. And how else would you have the excuse to go on the swings at the park, play "hide and seek" in the local National Trust grounds or watch a children's film such as Despicable Me at the cinema?

Potential Advertisers

If you sell a product or service that is of interest to SAG members, you may want to consider advertising in Sagacity. We offer, quarter, third, half and full-page spaces with differing costs for full colour and bi-tonal. As a guide, a full page and full colour advertisement will cost £200 for a single insertion whilst a quarter page bi-tonal advertisement will cost as little as £55. We also offer discounted rates for repeated insertion of the same advertisement copy (10% for 2 insertions to 25% for 6 insertions). In addition, we offer the facility to send mailshots to all SAG members (hard-copy or e-mail) and advertorial copy in Sagacity. Please contact the Editor, Russell Joyce (sag-journal@sagroup.org.uk) for further details. All enquiries regarding advertising must be addressed to the Editor. Invoices for payment will be sent by the Treasurer. Please send an original copy to the Editor and a further copy to the Treasurer to enable an invoice to be raised. The advertisements carried by Sagacity are entirely independent of any endorsement by the SAG Committee.



What is your ideal holiday book and why?

I find reading enjoyable, relaxing and informative and it is one of my favourite pastimes. I have run a book club for the past few years and each member take turns to host the meetings and choose the book that we will read. I have found other peoples book choices fascinating and having the chance to read others choices has really expanded my reading horizons. My favourite books so far are:

- "The Rosie Project" by Graeme Simsion: a professor of genetics with undiagnosed Asperger's Syndrome uses a questionnaire to try and find his life partner.
- "The Checklist Manifesto: How to Get Things Right" by Atul Gawande: the author is tasked by the WHO to prepare a checklist to be used in the operating theatre and investigates other industries checklists to work out how to approach his task. It doesn't sound thrilling does it? But I was completely gripped and amazed how the author could make this subject matter so enthralling!
- "The Wind Singer" by William Nicholson: whilst this is not a book club option, it is worth mentioning as it was recommended by my son, a voracious reader. It is a young adult fantasy novel which follows the quest of twins Kestrel and Bowman Hath, and their friend Mumpo to restore the "Voice of the Wind Singer" to their city and bring happiness to their cruel society.

Your epitaph? Or, less morbidly, a pearl of consummate wisdom you would like to hand down? Or maybe an inheritance track? Or maybe all three!

I believe that we all should do our best with the time and resources we have and be happy and proud about what we have achieved. All too often, we dwell on what we didn't achieve: if it's important then find a way to get it done, if it's not, let it go!

I hear you are a passionate choral singer. What persuaded you to start singing formally?

I was invited by a friend to join a local choir several years ago. I decided to put myself in the second soprano group, the group between the sopranos and the altos, and this has turned out to be quite a challenge. It has been a very steep learning curve as I do not read music, but singing with a like-minded, friendly, funny group of ladies never fails to lift my spirits on a Thursday evening!

You have recently spent some time supporting your husband's property business. Women represent only 15% of the property and construction workforce. Are you a budding Sarah Beeney or more Kirstie Allsop?

My husband and I have been involved in the property business in Berkshire and Dorset for 15 years. I am the organised administrative support dealing with accountants, finance and paperwork. My husband met Sarah Beeney some years ago when we sold a house to Channel 4 for a property programme. She came across as a practical and pragmatic lady which I tend to identify with more than the creative Kirsty Allsop.

Draft Addendum to ICH E6 meets ALCOA:

Moving toward a practical definition of data integrity

Oliver Herrmann, CEO, Q-FINITY

The draft addendum to the ICH E6 Good Clinical Practice Guideline published in June 2015 introduces some new themes to the guideline that have already been hot topics within the pharmaceutical industry for some time (incl. risk-based monitoring, risk-based quality management) and elaborates on others, including data integrity. It is this last topic this article will discuss.

What is "data integrity"?

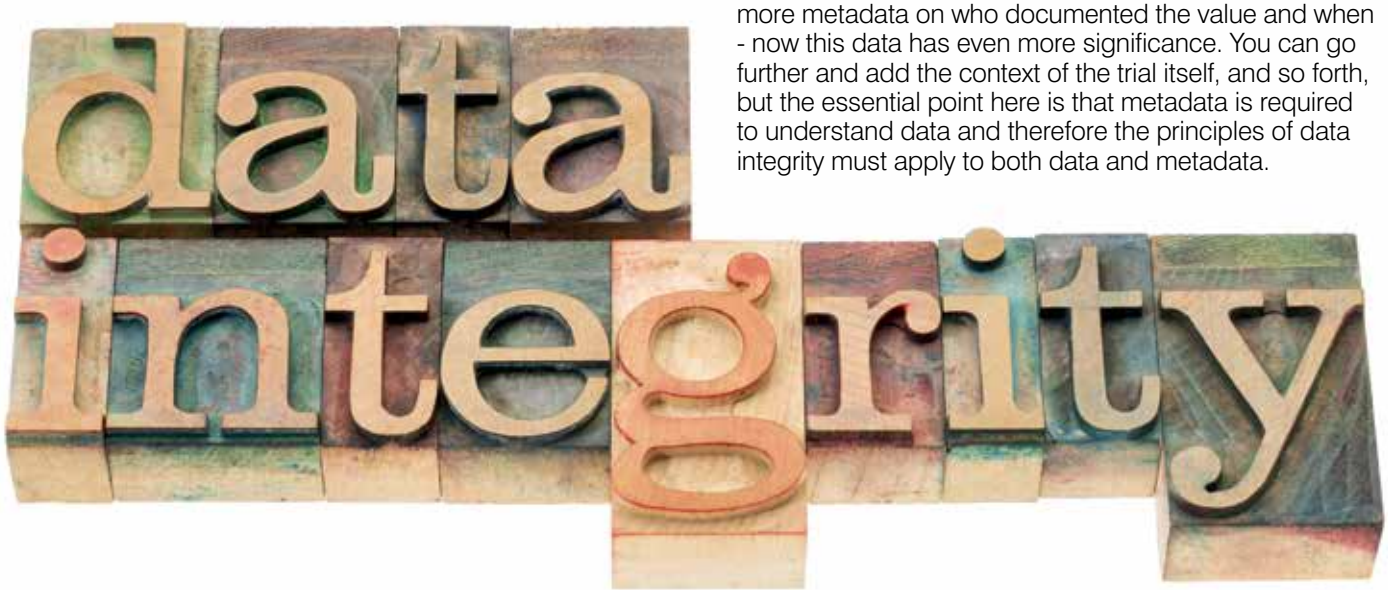
The concept of data integrity is not really "new". The 1996 Version of the ICH E6 Guideline referred to the "integrity of [the trial] data" in several places (section 5.2.1, 8.1 and 8.3.13). Essentially, data integrity is a quality characteristic of data; that is, your goal normally is to maintain the integrity of at least your critical data throughout the data lifecycle. In clinical research, data is something we deal with every day. Data is collected at clinical trial sites, is transmitted, processed, monitored, reported, analysed, transformed, backed up, restored and archived. Data is used to take decisions during clinical trials and is used by regulators as the basis for regulatory decisions of various kinds. In fact, the whole point of a clinical trial is essentially to produce the data needed to answer some question about a treatment or a disease or both.

What key criteria help evaluate the integrity of data?

In section 4.9.0, the draft Addendum to ICH E6 lists key words that will be familiar to many of us: "Source data should be attributable, legible, contemporaneous, original, accurate and complete." The first five terms are often referred to by the acronym "ALCOA", while the last two represent additions to the original ALCOA terms over the past years. ALCOA helps us with the question of data integrity by giving us a list of characteristics to check our data against. If our data does not fulfil these criteria, then data integrity is at risk. Though the draft Addendum to ICH E6 uses these terms primarily in connection with source data, the ALCOA principles can be very valuable in checking the integrity of data when it flows from one process step to another or from one system to another.

What data are we looking at when we refer to "data integrity"?

Data does not simply exist in a vacuum. It is collected and recorded by people, by electronic devices or equipment. It is the output of some process that generates the data at a certain time, such as the analysis of a specimen or a physical examination. All of these aspects create a context for the data that is essential for understanding the actual meaning of the data. For example, the value "160" with the unit "mmHg" on its own is devoid of meaning except that it is a pressure measurement. Add the label "systolic blood pressure" and you have an even fuller meaning. Now associate this blood pressure value with a certain patient in a particular clinical trial at a certain visit and add some more metadata on who documented the value and when - now this data has even more significance. You can go further and add the context of the trial itself, and so forth, but the essential point here is that metadata is required to understand data and therefore the principles of data integrity must apply to both data and metadata.



What data integrity is NOT

Data integrity is not primarily about IT systems. IT systems are important and must support data integrity, but data integrity applies to data in whatever form it is being held in, electronic or paper. It therefore helps to take a process-based approach to data integrity and this is what we will look at next.

A process-based (and risk-based) approach to data integrity

This approach looks first at the process or processes that are associated with data. This gives a horizontal perspective to the question of data integrity, which must be maintained throughout the data lifecycle (i.e. through time). For example, data on adverse events arises at a site where an event is observed and then documented as source data. The data may be recorded in a patient file that is electronic of paper, it may be captured in a paper CRF or an electronic CRF and transmitted in various ways (physically collected, faxed, electronically transmitted via the internet) to the sponsor. Further steps are then taken with the received data.

Looking at the first few steps of the process described here, we can see that some of the steps are manual and some may be automated or supported by technology in some way, yet the data flows through these different steps and should remain essentially unchanged by it. If the value "160 mmHg" is observed and recorded at the start of the process then that same value needs to arrive unchanged at the sponsor, across interfaces between systems and through all process steps relevant to that bit of data. With each step it will be necessary to ensure that the data's integrity was maintained. For manual process steps, this entails some form of manual QC checks, while automated process steps require some form of verification or validation to ensure data integrity.

Computerized systems are just one example of tools that support process steps by automating them. When data flows "through" them, data integrity needs to be a key consideration in the validation of those systems.

Which brings us to a final aspect of the draft Addendum to ICH E6, namely the risk-based approach to just about everything (monitoring, quality management, though – strangely - not validation of computerized system). Risk also plays a role in data integrity. Not all data are created equal when it comes to risk. Some data are less vulnerable to unauthorized changes, manipulation or corruption and others are not essential to the success or failure of a clinical trial, while other data is absolutely essential. Conducting a risk assessment on data types can help prioritize the data you will subject to rigorous data integrity controls.

In summary, by integrating the ALCOA principles into our data governance approach to data integrity and by utilizing a process and risk-based approach to data integrity in the GCP environment, we are able to more effectively focus our efforts to maintain the integrity of critical data.

About the author:

Oliver Herrmann is the Founder and CEO of Q-FINITY Quality Management (Germany), Deputy Chairman of the ISPE GAMP D-A-CH Board, Member of the Steering Committee ISPE GAMP D-A-CH, Chair ISPE GAMP Global R&D and Clinical Systems SIG. Oliver is a CSV Trainer, a CSV Coach, and in 2009 he founded the GAMP DACH GCP working group in Germany. *oliverherrmann@q-finity.de*

About Q-FINITY:

In 2004, Oliver founded **Q-FINITY** to combine process management with the requirements for the validation of computerized systems and share this experience via an integrated service portfolio. In the past 12 years Q-FINITY has gained extensive experience in planning, development, execution, documentation, and auditing of strategies, projects and measures for GxP regulated environments. This includes key projects with the focus on chromatography LIMS, PCS and MES through ERP, Pharmacovigilance, EDC, Efficacy, and DMS. *http://q-finity.com*

MHRA Draft Guidance on GxP Data Integrity …a Few Thoughts

Eldin Rammell, Director, Rammell Consulting Ltd

In July 2016 the Medicines and Healthcare products Regulatory Agency (MHRA) released a definitions and guidance document on the topic of data integrity for GxP regulatory data. The public consultation period closed on 31 October 2016. However, I've been hearing an increased interest in this topic over recent days so have provided my perspective.

I provided an official response to the consultation request and if you are interested you can read it at *http://bit.ly/2jkDAvG* . In summary, I welcome the effort to provide some clarity by the MHRA on this topic, as well as promoting consistency between the different GxPs. However, I have a big concern about proportionality and am worried that once this guidance becomes final, industry will take a knee-jerk response and apply disproportionate measures to ensure data integrity and alignment with the guidance. We need to remember that many of the electronic systems that are in use hold "regulated data" in some shape or form but errors that concern data integrity will have little or no impact on data reported to regulatory agencies or ultimately to the safety and well-being of the public. I would not like to see "heroic measures" employed by industry to secure data integrity and for regulatory inspectors to expect perfect systems when the data within the IT systems really does not justify this approach. Remember, it is the regulatory agencies that are encouraging us to "take a risk-based approach"!

In addition, I thought there were many inconsistencies and ambiguities within the draft document. For example, there are three different terms used to describe a copy and these are used interchangeably: true copy; certified copy; and verified copy. The term "dynamic data" is introduced within the guidance without a definition and is then used in a way that does not give the reader a clear understanding of what is meant by this term. And the term "durable storage" is used without explaining exactly what this term means.

Finally, I think the requirements described for the long-term retention of audit trails, electronic signatures and other "dynamic data" are in conflict with the requirement to maintain accessibility and usability over an extended period of time (in excess of 25 years for GCP-regulated data). Given that we're being encouraged to adopt a risk-based approach, I would expect to see some pragmatism in the document to give readers some realistic options for long-term digital preservation, whilst maintaining data integrity.

I shall look forward to seeing the final published guidance document!

About the author:

Eldin founded Rammell Consulting in 2004 following a 17-year career as an archivist and records manager at Glaxo (now GSK) and Pfizer. He has a very broad experience within life sciences, including GxP-regulated functions (pre-clinical, clinical & manufacturing) through to non-GxP functions such as human resources, finance and engineering. He is active in several industry groups including the DIA TMF Reference Model and is current Chair of SAG. He enjoys presenting and is a regular speaker at various industry conferences. He is originally from Birmingham and now lives with his family in Worcester, UK.

About Rammell Consulting:

Rammell Consulting Ltd provides records and information management consultancy to life science organisations. Founded in 2004, the company has supported around 50 different organisations around the world, from virtual biotechs to multinational pharmaceutical companies. The company has particular expertise in the management of clinical trial documentation and the interpretation of related GCP regulations. *http://rammell-consulting.co.uk*

MHRA
Regulating Medicines and Medical Devices

Update on the TMF Reference Model

Karen Roy, Senior Vice President, Client Solutions, Phlexglobal Ltd

The Trial Master File (TMF) Reference Model provides standardized taxonomy and metadata, and outlines a reference definition of TMF content using standard nomenclature. The Model was developed - and is being maintained - by an industry collaborative effort, managed under the auspices of the Drug Information Association (DIA) Document and Records Management Community group.

As the TMF Reference Model enters its 9th year of existence, I continue to be impressed by the level of enthusiasm and interest in the trial master file (TMF) world. We meet as a group at least six times a year, and the calls have over 100 people each time!

With over 600 members from over 200 companies, it is truly a global Clinical Research initiative that has gained significant momentum and changed the face of TMFs for the future.

Version 3 was released in June 2015, and whilst the next version is not currently planned, there are many initiatives underway. These initiatives focus on a variety of aspects of TMF management, but one that really looks to the future is the exchange mechanism. This initiative will help standardise the exchange of TMF documents and metadata between different parties – CROs and sponsors, sponsors and sponsors, and maybe even regulators in the future. The first release will be in early 2017, and with many of the eTMF vendors on board, it is destined for success. Integral to the exchange mechanism are the metadata and sub-artifact initiatives.

Quality is naturally a focus of the TMF Reference Model group – with initiatives on quality, inspection preparation, milestones and dating conventions contributing.

Finally, the annual survey is due to be released: find it on *www.tmfrefmodel.com*, along with a host of other useful resources, including a user guide (currently being updated as an initiative along with adding an implementation toolkit).

It truly is Too Much Fun!

About the author:

Karen Roy graduated as a Pharmacist in South Africa and began working for Eli Lilly. In 1992, she moved into Clinical Research with Chiltern International, initially managing the Clinical Development Department then establishing and managing a new and novel global group, EDC Solutions. In 2007, Karen joined Phlexglobal as Chief Business Development Officer where she is now Senior Vice President, Client Solutions in 2015. With her clinical and EDC background, Karen has taken a lead role in Phlexglobal's eTMF initiative, to promote, develop and implement support of client eTMF systems as well as Phlexglobal's eTMF Solution, PhlexEview. Karen is Co-Chair the DIA TMF Reference Model, an industry driven initiative to standardize the content, naming and structure of TMFs. *kroy@phlexglobal.com*

About PhlexGlobal:

Phlexglobal is a specialist provider of technology-enabled, Trial Master File (TMF & eTMF) document management solutions and other support services to the global clinical research market. It offers a unique combination of clinical trial knowledge, document management skills, regulatory understanding and technical expertise to deliver a range of flexible, targeted solutions to meet business needs. *http://www.phlexglobal.com*

DIA DEVELOP INNOVATE ADVANCE

ICH GCP Guidelines (E6) Addendum Now Available

Eldin Rammell, Director, Rammell Consulting Ltd

So after securing approval at the November ICH meeting in Osaka, the revised text of the ICH guidelines for Good Clinical Practice – otherwise known as ICH E6(R2) – has been published on the ICH website….. and also available to download at http://bit.ly/2iReZxJ. I recently highlighted some of the issues that I thought needed to be addressed. Although many were not resolved by the final approved wording of the guideline (no surprise there!), I was pleased to see some changes since the initial draft was circulated for consultation. I have these highlighted below.

The revised guideline now includes a definition for a *"certified copy"* and provides for such copies replacing the originals. Section 8.1 states:

"When a copy is used to replace an original document (e.g., source documents, CRF), the copy should fulfill the requirements for certified copies".

This statement suggests strongly to me that it is acceptable to generate a certified copy (e.g. a digital scan of a paper document) and for the copy (the digital file) to completely replace the original paper version i.e. the paper copy can be destroyed. If the paper original is being retained, then the copy is not actually replacing anything….. it is being filed in addition to the original! You may want to retain originals for other reasons (e.g. originals may have greater evidential weight if relied upon in court) but this is not needed to comply with the guidelines here.

The final definition of a certified copy is slightly different from that first proposed but I think the subtle change is extremely important. The original wording proposed was:

"A paper or electronic copy of the original record that has been verified (e.g. by a dated signature) or has been generated through a validated process to produce an exact copy having all of the same attributes and information as the original."

The two highlighted words are significant and were mentioned in my feedback to ICH during the consultation period. *"Exact"* is a very precise term, as is *"all"*. It is often the case that conversion of documents from one format to another results in a copy that is not 100% identical to the original in EVERY respect. But still, it contains all of the information, content and structure that is critical from a GCP compliance perspective and to support patient safety and data integrity. So the revised definition takes account of this nuance of document conversion:

"A copy (irrespective of the type of media used) of the original record that has been verified (i.e., by a dated signature or by generation through a validated process) to have the same information, including data that describe the context, content, and structure, as the original."

So, I would argue that a PDF rendition of an email potentially loses some metadata components related to the email header (so is not an *"exact copy"* based on the original definition) but retains *"the same information"* contained within the email, the structure of the email and the context of the email, and would therefore constitute a certified copy (if produced through a validated process). And of course the ICH definition allows for certification via use of a validated process, not requiring a dated signature to certify each and every copy! It is worth noting that the current FDA definition of a certified copy differs from the ICH addendum definition but the FDA have stated that the *"draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or Agency) on this topic".*

The second small but significant change that is of interest from a records management perspective is the specific inclusion of the requirement for *"systems for archiving"*. The original addendum included the following statement in section 8.1:

"The sponsor and investigator/institution should maintain a record of the location(s) of their respective essential documents. The storage system (irrespective of the media used) should provide for document identification, search and retrieval."

The final text states:

"The sponsor and investigator/institution should maintain a record of the location(s) of their respective essential documents including source documents. The storage system used during the trial and for archiving (irrespective of the type of media used) should provide for document identification, version history, search, and retrieval."

So there are three new concepts that are emphasised here:

1. The TMF inventory or index that is maintained both by the sponsor and by the investigator / institution must include all records considered part of the TMF, including source documents.
2. The issue of long-term retention and preservation of TMF content must be addressed and those systems selected for archival purposes must meet the same requirements for document identification, version control, search and retrieval as systems used during the trial.
3. The system for good version control and maintenance of an immutable audit trail of version history throughout the retention period must be assured – including those systems used for archiving.

The GCP addendum includes many other changes, some of which are directly relevant for records management and TMF management and can easily be found by reference to the additional sections in the guideline. I've just highlighted here what I consider to be two of the most significant ones for TMF management as they relate to concepts that are often misunderstood and variously interpreted across industry.

About the author:

Eldin founded Rammell Consulting in 2004 following a 17-year career as an archivist and records manager at Glaxo (now GSK) and Pfizer. He has a very broad experience within life sciences, including GxP-regulated functions (pre-clinical, clinical & manufacturing) through to non-GxP functions such as human resources, finance and engineering. He is active in several industry groups including the DIA TMF Reference Model and is current Chair of SAG. He enjoys presenting and is a regular speaker at various industry conferences. He is originally from Birmingham and now lives with his family in Worcester, UK.

About Rammell Consulting:

Rammell Consulting Ltd provides records and information management consultancy to life science organisations. Founded in 2004, the company has supported around 50 different organisations around the world, from virtual biotechs to multinational pharmaceutical companies. The company has particular expertise in the management of clinical trial documentation and the interpretation of related GCP regulations. *http://rammell-consulting.co.uk*

Dates for Your Diary SAG Training Courses

21st Mar 2017	The Role of the Archivist and the Operation of a GLP Archive
23rd Mar 2017	The Role of the Archivist and the Operation of a GCP Archive
11th Apr 2017	TMF Essentials (USA)
27th Apr 2017	SAG Conference
9th May 2017	TMF Essentials (UK)
10th May 2017	Management of Electronic Records
12th Sep 2017	TMF Essentials (UK)
13th Sep 2017	Management of Electronic Records
17th Oct 2017	The Role of the Archivist and the Operation of a GLP Archive
19th Oct 2017	The Role of the Archivist and the Operation of a GCP Archive

The Role of the Archivist and the Operation of a GLP Archive

The primary focus of the course is on the implementation of archive procedures within an organisation and the operation of an archive in compliance with GLP. The principles of archiving covered in this course are also relevant for any research or scientific archive.

Date(s): Tuesdays 21st March & 17th October 2017
Location: Qualogy, Rushden (near Nottingham) UK
Cost: £350 +VAT for SAG members
£390 +VAT for non-members
Bookings: *http://sagroup.org.uk/training/glp-gcp-training-courses*

The Role of the Archivist and the Operation of a GCP Archive

The primary focus of the course is on the implementation of clinical archive procedures within an organisation and the operation of an archive in compliance with GCP.

Date(s): Thursdays 23rd March & 19th October 2017
Location: Qualogy, Rushden (near Nottingham) UK
Cost: £350 +VAT for SAG members
£390 +VAT for non-members
Bookings: *http://sagroup.org.uk/training/glp-gcp-training-courses*

TMF Essentials (UK)

This one-day training course is deigned to be suitable for anyone with responsibility for establishing or maintaining trial master files. The course covers some of the underlying records management principles (e.g. record definitions and records lifecycle) and covers the regulatory requirements for trial master files including creation, maintenance and long-term retention.

Date(s): Tuesdays 9th May & 12th September 2017
Location: Heathrow Touchbase Meeting Centre, Bath Road, Hounslow TW6 2AB UK
Cost: £350 +VAT for SAG members
£390 +VAT for non-members
Bookings: *http://sagroup.eventhq.co.uk/tmf-101*

TMF Essentials (USA)

This one-day training course is deigned to be suitable for anyone with responsibility for establishing or maintaining trial master files. The course covers some of the underlying records management principles (e.g. record definitions and records lifecycle) and covers the regulatory requirements for trial master files including creation, maintenance and long-term retention.

Date(s): Tuesday 11th April 2017
Location: Daiichi Sankyo Learning & Conference Center, Parsippany, New Jersey, USA
Cost: £350 +VAT for SAG members (appx $520)
£390 +VAT for non-members (appx $465)
Bookings: *https://sagroup.eventhq.co.uk/tmf-101-us*

Management of Electronic Records

The course has been designed to provide practical training and guidance to those responsible for the management of electronic records, including:

- the management of records in regulated business systems (such as electronic trial master files and SharePoint sites);
- the management of record life-cycles, including record creation and templates; and
- the management of electronic archives.

The course covers all aspects of managing electronic records and the specific regulatory requirements that apply in this area. Specific topics covered include: Regulatory and Legal Requirements; File formats and Storage Media; Electronic Record-keeping Tools; e-Mail; Electronic Signatures; Digital Preservation Strategies; Archive Solutions

Date(s): Wednesdays 10th May & 13th September 2017
Location: Heathrow Touchbase Meeting Centre, Bath Road, Hounslow TW6 2AB UK
Cost: £350 +VAT for SAG members (appx $520)
£390 +VAT for non-members (appx $465)
Bookings *http://sagroup.org.uk/training/management-of-electronic-records*

Detailed programmes for each course and booking forms are available on the training page of the SAG website: *www.sagroup.org.uk/training*. To reserve your place, please download and complete the booking form.
If you have questions, please contact *training@qualogy.co.uk*

Dates for Your Diary SAG Conference

This major sector-specific gathering provides an annual opportunity to hear views from regulators, experts, thought-leaders, and leading practitioners in their field on key challenges and trends in records management facing the life science and healthcare sectors.

The 2017 Conference, themed **"Tackling and Resolving Challenges"**, will include a packed programme of inspirational speakers, lively discussions and networking opportunities , all centred around the latest thinking, industry innovations and best practice.

The following presentations are currently confirmed:

- An Update on Data Integrity Guidance - MHRA Speaker
- The Role and Use of Portable Document Format (PDF) Files in Records Retention
- The Application of Mind Mapping Tools and Techniques for Records Managers and Archivists
- Implications of the General Data Protection Regulation (GDPR) on Collecting and Retaining Personal Data in Drug Development Studies
- Understanding when Destruction of Original Records is Permissible
- Archiving and Managing Clinical Trial Records from Non-commercial Clinical Trials - A Case Study
- Practical Information Governance for Records Managers and Archivists
- Operating a Global Records Management Programme in a Complex, Electronic Environment
- Metadata and Data Integrity
- Litigation and the Role of Records Management and the Archivist

Awaiting Confirmation:

- The Role of the National Institute for Health and Care Excellence (NICE) - NICE Speaker
- Paperless GMP Records
- Project Management Skills for Records Managers and Archivists
- Developing a Contract for Records Storage

Date(s)	**Thursday 27th-Friday 28th April 2017**
Location	**The Midland Hotel, 16 Peter Street, Manchester M60 2DS**
Cost	**See opposite**
Bookings	**https://sagroup.eventhq.co.uk/sag-2017-conference**

SAG offers range of pricing options including:

Full Delegate: Two nights' bed-and-breakfast accommodation checking-in on Wednesday 26th April (check-out Friday 28th April), two-day conference, drinks reception, conference dinner on the night of arrival (Wednesday 26th April) and Thursday 27th April, and all conference session refreshments

24-Hour Delegate: One night bed-and-breakfast accommodation, one day conference sessions, including lunch and refreshments throughout the day. This rate is available for Thursday 27th April (hotel check-in Wednesday 26th April) or Friday 28th April (check-in Thursday 27th April). The rate does NOT include the drinks reception or gala dinner on Thursday 27th April.

Day Delegate: Admission to the conference sessions on 27th April or 28th April, including lunch and refreshment breaks. This rate does NOT include accommodation, the drinks reception or gala dinner.

Drinks Reception & Dinner: For day delegates, 24-hour delegates or delegates wishing to bring a guest.

SAG members whose membership is fully paid at the time of booking will be entitled to a 15% discount on the conference rates quoted below. The discount will be applied at the payment screen subject to the appropriate discount code being entered. The use of the discount code will be validated against the current membership list.

	until 5th Mar 2017	*thereafter*
Day 1 Thursday 27th April	*£165.00*	*£220.00*
Day 2 Friday 28th April	*£165.00*	*£220.00*
Full conference Day 1 & Day 2	*£330.00*	*£440.00*

Special Interest Group Membership:

My e-Records SIG Experience

Heather Hanger, QA Specialist, Exco InTouch (UK)

Hello! I'm Heather Hanger, QA Specialist and Archivist for Exco InTouch, the leading provider of mobile and digital patient engagement and data capture solutions for clinical research and healthcare providers. Exco InTouch have offices in North America, Canada and in the UK in Nottingham, where I am based.

I joined the Scientific Archivists Group (SAG) in 2013, in order to assist me with understanding the requirements of my newly-appointed Archivist role. From the start, I found the group to be very warm and welcoming, and extremely useful in progressing my archiving knowledge. The Sagacity articles, conferences, workshop training sessions and LinkedIn group discussions were all incredibly helpful.

In 2014, the Scientific Archivists Group published "A Guide to Archiving of Electronic Records" which I found to be very useful. A few months later I became aware through the LinkedIn group of the launch of an Electronic Records Special Interest Group (e-records SIG). This was being set up in response to the publication of the Guide, and would complement the existing GCP Special Interest Group.

Working for a technology vendor whose records are nearly all electronic, I immediately decided to get involved, as I realised that I would be in a good position to contribute to the group and learn from others.

The initial meeting was held early in October 2014, over teleconference, and chaired by Hugh O'Neill. The Autumn SAG workshop followed a fortnight later, which was a great opportunity for many of us e-records SIG members to meet face-to-face.

Following the first meeting, a pattern of monthly meetings was quickly established, where we would consider various topics that had come up on the LinkedIn discussion threads, with the aim of producing guidance documents for the use of SAG members and the wider community in order to promote the SAG. Regular communication is maintained between the formal meetings through the use of email and shared files.

The first guidance document that we worked on was entitled "Archiving Audiovisual Files", and was published in May 2015. Hugh did a great job in delegating the tasks between us, keeping us on track and even finding a subject matter expert to review the final draft.

Following the successful publication of our first guide, we chose "The Role and Use of PDF in Records Retention" as our second topic of interest from the LinkedIn discussions. This turned out to be a very large topic, which required a lot of research from all of us! Once again, Hugh did an excellent job in keeping us motivated and contributing through the course of our research and reviews. The guidance paper was published in November 2016 and provides a lot of information within its 26 pages.

I have been a member of the e-records SIG for two years now, and the experience has benefitted me immensely. The opportunity to research and share knowledge with so many experienced people has really helped me develop my subject matter expertise, and provide me with plenty of real-life understanding for my role in archiving electronic records.

The regular teleconference meetings also help with getting to know others so much better, and are a great way of building networks with professionals who have similar interests.

Because SAG has given so much to me, being a SIG member is a really great way to give something back! Helping to create papers that promote SAG as a respected thought-leading organisation allows me to make a positive contribution to something I have a real interest in.

As I write this, we are almost in December… and instead of thinking about Christmas, the e-Records SIG is turning its attentions towards the subject of electronic signatures!

This is a topic that I am especially looking forward to, as I have practical experience in this area following our recent migration from one digital signature solution to another in the summer.

I am sure that once again, the combined experience and research of the e-records SIG will produce a guide which will be of great use to other archivists dealing with electronic records. Watch this space!

SAG members can find out more about the e-records SIG through the LinkedIn Group.

Guidance papers produced by the e-Records and GCP Special Interest Groups can be found on the Publications page of the SAG website.

The GCP and e-Records SIG members are always interested in hearing from others with similar interests. If you are interested in joining either of the existing SAG SIGs, please contact Alex or Hugh or Alex.

Maybe you have expertise in a different area, such as GLP. If so, SAG welcomes proposals from those who would be interested in setting up their own SIGs within the Group.

The SAG Linkedin Group - FAQs

What is the SAG LinkedIn Group?

To answer this question, we first need to answer the question: "What is LinkedIn?" LinkedIn is the world's largest online professional network with hundreds of millions of members. The service enables you to connect with people you know and to join groups of people with similar interests to your own.

How is it different from other social media applications like Facebook?

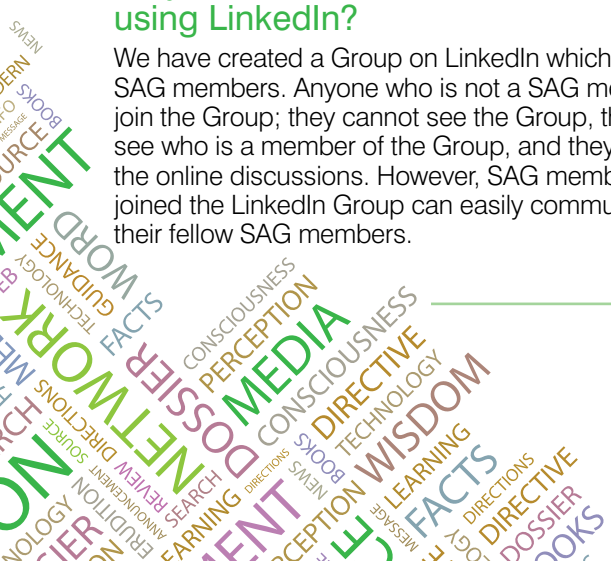
The underlying philosophy of LinkedIn is to build a network of connections by linking up with people that you personally know and trust on a professional level. These connections are called "1st-degree" connections. Depending on the security settings that each member has selected, you might also be able to see the 1st-degree connections of colleagues in your network - so these are 2nd-degree connections – and also the 1st-degree connections of those individuals – these are your 3rd-degree connections. LinkedIn also allows you to join Groups. These are networks of people who are interested in a particular subject. Group members can then join online discussions about topics of mutual interest.

I am concerned about online privacy and security. Is this a problem?

People are justified in being concerned. However, with regards to security and privacy provision, LinkedIn is one of the best online networking tools. For individuals who prefer to remain private online, LinkedIn allows you to lock down your profile information so that only your 1st-degree connections and members of Groups that you have joined can see your profile and the only information that they can see is your name. This information will not be available to people outside your group of connections or to people outside the Group that you are a member of. It will not be available, for example, via a Google search. You can then choose how much additional information these people can see or whether you wish to make your profile visible to LinkedIn members outside this immediate circle. If you choose, you can also make your profile visible to the public; this will then be searchable by standard internet search engines.

Why is SAG interested in me using LinkedIn?

We have created a Group on LinkedIn which is just for SAG members. Anyone who is not a SAG member cannot join the Group; they cannot see the Group, they cannot see who is a member of the Group, and they cannot see the online discussions. However, SAG members who have joined the LinkedIn Group can easily communicate with their fellow SAG members.



You can follow discussions on the discussion board and choose whether to just read the information posted or to get involved and make contributions.

It is also a great way for the SAG Committee to pass on information quickly and easily to all of our members. Rather than sending everyone an email and running the risk of emails not being received, getting blocked by spam filters or just getting lost in the deluge of emails we routinely receive, information broadcasts are easily accessible via the LinkedIn Group. You can choose to receive a notification each time information gets posted to the SAG LinkedIn Group or perhaps receive a digest of information once each day or once each week. This is also a great way of making your opinions known about certain issues. For example, we recently asked members via LinkedIn about their training needs.

How can I join the SAG LinkedIn Group?

As previously described, the security settings of the SAG LinkedIn Group are such that you will not be able to simply login to LinkedIn and join the group. If you have recently joined SAG, you will have received a personal LinkedIn invitation. If you no longer have this or have been a SAG member for some time, please contact the SAG Membership Secretary (membership@sagroup.org.uk) and request an invitation to join the Group.

Further information about LinkedIn and the SAG Forum is available on the SAG website *http://sagroup.org.uk/sag-forum.*

Call for Future Articles & Speakers

Have you seen an item of news that you think would be of interest to SAG members?

Have you been working on a project that has been challenging or might be of interest to other SAG members?

Would you like to raise awareness of a particular issue, trend, or new practice that you have recently discovered?

Have you ever wondered about submitting an article to Sagacity or giving a presentation at one of our conferences?

If so, please let us know and we may include it in the next edition of Sagacity or invite you to speak at the next SAG conference. Indeed SAG is keen to learn from others' experiences, to welcome new, thought provoking contributors and speakers and will be delighted to hear from you. Please contact Russell Joyce or e-mail *sag-journal@sagroup.org.uk.*

Scientific Archivists Group

Promoting excellence in records management

www.sagroup.org.uk

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