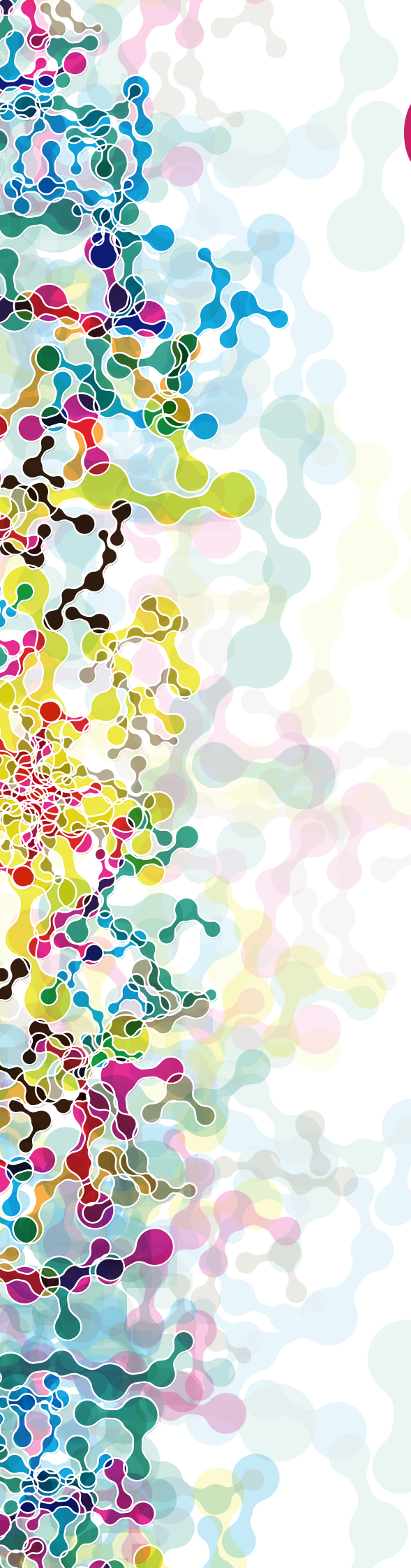

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ON record

THE JOURNAL OF THE HSRAA

EDITION 4: AUGUST 2019

THIS ISSUE HIGHLIGHTS

HEALTH SCIENCES RECORDS & ARCHIVES ASSOCIATION

INSIDE THIS ISSUE

HEALTH SCIENCES **RECORDS & ARCHIVISTS** ASSOCOATION

LETTER FROM THE CHAIR

Over the course of the past few months, HSRAA has seen a few changes. Its Chairperson, Eldin Rammell has resigned due to personal commitments outside the HSRAA. Its lead of the GCP Special Interest Group also had to make a difficult decision to depart from his role. The HSRAA Operations Committee has been struggling to replace members lost to external circumstances..

And before you think this is a letter of complaint, it is not! This letter is a lamentation on the future of associations such ours.

HSRAA has a long established, and well-deserved reputation for reliability and professionalism among GxP archivists and with regulatory bodies such as the MHRA and EMA. This reputation's foundation was based on solid industry expertise shared via UK based face-to-face training, well-constructed whitepapers, and profitable information sharing. With the shift in the Archivist's role in the pharmaceutical industry, a new focus has come to play: data/records management or information management. With the increasingly extensive use of electronic records, archiving and records management has become a far more complex function within life science organisations.

How successful has the HSRAA been in mirroring this change? From the archiving of physical media, there came records management, including electronic archiving and electronic record management, digital preservation, Trial Master File, inspection readiness, GDPR and many more. With the expansion of its membership, it has become more and more challenging to ensure HSRAA retains its purpose, meaning and relevance to its members.

So now we call to you: what is it that you the members need?

- Training? And, if so, via classroom or via webinars?
- More white papers, opinions, analysis, and guidance?
- Cheat sheets and other aids?
- Mentoring programmes?
- Rotating committee memberships?

To help HSRAA serve you better and provide value for money, please complete completing the survey. Looking forward to hearing from you,

Dora
chairperson@the-hsraa.org

LETTER FROM THE CHAIR
Dora Endreffy

CHANGES TO THE HSRAA OPERATIONS COMMITTEE MEMBERSHIP

Retiring Members

At the end of June 2019, Eldin Rammell stepped down from the HSRAA Operations Committee. HSRAA is hugely indebted to Eldin for his considerable contributions, his leadership, and strategic vision as Chair of the Operations Committee. Eldin will remain as a Director of SAG Ltd (the HSRAA parent company) and continue to work with the other Directors of SAG Ltd. (currently Russell Joyce and Jamie Toth) on developing the strategic vision for the Association.

Whist awaiting appointment of a new Chair, Russell Joyce has acted as interim Chair.

Alex Dingenouts has also be stepped down from his roles as Technical Manager, member of the Operations Committee, and Lead for the GCP Special Interest Group. HSRAA thanks Alex for his assistance.

HSRAA therefore had two vacancies on the Operations Committee, each for two-year tenure.

New Appointment

HSRAA is also pleased to announce the appointment of a new HSRAA Operations Committee Chairman, Dora Endreffy. Dora has served on the Operations since 2017 and brings a wealth of experience to the role.

Following a call for nominations, HSRAA is pleased to announce a new Operations Committee members: Roxanna Boyd, Archivist and Records Specialist at TauRx Therapeutics Ltd. A very warm welcome to Dora and Roxy!

CHANGES TO THE HSRAA OPERATIONS COMMITTEE MEMBERSHIP

LETTER FROM THE EDITOR

Dora Endreffy

LETTER FROM THE EDITOR

Dear Reader.

This ONrecord issue is dedicated to the topics and presentations shared during the 2019 HSRAA conference in Cardiff.

I am certain all of us had different key take away points and I also know that some of us left the conference with somewhat controversial impressions. The root cause of the controversy was the substantially larger focus on information technology in the presentations. Some of us questioned why this was needed.

I will not tell you what you think, neither what your takeaway should have been; but I will share my "aha" moment with you.

We manage records, data, documents, etc…but we still think of these as something that has 4 sides, a top and a bottom and of course margins. Something like this:

In recent years, I have heard a lot of complaints for my colleagues in operations relating to system upgrades or implementations. The majority of these were around IT not understanding the requirements of the business, the systems unable to reflect manual procedures that had been working oh so well for X number of years before, the system unable to cater for the operative needs.

On the other hand, as a Records Manager I have also heard a lot of complaints from IT relating to the business requirements towards an upgrade or a new system. The list ranges from: the business never provided a clear required data flow including interactions; never got clear audit trail requirements, to the business misusing the system functionalities desperately trying to mirror the manual processes in the new application. Note, when IT talks about data, this is what we see on their shared screen:

So who is right and who is wrong here? Are we just simply lost in translation? I believe we are.

The heights of information technology have long surpassed the average person's knowledge of IT. An average end user will not be able to judge upon first glance how to revisit their existing manual processes to ensure they can get the most out of the system functionality. Similarly, the developers will not know what the archiving requirements are of the data (and hence the system itself) and the related audit trails (in fact what kind of audit trail will be required at all). We must start building a bridge.

Maybe Records Managers and Archivists should start seeing the world less like a paper page, maybe even venture into the world of basic coding to readjust our own brains.

And IT should understand that we have no idea what we need. Maybe take a picture frame and put it around their codes to try to see the world from our perspective and then take our hands and teach us to see their world without the margins and the limits.

Welcome to the future of Records Management!

Dora

chairperson@the-hsraa.org

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 *https://the-HSRAA.org* 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).

MEMBERS PAGES

Ashley Cole

Membership renewals

During the course of 2018, HSRAA made significant progress broadening awareness of the organisation by collaborating with partner organisations such as Marcus Evans, ExL Pharma, DIA and IQPC, delivering full-day training workshops on GxP records management and TMF Essentials. This has been particularly successful in marketing HSRAA, resulting in increased membership and enhanced industry-wide engagement with HSRAA. If you are attending industry meetings, conferences, events please consider promoting HSRAA and encourage colleagues to join as members

Existing members receive three reminder e-mails:

- 60 days prior to expiry of membership
- 30 days prior to expiry of membership
- 7 days prior to expiry of membership

This should provide ample opportunity to renew membership and to make the relevant payment. Once payment is received, no further e-mail reminders will be issued.

Payment must be made before the expiry date otherwise membership will automatically expire along with membership benefits e.g. access to the member-only pages on the HSRAA website. HSRAA regrets that it cannot make allowances for delays caused by company finance systems or any extra-ordinary processes.

Any member who allows their membership to lapse will then not be able to log in to make a renewal payment and will need to apply online for a new membership. It is therefore advantageous to ensure that membership is renewed promptly.

New Members

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

Name	Organisation	Name	Organisation
Catherine Hoet	DigiDyco	JP Miceli	Advanced Clinical
Bob Thompson	Reckitt Benckiser	Pawel Rucki	GW Pharma
Rachel Bannister	Reckitt Benckiser	Marco Alberici	Chiesi
Rachael Cameron	Clintec	Janina Babiarz	PSI
Joanna Faraj	Mitsubishi Pharma	Lyn Thompson	Newcastle Clinical Trials Unit

REDUNDANCY

If any members have been made redundant during the last 12 months and are still without employment, remember that the HSRAA 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@the-HSRAA.org*).

RETIRED MEMBERSHIPS

A reminder to retired members that HSRAA 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@the-HSRAA.org*).

Important -Member Contact Details

Almost all HSRAA communications to its members are via email. HSRAA wants to continue to ensure that members receive HSRAA information as frequently and seamlessly as possible.

In order to ensure that this is done, please check your personal details within your HSRAA profile (e.g. primary contact email address, address of residence as well as providing a secondary email address). Please also review your current employment and position details and update if required (please see instructions overleaf).

HSRAA appreciates you taking time to review and update this information. Your cooperation allows HSRAA to continue to circulate new and exciting information, as well as notify you of future events, training and online webinars that the HSRAA offers.

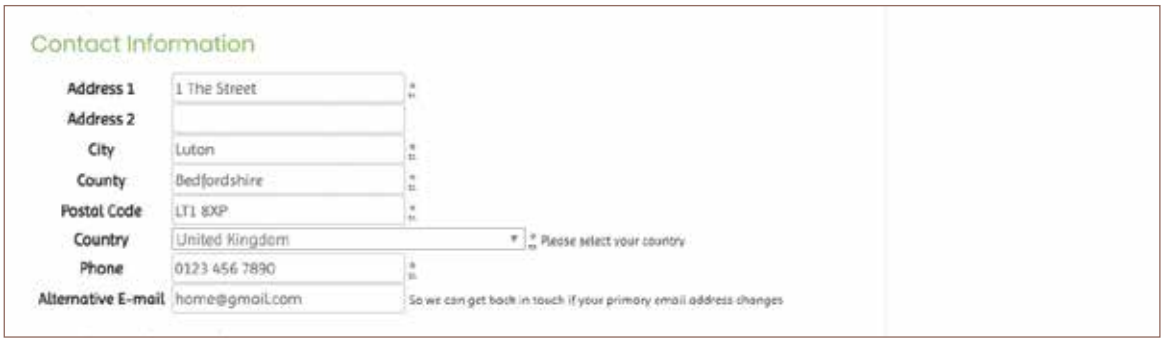
If you have any enquires regarding management of your account, please feel free to contact *membership@the-hsraa.org* where we will be more than happy to help.

...continued

Important -Member Contact Details *(continued)*

1. On the Home Page, click on 'Profile'

2. Review your contact information, specifically the primary e-mail address and contact details



3. Review your member information, specifically the profile i.e. current employer's name, current role, employer type and company's website details)

HSRAA SPECIAL INTEREST GROUPS

Special Interest Groups (SIGs) within HSRAA 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 HSRAA website. The intent of SIGs is that they will:

- act as autonomous groups within HSRAA, respecting and abiding by the rules of HSRAA
- 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 HSRAA via publications and meetings.

The first step for setting up a SIG is to identify a Lead. Without a volunteer to lead a SIG cannot be formed. Two SIGs have already been formed: GCP and Electronic Records. However, HSRAA 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@the-HSRAA.org*.

eRecords Special Interest Group

Hugh O'Neill

New Guidance Published

The eRecords Special Interest Group has published a new guidance document: "A Guide to the Use Management and Archiving of Electronic Signatures" (published June 2019). This guidance is FREE to download (*https://the-hsraa.org/download/a-guide-to-the-use-management-and-archiving-of-electronic-signatures*) and a jolly good read! Congratulations and thanks to the team!

Review of the HSRAA eRecords Archiving Guide

The SIG will carry out a review and update of the existing electronic records archiving guidance (which is very out of date) and then close the group. If you are interested in participating help with the review of the electronic records guidance please contact me via the address below.

Future of the eRecords SIG

Active membership of the eRecords SIG has dwindled and it may be time to close the group. Electronic records are no longer the special case that they were a few years ago and it makes sense to treat all records as equal and divert our attention to the more general viewpoints of the GCP and GLP SIGs. The SIG will complete the review of the eRecords Archiving Guide as its final project. In the meantime, I should like to than k all who have contributed and supported the work of the group during its 4+ years of activity!

Hugh
eRecords SIG Lead
Hugh.oneill@croftdata.co.uk

Potential Advertisers

If you sell a product or service that is of interest to HSRAA members, you may want to consider advertising in "ONrecord".

HSRAA offers 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. Discounted rates are available for repeated insertion of the same advertisement (10% for 2 insertions to 25% for 6 insertions).

HSRAA also offers the facility to send mailshots to all HSRAA members (hard-copy or e-mail) and advertorial copy in "ONrecord".

Please contact the Editor, Russell Joyce (*publications@the-HSRAA.org)* for further details.

All enquiries regarding advertising must be addressed to the Editor. Invoices for payment will be sent by the Treasurer.

Advertisements in "ONrecord" are entirely independent of any endorsement by HSRAA.

Good Clinical Practice Special Interest Group

Alex Dingenouts & Eldin Rammell

MHRA GCP Stakeholder Engagement Meeting

Eldin Rammell represented HSRAA at the May meeting of the GCP Stakeholders Engagement Meeting, held in London. The meeting was attended by 37 industry representatives and 7 MHRA staff. The agenda included an interesting presentation and discussion on the emergence of artificial intelligence use in clinical research application and its impact with respect to data integrity and GCP compliance. This topic aligned nicely with a presentation from Barney Horne, RQA on challenges when using electronic systems, especially those for validation. It is clear that system vendors need to take greater responsibility for understanding and complying with GCP requirements. The minutes of the meeting can be downloaded from the MHRA website (*https://www.gov.uk/guidance/good-clinical-practice-for-clinical-trials*).

eTMF and Audit Trials

The lack of audit trails when trial content is migrated from one party to another is becoming a common inspection finding. This arises out of a lack of understanding regarding the requirements for audit trails in applicable regulations. A project team on the GCP Special Interest Group is in the final stages of publishing a guidance document to assist companies in understanding the regulatory requirements, focusing on how organisations can align with the requirements.

Managing the Investigator Trial Master File

The HSRAA 'inherited' a reflection paper from the GCP-RMA that was originally published by the Records Management Working Party in the European Forum for GCP (EFGCP)…. back in 1995!. As this paper is now almost 25 years old, it is ready for review! A new project team has been formed to review the content of the legacy GCP-RMA document and to bring it right up-to-date. This will include, amongst other things, the challenges of managing and archiving electronic documents at the investigator site. Chris Jones is leading the project with the inaugural meeting taking place on 17th June. This team is very small and so would welcome additional participants who have some experience with investigator TMFs (also known as ISFs). The aim is to have an update document ready for publishing by the end of September. So if you have a few hours available; please get in touch with Chris.

Change of Chair

Effective from 1st July 2019, Alex Dingenouts is standing down as Chair of the SIG and handing over the baton to Eldin Rammell (who recently stood down as Chair of the Operational Committee). Eldin is looking forward to working with the SIG members and would welcome others to join who have an interest in GCP records.

Alex Dingenouts
GCP SIG Chair (outgoing)
alex.dingenouts@astellas.com

Eldin Rammell
GCP SIG Lead (incoming)
erammell@phlexglobal.com

ARCHIVING GXP DATA - IS IT ACTUALLY ROCKET SCIENCE?

Eldin Rammell, Director, Expert Solutions, Phlexglobal Ltd

Just how difficult can it be to archive electronic data generated from a drug development project? Surely it is enough to create an "Archive" folder on a secure network drive and save it there? So long as access is strictly controlled, that is OK, right?

These are questions I hear quite frequently from colleagues in the pharmaceutical and biotechnology industry. Unfortunately, there is still a lot of misunderstanding on this topic, even down to what the term "archive" actually means; in the IT world, it is often synonymous with data back-ups. When we're talking about data that is governed by GxP regulations, archiving is very different from IT back-ups. The regulations that our industry are obliged to follow have identified some very specific requirements in relation to archiving. Some of these apply only to archiving of electronic data (such as the requirement to address software and hardware obsolescence) but most apply to all data, irrespective of the format or storage media.

We see lots of problems when electronic records that should be archived are simply held within live systems. The relevant regulations do permit archiving in live systems, such as an eTMF application, but only if certain conditions are met. There are several disadvantages with this approach, however.

One is the problem caused by the sheer volume of data. An eTMF for a study containing scanned pages can grow to be a very significant volume of data ...somewhere in the region of 1Tb -2Tb of data for study if storing original TIFF files and JPG files. As each new study is initiated, this data store gets added to and grows year on year. With retention times of up to 25 years, you can see that within only a few years, you will have many terabytes or even petabytes of data stored online. Even though the studies may be tagged within the system as being 'archived', the data is still held on your live servers, subject to backup and processes to which all your live data is subjected. You can imagine that this might be an impact on system performance. The software may be sophisticated enough to exclude archived data from certain search tools but a system that holds only ongoing and recently closed trials will be more efficient than a system that also hold trial content from the last 10-20 years.

...continued

ARCHIVING GXP DATA - IS IT ACTUALLY ROCKET SCIENCE?

(continued)

Now imagine you have a system upgrade … an activity that may happen 3-4 times each year for some systems. Each time the system is upgraded, the underlying database content needs to be migrated to the new version. Oftentimes, this will not be problematic, but sometimes the current data needs to undergo an update to be compatible with the new version. There is no problem with this per se, so long as the changes are documented and the migration follows a validated process. However, the migration of several hundred terabytes of records could be more problematic than migration of only your current data.

Another potential issue we see is the risk to your archived records if held on live systems. They are typically 'locked' if in an archived status but nonetheless they still have the potential to be accessed, if only by personnel nominated as archivists and by system administrators. Any system error, malfunction, or accidental or deliberate failing of the system has the potential to affect archived data. Archived data held in separate archive storage systems are less prone to the day-to-day risks that affect our line of business systems.

Finally, for organizations that are subject to GxP regulations, it is necessary for archived data to be under the control of a named archivist. It is not impossible to achieve this where archived data is held in live systems but it is more difficult to achieve. This is especially so when all users still have access to the original content that they had access to before the data was tagged as 'archived', though the access level may have been changed to read-only. An archivist, according to the GxP regulations, is designated by management to be accountable for the day-to-day management of the archive, including the operations and procedures for archiving, and for ensuring the ongoing accessibility, preservation and integrity of archived records. This is easier to achieve and to demonstrate compliance in situations where archived electronic records are moved out of live systems at the time of archiving and stored securely in an electronic environment that is more suitable for long-term retention …in exactly the same way that we provide specific archive solutions for our paper records, under the control of the archivist.

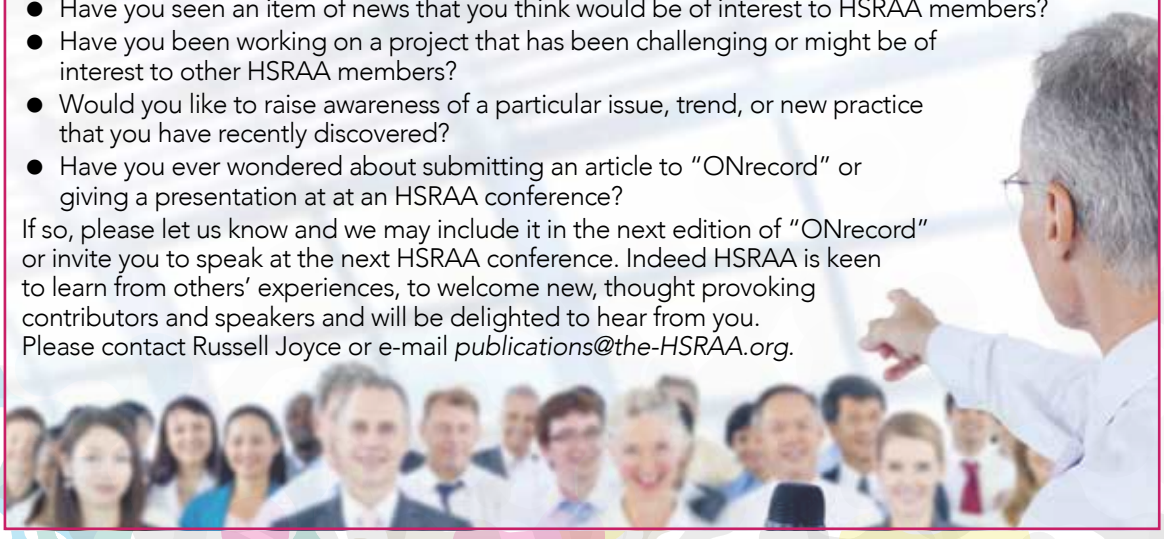
So what is the recommended approach to archiving electronic regulated records? There isn't enough space here to provide the answers in a short article but here are a couple of pointers to where you can find help. Firstly, read through the HSRAA guidance on archiving electronic records (downloadable from the HSRAA website). This contains plenty of helpful advice. You can also access a webinar recording on this topic here: *https://arkivum.com/blog/eldin-rammell-phlexglobal-archiving-gxp-data-is-it-actually-rocket-science/*

About the Author: Eldin Rammell is Director, Expert Solutions at Phlexglobal Ltd. His role includes advising clients on trial master file strategy, processes and technology optimisation. In addition, he drives thought-leadership to further advance Phlexglobal's industry reputation and position. Prior to joining Phlexglobal, he was a freelance, records management consultant for nearly 15 years, following a 17-year career as an archivist and records manager at Glaxo (now GSK) and Pfizer.

Call for Future Articles & Speakers

- Have you seen an item of news that you think would be of interest to HSRAA members?
- Have you been working on a project that has been challenging or might be of interest to other HSRAA 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 "ONrecord" or giving a presentation at at an HSRAA conference?

If so, please let us know and we may include it in the next edition of "ONrecord" or invite you to speak at the next HSRAA conference. Indeed HSRAA 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 *publications@the-HSRAA.org.*



GDPR FINES AFTER ONE YEAR: KEY TAKEAWAYS FOR BUSINESSES

Richie Koch, Managing Editor, GDPR EU

The data protection agencies have issued enough GDPR fines to draw some conclusions about what actions companies can take to mitigate their punishment. Recently published frameworks and EU opinions also shed light on the future of GDPR fines.

The purpose of the EU's General Data Protection Regulation was to give everyday EU citizens greater control over how their personal data is collected and used. Given how reliant many companies are on processing their users' personal data (and how big some of these companies are), to get these companies to comply with GDPR regulations meant the data protection agencies had to have serious teeth to punish infractions. And Article (*https://gdpr.eu/article-83-conditions-for-imposing-administrative-fines/*) certainly got businesses' attention with its two-tiered fine structure; relatively minor infringements are "subject to administrative fines up to €10 million, or in the case of an undertaking, up to 2 percent of the total worldwide annual turnover of the preceding financial year, whichever is higher" while more serious infractions are "subject to administrative fines up to €20 million, or in the case of an undertaking, up to 4 percent of the total worldwide annual turnover of the preceding financial year, whichever is higher."

The GDPR was passed on May 25, 2018, but it was not until recently that companies had a clear picture of how GDPR fines would be applied. This article will examine the fines that have been assessed so far to see what lessons can be learned. We will also look at two important documents from the EU and the Dutch DPA that contain clues about what GDPR fines will look like in the future.

Lesson 1: Expect more GDPR fines in 2019

The Polish data protection agency, known as the UODO (*https://uodo.gov.pl/en*), issued its first GDPR fine on 26th March (*https://www.infosecurity-magazine.com/news/polish-regulator-issues-first-gdpr/*), a €220,000 fine to an unnamed firm. This firm was found to have intentionally violated the GDPR when it scraped public data on some six million Polish citizens, including their names, email addresses, telephone numbers, and addresses, but only

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GDPR FINES AFTER ONE YEAR: KEY TAKEAWAYS FOR BUSINESSES

attempted to contact 90,000 data subjects to obtain their explicit consent to use their data.

This ruling provides an important precedent on how the data processing industry scrapes and uses public data. It establishes that these companies must at least make an effort to contact the data subjects to get their consent to use their data. It also shows that nearly one year after the GDPR became the law of the land, we are still in the early days of enforcement.

Part of this is to be expected. The GDPR is as complicated for regulators as it is for businesses being regulated. Many of these regulatory bodies spent most of 2018 staffing up, finalizing their internal procedures, and finishing up last pre-GDPR investigations. Moreover, it was always assumed that there would be a glut of cases at the introduction of the GDPR as businesses adapted to the new regulations. The European Data Protection Board (EDPB) released a preliminary report (*http://www.europarl.europa.eu/meetdocs/2014_2019/plmrep/COMMITTEES/LIBE/DV/2019/02-25/9_EDPB_report_EN.pdf*) stating that of the 206,326 cases reported under the GDPR across the 31 countries in the European Economic Area (EEA), the national DPAs have only resolved only 52 percent of them.

As regulators work through this backlog, businesses can expect more fines of greater amounts.

Lesson 2: Businesses can receive reduced GDPR fines by cooperating

One of the first fines levied under the GDPR (*https://www.tripwire.com/state-of-security/security-data-protection/german-social-media-provider-fined-e20k-for-data-breach/*) was against an unnamed German social media provider (later confirmed to be Knuddels -*https://threatpost.com/knuddels-flirt-app-slapped-with-hefty-fine-after-data-breach/139384/*) for a data breach that exposed 330,000 users' email addresses in September 2018. Knuddels immediately took steps to resolve the situation (*https://forum.knuddels.de/ubbthreads.php?ubb=showflat&Number=2916081* in German), including informing its users of the breach, temporarily deactivating the affected accounts, reporting the breach to the German data protection agency (*https://www.baden-wuerttemberg.datenschutz.de/*) and taking steps to improve the security of its platform.

In response, the LfDI issued a fine of €20,000, saying it was a proportionate punishment and citing the company's exemplary cooperation (*https://www.baden-wuerttemberg.datenschutz.de/lfdi-baden-wuerttemberg-verhaengt-sein-erstes-bussgeld-in-deutschland-nach-der-ds-gvo/*) and transparency as the reason it did not deliver a more severe punishment.

Lesson 3: GDPR fines are generally well below the maximum amount allowed

The EDPB, which is made up of regulators from across the EEA, released its prelimary report (*http://www.europarl.europa.eu/meetdocs/2014_2019/plmrep/COMMITTEES/LIBE/DV/2019/02-25/9_EDPB_report_EN.pdf*) examining the first nine months of the implementation of the GDPR. According to the report, the total of the fines issued under the GDPR totaled €55,955,871—but almost 90 percent of this amount is due to one fine, the €50 million fine Google received from CNIL (*https://www.cnil.fr/en/cnils-restricted-committee-imposes-financial-penalty-50-million-euros-against-google-llc*) , the French data protection agency. While the EDPB report does not specify how many fines have been issued, by using the 91 fines described in the DLA Piper survey (*https://www.dlapiper.com/en/uk/insights/publications/2019/01/gdpr-data-breach-survey/*) released in February and removing the Google outlier, we can calculate that the average GDPR fine a company faced was approximately €66,000. Furthermore, when you consider that the report says that DPAs have already handled roughly 100,000 self-reported breaches and user complaints under the GDPR, it becomes clear that most DPAs are being conservative when assessing GDPR fines.

Looking forward: The framework surrounding GDPR fines is still being created

The Dutch data protection agency, the Autoriteit Persoonsgegevens (*https://www.autoriteitpersoonsgegevens.nl/en*) , released the framework it will use to determine how severe a fine will be. While Article 83 was effective at grabbing headlines (a fine of 2 percent or 4 percent of global annual revenue will get any business's attention) it gave very little concrete guidance as to how a data protection agency should calculate the amount of a fine. (The GDPR does specify 10 criteria DPAs must use to calculate GDPR fines (*http://gdpr.eu/fines*).

The Dutch framework (*https://autoriteitpersoonsgegevens.nl/sites/default/files/atoms/files/stcrt-2019-14586.pdf -in Dutch*) has four categories of violations, and each category has a defined "default" fine, along with a range of possible fines depending on the severity of the violation.

Category of fines	Range	Default fine
Category I	€ 0 and € 200.000	€ 100.000
Category II	€ 120.000 and € 500.000	€ 310.000
Category III	€ 300.000 and € 750.000	€ 525.000
Category IV	€ 450.000 and € 1.000.000	€ 725.000

Category I applies to relatively simple or clerical violations. Failing to share the contact details of the company's Data Protection Officer (DPO) or to adequately record the responsibilities of processors or joint controllers both qualify as Category I violations.

Category II refers to when a company does not fulfill specific GDPR requirements regarding data processing. Examples of these violations include when a company does not conclude a data processing agreement with their processor, respect the DPO's independence, conduct an impact assessment, or adequately secure their users' personal data.

Category III violations refer to a company's refusal to be transparent, such as failing to notify users and the Dutch data protection agency of breaches or refusing to cooperate with the Dutch DPA.

Category IV violations are the most severe. They apply to the unlawful processing of special categories of data (such as the national identification number), illegal profiling, or refusing to comply with specific directives from the Dutch DPA.

GDPR scholars will note that the Category I and II violations do not correspond with those that are punishable by the lower tier GDPR fines (€10 million or 2 percent of global annual turnover), nor do Category III and IV violations only correspond with those that are punishable by the upper tier of GDPR fines (€20 million or 4 percent of global annual turnover). The Dutch DPA also reserves the right to levy the maximum fine allowable under the GDPR if it finds this framework not proportionate to the offense.

The head of the UK's Information Commissioner's Office (ICO) said they are coordinating with both the Dutch and Norwegian DPAs (*https://www.theregister.co.uk/2019/03/14/more_than_200000_gdpr_cases_in_the_first_year_55m_in_fines/*) to create a harmonized framework. Look for more countries to follow the Netherlands' lead.

Looking forward: ePrivacy violations count toward GDPR fines

On March 12, the EDPB issued an opinion (*https://edpb.europa.eu/our-work-tools/our-documents/opinion-board-art-64/opinion-52019-interplay-between-eprivacy-directive_en*) that went a long way toward clarifying the interplay between the ePrivacy Directive and the GDPR. One of the most important rulings was that violations of the ePrivacy Directive could be factored into a GDPR fine as long as a country's national laws designate the same data protection agency in charge of enforcing both pieces of legislation.

This is an important distinction, because the ePrivacy Directive is implemented through national legislation. While the amount of an ePrivacy fine can vary from nation to nation, they are almost always less than the maximum allowed GDPR fine. For example, the UK's ICO capped the penalties for violating the ePrivacy Directive at £500,000 (*https://ico.org.uk/media/for-organisations/documents/1545/cookies_guidance.pdf*). However, according to the EDPB's opinion, certain data processing activities, like using cookies for behavioral advertising, fall under the material scope of both the GDPR and the ePrivacy Directive.

Furthermore, the EU's Advocate General has now linked the GDPR's definition of consent, which requires an unambiguous affirmative action, to the ePrivacy Directive. On March 21 in the Planet49 case (*http://curia.europa.eu/juris/document/document.jsf?text=&docid=212023&pageIndex=0&doclang=EN&mode=req&dir=&occ=first&part=1&cid=5505677*), the AG's office ruled that pre-ticked boxes do not qualify as a user's express consent for cookies, clarifying that GDPR's strict conditions for valid consent, described in Article 4 (*https://gdpr.eu/article-4-definitions/*), are applicable when judging the validity of consent under the ePrivacy Directive (*https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32002L0058:en:HTML*), notably under Recital 25. Together, these rulings make underline the proper way to receive a user's consent and why their consent is so critical.

No company wants to pay a GDPR fine. By using our GDPR checklist (*https://gdpr.eu/checklist/*) and keeping up to date on the latest developments and interpretations of the different regulations, you can avoid costly GDPR violations.

About the Author: Richie Koch is Managing Editor of GDPR EU. Prior to joining ProtonVPN, Richie spent several years working on tech solutions in the developing world. As a senior editor at Latterly magazine, he covered international human rights stories. He joined ProtonVPN to advance the rights of online privacy and freedom. For more information and resources about the GDPR, see *https://gdpr.eu/*

THE FRAMEWORK FOR THE DESTRUCTION OF PAPER – VERSION 2.0

Lisa Mulcahy, Mulcahy Consulting LLC
on behalf of the Framework for the Destruction of Paper 2018 Team

Historically, paper documents have been created, used, managed, archived, and destroyed as documentation for support in the conduct of clinical trials. Rapidly, the documentation process has changed from creating and managing paper documents into producing and managing documents in electronic formats. Remaining paper documents is scanned into a digital format and uploaded into an ECMS. The process to convert paper to electronic creates redundancy and duplication in the management of the documentation in support of the business process as well as the possibility that 2 copies of the same document exist. The destruction of the scanned paper document is a complicated topic and necessitates a thorough examination of the requirements that confirm the electronic version is a complete and accurate representation of the paper that was scanned. .

Through the support of the DIA Document and Records Management Community, an effort was organized in 2018 to review and revise Framework for the Destruction of Paper (v2.0), which was originally published in 2012. Review and revision of this Framework has involved more than 80 professionals from more than 70 biopharmaceutical and device companies, contract research organizations (CROs), consultancy companies, and technical vendors. The scope of the initial and this latest effort is on GCP records created in support of a clinical trial in the regions involved with the creation and maintenance of the International Conference on Harmonization-Good Clinical Practice.

The goal of the Framework is to provide a single, unified interpretation of the applicable laws, regulations, guidance, and industry best practices that apply to a complex, legally defensible, and regulatory compliant paper destruction process for the regions in scope. The Framework does not provide prescriptive guidance for the detailed processes. The intent of this Framework is not to recommend specific organizational decisions on technology tools or internal processes regarding creation of documents. This detail will be unique to each organization and the decisions owned by the internal stakeholders that use the Framework to establish their own policies and procedures.

Recommendations in this revised version continue to be derived following extensive discussions and research in the same 5 topic areas of focus as were explored in version 1.0; namely Technology, Quality, Records Management, Regulatory, and Legal. The goal of this group was to revise the 2012, version 1.0, of the Framework for the Destruction of Paper,

which is a Framework which may be used and adapted by any individual, company, institution, or organization, hereinafter referred to as organization, for their own use. Therefore, the attention of participants on this effort was drawn to the non-commercial nature of this forum. The discussions of the group who created the version 1.0 of the Framework and this group who reviewed and revised version 2.0 of the Framework has not been a forum for promotion of products, capabilities, or specific companies.

The opinion of the biopharmaceutical industry professionals within this effort that the reduction of the creation of paper is paramount to the process of better content management. Making paper copies and printing electronic records that then get scanned into a digital format results in process redundancy and inefficient use of resources. When only necessary that an original or copy of a paper document be created or collected, this Framework recommends the destruction of that paper following a verified conversion of the document into a digital format. This recommendation is conditional on the following:

1. A qualified organizational risk-benefit analysis take place that considers the 5 topic areas (see below) and resultant process is in place and monitored for compliance that ensures the digitized copy is a complete and accurate representation of the paper version;
2. The digitized copy is placed in a validated electronic content management system and an archival process in place to manage the electronic records; and
3. A training plan covering the applicable Policy and SOP(s) have been created, is available within the organization, and users have successfully completed the training before utilizing the process to destroy the paper document.

It is acknowledged that the resulting Framework will need to be integrated with each organization's own policies and practices. If an organization had utilized v1.0 of the Framework, it is recommended that they review this updated version for continued alignment. The Framework will continue to be vetted through many pharmaceutical and device research and development companies, CROs, consultancy companies, and technical vendors, in addition to Regulatory Agencies and other defining bodies who could either be contributors or stakeholders who review GCP documentation. Tools are in development that support the implementation of the Framework at an organization and include decision tree, summary of changes from version 1.0 to 2.0, the workbook version of the Framework, and process maps. The Framework for the Destruction of Paper and supporting implementation tools, as they are developed, are available on the following website: *www.paperdestruction.org*.

The Framework is non-binding in accordance with the DIA's scope and mission. It should be a reference for the industry and should not be considered mandatory or an official standard, but rather as an opportunity for harmonization across the industry. The Framework does not endorse or require any specific technology for implementation.

The Framework for the Destruction of Paper is free and available through the following links on the DIA website and on the website that has been established for the paper and all supportive tools developed to facilitate its use:

- *https://www.diaglobal.org/en/resources/tools-and-downloads#Destruction-of-Paper*
- *www.PaperDestruction.org*

The amount of time and professional expertise that was contributed selflessly to the revision and creation of version 2.0 of the Framework needs to be acknowledged. This Framework is the product of thousands of hours from devoted volunteers associated with companies, large and small, who supported the effort. The activities of this team continues and so it welcomes new members, in whatever capacity they can contribute. To become involved with the continued enhancement and maintenance of this framework, contact *mulcahyconsulting@comcast.net* or join the LinkedIn Group "TMF Reference Model" and request assistance to connect with this work group.

About the Author: Lisa Mulcahy is the Owner and Principal Consultant of Mulcahy Consulting, LLC. Lisa has 25+ year career in the pharmaceutical industry, in the areas of Clinical Operations and Quality Management. Over 10 years ago she became an independent consultant, focusing solely on Trial Master File process and management assisting clients with assessment and improvement of their current state, development of future design, and implementation of systems for the management of electronic records of the TMF. She is experienced in the quality assessment of study-specific TMFs.

Lisa is an industry thought leader in the management of the TMF as well as a frequent speaker and experienced workshop leader at TMF-related professional meetings.

Lisa is chair of the DIA Document & Records Management Community. She led the team of industry representatives who recently reviewed and revised the Framework for the Destruction of Paper, v2.0. She is a co-founder and a Steering Committee member of the volunteer team of industry representatives through the assistance of DIA that created, maintains, and expands the TMF Reference Model (*https://tmfrefmodel.com*).

FIRST IMPRESSIONS

Roxy Boyd, Archivist and Records Specialist, TauRx Therapeutics

FIRST IMPRESSIONS

This year I attended my first HSRAA annual conference, this year held at the Voco St. Davids Hotel in Cardiff and have been asked to write about my experience.

This year I attended my first HSRAA annual conference, this year held at the Voco St. Davids Hotel in Cardiff and have been asked to write about my experience.

I am the Archivist at TauRx Therapeutics, a small pharmaceutical company in Aberdeen, Scotland, that is currently conducting clinical trials on a promising new drug for Alzheimer's disease. I have worked in the industry since 2017, previously as a Project Assistant for a medium-sized CRO and then as a Records Specialist at TauRx before taking on the Archivist role at the company.

The location of the conference was lovely (we were even bumping shoulders with some celebs - although sadly I don't think Damian Lewis was there to talk about records and archiving!) I cannot praise Jo Rammell enough for her choice of venue and the organisation of this event, the presentations, the networking dinner and everything in between ran seamlessly.

This was my first industry conference and if I'm completely honest, I was worried about how much caffeine I might have to consume to keep up with all the presentations! The speakers were engaging and passionate about their work, and I learned something new from each one. A couple of talks that stood out for me were

1. 'Good Data Governance' by Hans de Raad. Hans spoke about data management using language that bridged the gap between IT and Records in the pharmaceutical industry, something that is more essential than ever as the industry continues to transition to entirely electronic solutions.
2. 'Records Management Technology and Vendor Selection: A Case Study' by Pawel Rucki. Pawel talked about his experience of selecting a records management vendor and how his company carried out this process, highlighting the importance of strong communication and vision, detailed planning and the road bumps likely to be encountered along the way.

Both presentations taught me things that have already improved how I do my job and allowed me to pass on knowledge on to my colleagues at TauRx.

As well as the presentations, there were a series of interactive debates on thought provoking topics – these were great fun as well as informative and got everyone involved and thinking about industry wide challenges in new ways. I particularly enjoyed the debate about the changing role of the archivist and the questions it raised about how much involvement an archivist should have in data management before records are archived.

The conference also gave me the opportunity to meet and learn from experts from various backgrounds with years of experience and well as others who are new to the industry. There were lots of discussions about the challenges that companies are facing and comparing different approaches to tackle these. The atmosphere was welcoming and inclusive, even of 'newbies' like me and I'm glad to be part of this community. In summary, I can't recommend attending this event enough and really hope to see everyone again next year.

THE FUTURE OF HEALTH SCIENCES RECORDS MANAGEMENT

Bob Thompson, GxP Archivist, Tribal Education/Reckitt Benckiser Health Ltd.

Health Sciences or GxP ('Good Practice' in which the 'x' in our case can be Good Laboratory Practice (GCP), Good Manufacturing Practice (GMP) and Good Clinical Practice (GCP)) is a highly regulated and auditable sector of archives and records management that neither Rachel or I were aware of when we began our careers as archivists. The 'Good Practice' series of professions seek to provide companies with operating guidelines, to prove traceability and accountability to regulatory authorities. Documentation is crucial to GxP. It is an exciting sector to be a part of, as the highly regulated environment means that good records management (known as Good Document Practice/GDP) is at the heart of all the work done at Reckitt Benckiser Health (RB). That means all records are valued for their legislative and legal ramifications. .

Fundamentally, we manage the research and development records of the 'health' products that RB produce. These records cover a plethora of subjects, from microbiology, analytical, clinical, vigilance, formulation and reports. We are not expected to be the experts of these records, or to appraise their research value. We simply provide the database, structure and access from which the users may confidently store their records and retrieve them as and when they require – as well as being experts on the GxP regulations.

Furthermore, because we are a research and development archive, the nature of the work that we keep is for long term retention, specifically Clinical Trials records, which are tested on human subjects and must be kept for a minimum of 25 years under GCP regulations. Technology in the labs and at clinical trials sites are also moving away from paper (and 'wet signatures') and onto computers, via e-signatures. This method of consent needs to be retained in digital preservation technologies, to maintain the documents authority. All of this means that in future our archive needs to be 'digital ready' in order to protect the original born-digital records. Because of this 'Digital Archives' is something that Rachel and I aim to deliver within the next few years at RB.

Very recently we were internally audited by our Quality department, in which we performed well. Auditors can ask us any questions they like on how we run our archive. They base their queries on our internally published Standard Operating Procedures (SOPs), which describe – in detail – the tasks that we perform in the archive. If we are seen to be doing work outside of these procedures, it will be seen as a deviation from the SOP and therefore something that we can be held accountable for. This was great practice, as the following week the 'Medicines and Healthcare products Regulatory Agency' (MHRA) came to audit the whole site. The MHRA are a government authority that can audit any company making healthcare products and medicines. Although the archive itself was not directly audited, the follow up to the audit (and often, the audit itself) are busy times for Rachel and I, as numerous teams across the site may want to access their historic records in preparation for the investigation. Records are needed for a multitude of reasons, and entirely on the auditor's behest, for example, environmental monitoring logs in stability chambers when testing the formulation of a product at a different ambient temperature; or staff training files showing that employees have completed all of their GxP training and are therefore allowed to work in GxP environment. All processes at RB are recorded and retained and can be called upon as evidence at any time by an auditor.

Currently we are holding talks with Arkivum about what a digital preservation and records management model at RB might look like. We are also going to hold similar discussion with rival digital preservation orgainsiation Preservica, so that we might ascertain who could offer us the best model for our complex needs in the future. In addition, I am working with a our legal team in our Slough office to capture the record types that are created and used at our R&D site, so that they might be included in the future Global Retention Schedule. This will go hand in hand with our digital archiving requirements from Arkivum or Preservica, allowing us to be prepared for the future in a sector that requires concise record creation and retention, allowing us to adhere to specific, legal and regulatory obligations.

About the Author: Bob Thompson is a GxP Archivist, is employed by Tribal and contracted to work for Reckitt and Benckiser in Hull, managing their Research and Development Archive.

DORA ENDREFFY'S "CONFERENCE CALL BINGO"

DORA ENDREFFY'S "CONFERENCE CALL BINGO"

Who just joined?

Can you e-mail that?

John. Are you there?

You're still sharing!

Is someone using their keyboard?

There's a terrible echo

Hi! Can you hear me?

Sorry! Still loading.

Next slide, please!

Everyone please mute

Is that a dog there?

Sorry! Go ahead.

So. I can … by … OK?

Sorry I'm late

I have a hard stop at…

Sorry! You cut out.

I'll get back to you.

Can you see my screen?

Sorry! Bad connection!

There's a lag

Sorry! Have to jump out

Sorry! Was on mute.

Hello? Hello?

Let's take it off-line

Can you repeat, please?

Join by 'phone then..

Can I have me control?

Next meeting?

THE CHALLENGES OF DEVELOPING AND LAUNCHING A STANDARD FOR TRIAL MASTER FILE INTERCHANGE

Paul Fenton, Co-Chair of the eTMF-EMS Working Group and CEO, Montrium Inc

In June 2018 the eTMF-EMS (Exchange Mechanism Standard) was officially launched at the Annual DIA conference. This standard aims to solve one of the biggest challenges we have in the eTMF environment; eTMF interchange. In this article we will discuss the process that we went through to develop the standard and more importantly the challenges that we faced and still face to get the standard fully adopted by the industry.

As an industry, we typically work within a fairly decentralized model where clinical trial activities are being performed by multiple organizations which are all producing records and essential documents in line with regulatory requirements. In the paper world, these records would be filed and eventually transferred back to the sponsor for archiving and long-term retention.

As we move towards electronic trial master files and electronic records, the transfer of eTMF content becomes more burdensome. We have an obligation to retain the records in a 21 CFR Part 11 / Eudralex Vol 4 Annex 11 compliant manner where we can retrieve not only the record but also audit trail information and metadata.

The TMF Reference Model is often used as a structure to organize and transfer TMF content, however, when using an eTMF we also need to collect and transfer metadata to give records context and of course audit trail and electronic signature information which needs to be perpetually linked to their records.

The TMF Reference model's initial mandate was to provide a model to allow a more standardized method for identifying and organizing both paper and electronic TMFs. It did not provide specific metadata standards for describing documents or standards for audit trail and metadata. This meant that even if TMF content was organized using the reference model, a significant amount of mapping and manipulation was still required to import electronic records into the sponsor system.

Given the great burden of doing this, content was typically transferred only at the end of the study which introduced a whole series of other issues relating to quality, timeliness, completeness, oversight and inspection readiness. With this problem in mind, the steering committee decided to launch an initiative to develop a standard which would resolve this issue and greatly facilitate the exchange of electronic TMF content between organizations and systems. We called it the Exchange Mechanism.

When we first embarked on the journey to develop the standard, we knew that we would need a broad range of individuals from different types of organizations to work as a team to determine what the minimum viable set of metadata would be. We also realized that we had to build something that was flexible and not too prescriptive, given the wide variety of activities that are documented in the TMF and the fact that each organization that compiles TMFs may have slightly different processes and standards. We reached out the pharma, biotech, CRO and vendor community and put together a team of around 20 individuals.

We then set about looking for inspiration for developing standards. We identified several existing standards within our industry that could be used as examples, notably ICH eCTD and CDISC ODM. We wanted to produce something that would be flexible and human readable and so decided to base our standard on an XML (Extensible Markup Language) transport format. The advantage of XML is that it is basically a text file which can be read by machines but also by humans. It is hierarchical in nature and can be validated for format and for required information. eCTD is also based on this format. We built out a hierarchy which allowed us to describe first of all the nature of the transfer, the clinical trial for which the transfer was being made and then the information required to locate and describe each artifact; metadata and file name/location. Deciding on the transport format was fairly straight forward, agreeing on the metadata to encapsulate in the XML was a much larger challenge.

There was a lot of discussion around what metadata we should and shouldn't include. We had to define metadata which would allow us to describe the type of artifact being transferred; the characteristics of the artifact i.e. copy or authoritative source, artifact type etc.; the affiliation of the artifact i.e. what site or investigator it belonged to and other metadata which would be useful to manage the artifact once it was ingested in to the receiving system.

The initial list that we drew up was significant and we had to start to reduce it down to a more manageable set of metadata. This involved months of discussions and reviews and quite some differences of opinion between the various stakeholders who were coming from different areas of the industry with different use cases.

...continued

We finally managed to put together the final metadata set which we felt would meet at least our initial use case of being able to transfer final TMF content. We also built in the ability to define organization specific rules, conventions and standards through the use of an exchange agreement and the ability to encapsulate non-standard metadata.

Developing the first version of the eTMF-EMS standard has not been without its challenges. Some of the biggest challenges with developing such a standard are aligning the different individuals involved and also keeping the momentum moving forward. As a voluntary initiative, it is always challenging to get individuals to donate time and energy and there was a lot of movement in the team as time went on. This often resulted in revisiting the same issues multiple times and also required us to be quite strict regarding the creative license of new members. Luckily, we have had a smaller group of core members who have been involved in the initiative since its inception who have become the guardians of the standard.

The other challenge we had related to the governance of the standard. Normally a standard is ratified by a standards body who provides a structure and organization to maintain the standard over time. Examples of standards bodies would be ISO, CDISC, ICH, Oasis etc. The eTMF-EMS standard was ratified by the TMF Reference Model steering committee, but this committee is not a formal organization and the standard does not belong to any particular organization at this point in time. The rules and processes for the maintenance and governance of the standard do not yet exist and at some point it would be beneficial to maybe register the standard with a standards body that will be able to maintain it in the long term.

The final challenge moving forward is to get sponsors to use the standard and for vendors to implement it. We are now moving towards this.

Since we launched the standard last year, we have set up two round table groups, one composed of eTMF vendors and the other composed of sponsors and CROs. The goal of these round tables is to provide a forum to exchange ideas and discuss problems as a group as we move forward with implementation and adoption. Progress is slowly but surely being made and for the standard to be truly adopted, we need the ultimate beneficiaries, the sponsors, to push for it. Several of the leading vendors have started to develop interfaces and we are encouraging sponsors and CROs to plan out pilots so that we can test the standard.

The initial integration solutions based on the eTMF-EMS will likely not replace any existing integrations, but will rather enable out of the box integrations, removing manual work for smaller scopes such as single study outsourcing. One advantage of an eTMF-EMS implementation is that vendors will be able to implement the EMS as part of the standard product, therefore most of the testing and validation can be performed as part of the product development and deployment, rather than as one-off integrations, which can be resource intensive and costly.

The vendor implementation of the specifications is expected to be done in stages, which will continually deliver functionality within the scope of the specifications. One of the initial functional scopes that vendors are planning is to ensure integrity (no record loss or corruption) of records in an exchange and that the artefacts is in a triage ready state in the receiving eTMF. Others will follow.

Once we have managed to implement the standard as an industry, there are a whole plethora of other possible uses that we have envisaged. Notably, the ability to use the standard to transfer not only documents but also data. The ability to perform continuous exchanges where the sponsor is able to maintain a complete copy of the TMF at all times so as to improve sponsor oversight. The ability to use the standard as a way of archiving TMFs for long periods of time. The ability to use the standard to describe events that are occurring in the study which in turn will make it easier to leverage event information to drive study processes.

The use of standards will overtime likely lead to more process alignment across all involved organizations, which should lead to better quality and enable more efficient outsourcing. The list of possible uses is long, we just need to get over the first hurdle of adoption…

About the Author: Paul Fenton is CEO and President of Montrium Inc (*https://www.montrium.com*),a specialist electronic content management solution provider and leader in compliance for clinical trials and quality processes. Paul holds a degree in management from London Metropolitan University as well as an MBA in Technology Management from the Université du Québec à Montréal. Paul has significant industry experience at a senior management level in the development, deployment and management of computerized systems for use in regulated clinical trials. He co-founded Montrium in 2005. He has worked on major clinical technology projects both in Europe and North America and has a strong background in CDISC and ICH standards as well as in the integration of systems and processes for clinical trials. Paul is a member of the TMF Reference Model steering committee and co-chair of the eTMF-Exchange Mechanism Standard working group. *pfenton@montrium.com*

BOURBON AND LAMP-POSTS. DATA INTEGRITY AND THE USE OF WEARABLE DEVICES

Russell Joyce, Director, Heath Barrowcliff Consulting Ltd

In July 2018 HSRAA was pleased to be invited to participate in the Health Archives and Records Group (https://healtharchives.co.uk/) Conference at Kings College, London to present on the subject of data integrity as it relates to the use of wearable devices in clinical trials and to facilitate a workshop on the same subject.

The day also included presentations from device manufacturers, clinicians using wearables for research and treatment purposes, and computer scientists developing technologies to analyse wearables data. Not only did the event prove a valuable opportunity to network with like-minded professionals from the National Health Service and related sectors but it also piqued my interest in the challenges posed by this rapidly evolving and relatively novel technology.

So What is Meant by Medical Devices?

A wearable medical device is "a device that is autonomous, that is non-invasive, and that performs a specific medical function such as monitoring or support over a prolonged period of time. The term ''wearable" implies that the support environment is either the human body or a piece of clothing"1. Medical devices can take many forms

- Ingestible sensor (for recording gastric conditions)
- Smart contact lenses (for measuring blood glucose levels)
- Biometric watch (for recording blood pressure)
- Body worn sensor (for recording heartbeat)
- Mobile analytics tool (for eDC)
- Wi-Fi skins sensors (for measuring temperature)
- Ambulatory infusion pumps (used for chemotherapy treatments)

Whatever the intended purpose of the device, it must meet stringent requirements to ensure "analytic validity" (i.e. evidence that the data is being correctly processed to generate accurate, reliable, and precise results), "clinical validity" (i.e. that there is a logical association between the data output and the targeted clinical condition) and "clinical utility" (i.e. evidence that the output data provides information of value in the context of clinical care).

Regulatory Environment

From a regulatory perspective the MHRA Guidance on Medical Device Stand-Alone Software (Rev. 2018) includes a useful decision tree to determine whether or not a device is really a medical device and therefore subject to regulatory compliance, The MHRA has also issued advice on software applications, which are almost always involved with wearable medical devices. Other regulatory instruments include

- EU Regulation 2017 / 745 Medical Devices (April 2017)
- MEDDEV 2.7 / 1 Rev4 Guidelines on the Classification of Standalone Software used in Healthcare within the Regulatory Framework of Medical Devices (2016)
- IMDRF Software as a Medical Device Clinical Evaluation (2017)
- FDA 21 CFR Parts 807, 812, and 814 Human Subject Protection; Acceptance of Data From Clinical Investigations for Medical Devices (2018)
- FDA Use of Electronic Records and Electronic Signatures in Clinical Investigations under 21 CFR Part 11 – Questions and Answers (2017)
- Selection of and Evidentiary Considerations for Wearable Devices and their Measurements for Use in Regulatory Decision Making: Recommendations from the Critical Path Institute ePRO

However, none of these mentions records management, archiving, or data integrity in relation to medical devices: and there is little in terms of specific data integrity guidance for wearable medical devices despite the fact that such devices are increasingly being used in clinical research.

As with life in general, the technology is moving more quickly than the regulations designed to ensure the safety of these devices and the integrity of the data that they collect. So how to know what is going to be accepted by the regulators? And how best to provide evidence to demonstrate that an endpoint is valid and reliable?

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Ensuring Data Quality

The answer (for the time being at least) is to rely on existing rules and established best practice guidelines in relation to software use and data integrity, which are variously defined as:

- "…a set of instructions that processes input data and creates output data" [MEDDEV on software]:
- "…the original record (data) […] the first capture of information […]. Information that is originally captured in a dynamic state should remain available in that state" [the MHRA on raw data and source data].
- "The extent to which "data is complete, consistent, enduring and available throughout the data lifecycle" [the MHRA on data integrity]
- "…data ownership and accountability throughout the lifecycle […] the design, operation and monitoring of processes / systems to comply with the principles of data integrity" [the MHRA on data governance].

In its broadest sense, data integrity refers to the extent to which data are complete, consistent and accurate over their entire lifecycle. Data integrity is a critical aspect in the design, implementation and use of any technology that stores, processes, or retrieves data. To have integrity and to meet regulatory expectations, data must from the point of generation meet ALCOA criteria (see Fig1): ALCOA+ is even better!

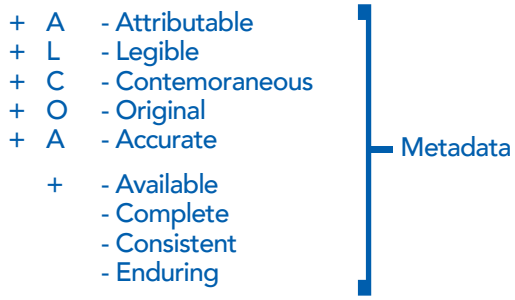

Fig 1

Because healthcare decisions increasingly rely on information provided by the output of these devices, regulatory bodies recommend that devices have level of rigour commensurate with the risk and impact of the device that provides sponsors and regulators with assurances of safety, effectiveness, and performance.

This means that they must be subject to computer systems validation to ensure accuracy, reliability and consistent intended performance at all stages from design through to decommissioning or transition. This aligns with ICH E6 Addendum R2 which talks about

1. improving management of risks to the integrity of key outcome / source data
2. appropriate use of technology and computer systems validation
3. retrieval and control of essential documents

The Problem of the Data Tsunami

Whilst the transformative potential of wearable devices is undeniable in that they allow clinicians to respond more rapidly to seamlessly, speedily collected, vast quantities of multi-layered data, it is also worth remembering that more data does not necessarily translate into better data or added value.

The real value of these devices lies in the ability to extract relevant data and the ability to use real-time analytics to monitor real-time progress, facilitate early intervention and reduce risks through remote monitoring and better support.

It is for clinicians to determine what constitutes relevant data in the context of establishing an association with a disease condition, to use their expertise to unlock the data's value to make it more actionable, contextualized and meaningful e.g. a sleep monitor will register each occasion on which the device wearer wakes up but cannot contextualise the reason why or the validity of the data.

It is for Records Managers and Archivists to understand what constitutes source data, critical audit trails, and essential data lineage elements, and to know how best to retain the data collected so that its integrity is preserved and it remains accessible, readable, and (where required) usable throughout the duration of the required retention period.

Records Managers and Archivists can also advise on guidelines and standards related to data collection, use, transparency, security, processing, storage, retrieval, and sharing. Working in collaboration with clinicians and information technology, Records Managers and Archivists also have a role to play in the evaluation of the device as "fit-for-purpose" as well as involvement in validation, particularly as it relates to data transfer, migration, conversion and the potential impacts on data integrity, reliability and trustworthiness.

In any event, a clear strategy is required to determine the "who, what, when, where, why and how" of both the device itself and its data outputs.

Bourbon and Lamp-posts?

In researching the use of wearable devices in clinical research I was reminded

of two similar quotations:

- "Gentlemen use manuscripts as drunkards use lamp-posts -not to light them on their way but to dissimulate their instability." (Alfred Housman 1903)
- "He uses statistics as a drunk uses a lamppost -for support rather than illumination" (Andrew Lang 1912)

In my mind these quotations amusingly illustrate the inherent propensity among all of us to use statistics selectively to provide evidence for only one side of a multi-sided argument. How you look at a lamppost depends on who you are, what you are, what your needs are, and your view on the world. That view changes with time and differing circumstances.

Many of these devices (particularly consumer-grade devices) record a vast range of data to variable standards, some of it relevant to the intended outcome, some of it not …or might it be?

This had me thinking:

Do we use data to prove a preconception or use the data to discover new conceptions?

Is the intent in collecting data to stimulate thoughtful response, careful framing, and vigilance for unintended consequences; or is it to prove what we already believe (whether right or wrong) to be true?

To most of us, lamp-posts are broadly unnoticed during daylight but very noticeable at night due to their useful illumination. If you are a cyclist, a lamp-post is a useful security anchor. To Gene Kelly, a novel dance prop. To a spider, a lamp-post is a home, a trap, and a source of food. And if you are a dog… But if you are a stargazer, lamp-posts (especially working ones) are a nuisance: collectively, they cloud the data you want to examine and limit your research abilities. So a lamp-post isn't JUST a lamp-post.

In Conclusion

The decision on whether or not to use a medical device lies squarely with clinicians who know what they want to measure and monitor and are best placed to know if a wearable device will help answer a specific research question or clinical endpoint in a study.

Nonetheless, Archivists and Records Managers will need to be prepared to address the challenges raised by these novel technologies, and to ask questions such as:

- Is the device "fit for purpose"? Does the purpose warrant use of a regulated medical device or might a consumer-grade device suffice? To guide that decision it will be necessary to know not only how the device will be used but how easy it will be to collect and retain the data to preserve its integrity.
- Can the device be validated, especially for data flow? It will be important to have tested infrastructure, policies and processes in place. What kinds of vulnerabilities are there with the wearable device from both technological and human perspectives (human error is often the cause of data integrity failure)? Who holds the data, especially in relation to consumer-grade devices, and for how long? Will the device itself need to be retained (if that is possible) or is it sufficient to retain just the outputs?
- Can the reliability of the data be assured? It is essential to understand how data is collected, transmitted, processed and stored. Consumer-grade devices pose unique challenges because they present data differently to those who wear the device and those who use the data from the device.
- Know the importance and relevance of the data. Know which data will be included and which will be excluded …and why …and justify it. From an ethical perspective a "can of worms" is opened if data is collected but neglected, ignored discarded as "not applicable" yet that data may have indicated a potential health risk for the patient.

Wearable devices provide convenience and instantaneous access to a wealth of real-time data and provide potential to more closely and accurately monitor patients and improve outcomes.

However, they also present data integrity challenges and so Archivists and Records Managers need to familiarise themselves with these novel technologies not only to better understand the purpose, meaning and value of the data collected but also to know how best to preserve that data to ensure its long-term accessibility, readability and usability.

About the Author: Russell Joyce is the director of Heath Barrowcliff Consulting Ltd, an independent consultancy specialising in records management and information governance in the healthcare and life sciences sectors. Russell is Director of the HSRAA, an active member of the Drug Information Association (DIA) TMF Reference Model Group Steering Committee, and Project Lead for the DIA Non-Interventional Studies TMF Model Project. He has spoken extensively on a wide range of records management and data governance issues for HSRAA, GCP-RMA, SMi Group, DIA, the Research Quality Association (RQA), Pharmaceutical Quality Group (PQG), ISPE/GAMP, NHS R&D Forum, and the Institute of Clinical Research (ICR).

Footnote 1
https://www.semanticscholar.org/paper/Wearable-Medical-Devices-Fotiadis-Glaros/c5fcae3be767730ce97cc0e9ffcedf0c5cdf392e

CHALLENGES OF A SOFTWARE VENDOR IN LIFE SCIENCES

Being a software vendor in the Life Science sector is highly rewarding

Ben Saxton, Head of Europe Sales, Formpipe Life Science

Being part of the delivery of safe and effective pharmaceuticals or treatment, albeit somewhat removed from the patient is something that drives all of us on a daily basis with a great purpose of benefiting the wider society.

However, working within such a controlled environment and with regulatory pressure correctly covering software systems brings challenges to vendors to understand their client whilst embracing exciting technological developments.

An industry leading developer once stated: "Trying to develop software within a highly regulated industry is a bit like trying to open a packet of peanuts with one hand."

So, what are the main challenges we face and how to do we overcome them?

Introducing efficiency whilst maintaining compliance

Good software will always introduce or increase efficiency whether in the business place or our consumer lives. The balance within Life Science is doing this whilst also meeting the regulatory compliance required. The challenge starts with supporting the client's business to understand their own risk appetite and how this translates into the software they choose. Do you play safe and follow the crowd or look at innovative new product that may raise questions but deliver efficiencies and increased margin.

These decisions are affected by the need to validate our software and can restrict or slow the adoption, for example, the benefits that system integrations can bring are great but the impact on change control or validation documentation needs to be considered before an active integration is made.

The result is that good software is delivered by people who understand the landscape and their guidance will bring added benefit to the wider client business. Life Science software needs to be developed, supported, maintained and sold by individuals who understand the industry and the daily challenges quality professionals face.

Making a product affordable whilst broad in appeal

Creating great software means making a product that is attractive to many. The challenge within our industry is doing this whilst also making it adaptable for lots of different scenarios. The solution lies in developing a generic product that can be configured and this requires product

owners and architects to look longer term, often taking a decision that results in additional work up front to ensure one generic product version and not bespoke solutions for single use customers.

This is amplified by the team needing domain specific knowledge and experience to deliver this correctly. Some product enhancements or additions may be deemed too costly to deliver once the market potential has been evaluated.

To overcome this challenge the vendor needs a talented and motivated team but also the support and understanding of clients and partners. Vendors have to be seen as a trusted partner rather than a traditional client supplier relationship to ensure two-way information and an engaged user group

Gaining the support of all the departments involved

Life Science organisations are notorious for being broad in character and operation, often a result of merger or acquisition, many organisations will operate in silos and bringing together hearts and minds is as important as understanding business need.

One example is moving from On Premise to Cloud solutions. Everyone understands the lower cost, lower risk and increased scalability benefits of Cloud are attractive but we also need to consider the challenges of documenting this, patching and security updates and any challenges data location may have. These discussions may be sensitive due to perceived threat some in IT may see from moving control outside the organisation. Vendors can easily get caught up in the internal battels between Quality, IT, Finance and, Production.

Understanding the business, it's current maturity phase and the culture is critical to being a positive influence on the project and organisation and enhancing leadership messages to the wider business.

These challenges are no secret and will be shared by all vendors. As business culture moves towards greater transparency I strongly believe those who work ethically, responsibly and with consideration for the humans involved will be rewarded.

About the Author: ***Ben Saxton*** is Head of Sales at Formpipe Life Science (*www.formpipe.com/lifescience*). A wide-ranging role means Ben is instrumental in marketing and sales activity, partner relationships and influences product development. Passionate about bringing simple solutions to complex business issues Ben is often a bridge between the technical team and the client requirements. Since 2017 he has been leading Formpipe's activities in digital data preservation within the European Private Sector *https://www.linkedin.com/in/saxtonben https://twitter.com/saxtonben*

DATES FOR THE CALENDAR

Date(s)	Event	HSRAA Presenter
SEPTEMBER		
9-10th	**Veeva R&D Summit**, Philadelphia	*Jamie Toth*
11th	**MHRA Good Clinical Practice Symposium**, Manchester	
16th -18th	**IQPC GCP Inspection Readines and TMF Inspection Readiness**, Bruxelles	*Jamie Toth / Eldin Rammell / Hobson Lopes*
16th -18th	**IQP Future Laboratory Informatics**, Amsterdam	*Dora Endreffy / Russell Joyce*
1st-3rd	**European TMF Summit**, London	*Jamie Toth / Eldin Rammell*
22nd-24th	**IQPC Combination Products**, Berlin	
OCTOBER		
10th	**HSRAA GxP Archiving Training Course**, Birmingham	*Eldin Rammell*
10th	**ICR Managing the TMF**, Maidenhead	*Russell Joyce*
29th-31st	**IQPC Cell and Gene Therapy Manufacturing**, London	*Dora Endreffy / Russell Joyce*
NOVEMBER		
5th-7th	**IQPC Early Access Programmes**, London	
12th-14th	**IQPC Data Analytics for Pharma Development** , Munich	
18th-20th	**IQPC Laboratory Informatics Summit**, Boston	
DECEMBE		
10th-11th	**IQPC Women in Pharma Manufacturing**, London	

DATA INTEGRITY: A RECORDS MANAGEMENT PERSPECTIVE

Eldin Rammell, Director, Expert Solutions, Phlexglobal Ltd

The conference agenda included several sessions with some aspect of data integrity in its content. This includes a half-day workshop on data integrity expectations; an update from the MHRA on their expectations; a discussion of the EMA eArchiving Working Party activities; and a review of data integrity issues when using wearables in regulatory research. And beyond the conference, the topic of data integrity is not new.

Over the last three years, industry has received completely new guidance in this area and also revised guidance documents from various sources. This includes:

- FDA Data Integrity and Compliance with cGMP Guidance for Industry, April 2016
- World Health Organisation Guidance on Good Data and Records Management Practices, May 2016
- PIC/S Good Practices for Data Management and Integrity in regulated GMP/GDP Environments, August 2016
- EMA Data Integrity Qs & As, August 2016
- MHRA 'GXP' Data Integrity Guidance and Definitions, March 2018 (revises 2016 draft)

I often hear data integrity referred to in the context of data archiving but it is extremely important to understand that the need to address data integrity requirements applies across the whole data lifecycle. This means identifying the importance of data integrity in record generation or record capture; in the multitude of processing activities that our data undergoes; in the data analysis and reporting; in decision-making; in the retention of data as required by regulations and legislation; the retrieval and re-use of the same data; and the controlled destruction of data (Fig.1).

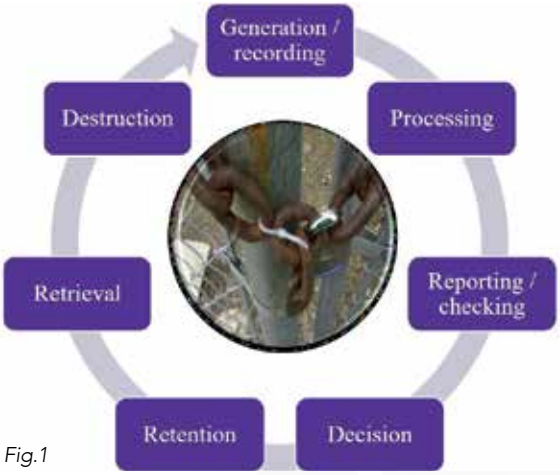

Fig.1

Our organisations however tend to focus on some areas more than others and there is often a weak link. Senior management have a tendency to focus data integrity efforts in areas that are perhaps already well controlled, forgetting the weak link. We need to ensure that activities associated with data integrity compliance focus on where there is the greatest risk of process failure. For example, it may be at the point where data is actually captured by a third party. Our own internal efforts may be limited in effectiveness if the weak link at source is not addressed.

As HSRAA members, we have a role to play. And so this article aims to look at data integrity from the perspective of the records manager or archivist. Where could we have some kind of influence or impact?

1. Data transfers / data migration

Records managers/archivists are often involved in data transfer and data migration projects. We can apply appropriate oversight of the project from an information governance perspective and ensure appropriate standards are developed and applied. The records manager/archivist can provide subject matter expertise, especially in smaller companies where there may be minimal understanding of data integrity issues. And following the transfer or migration project, the records manager/archivist is likely to have some form of responsibility for the records, either immediately or when they become in active. Standard archival processes and systems should be in place to maintain data integrity.

2. Retention of audit trails

Many of the applicable regulations require the preservation of electronic audit trails and to maintain their accessibility and usability for as long as is practical. As subject matter experts, we can ensure our companies understand this requirements. We can also provide guidance in terms of industry best practice approaches to audit trail preservation.

3. Consider requirement for preservation of dynamic records

The EMA and MHRA have written extensively in recent years on the differences between static records and dynamic records. In terms of data integrity, we should make best efforts to ensure that the dynamic nature of data is maintained for as long as possible. However, there will be instances where static records (e.g. a hard-copy printout) will need to be generated from dynamic .when can static so we need to understand the expectations of regulatory agencies and guide our colleagues accordingly.

The decision on whether to convert data files to a different file format, when this should take

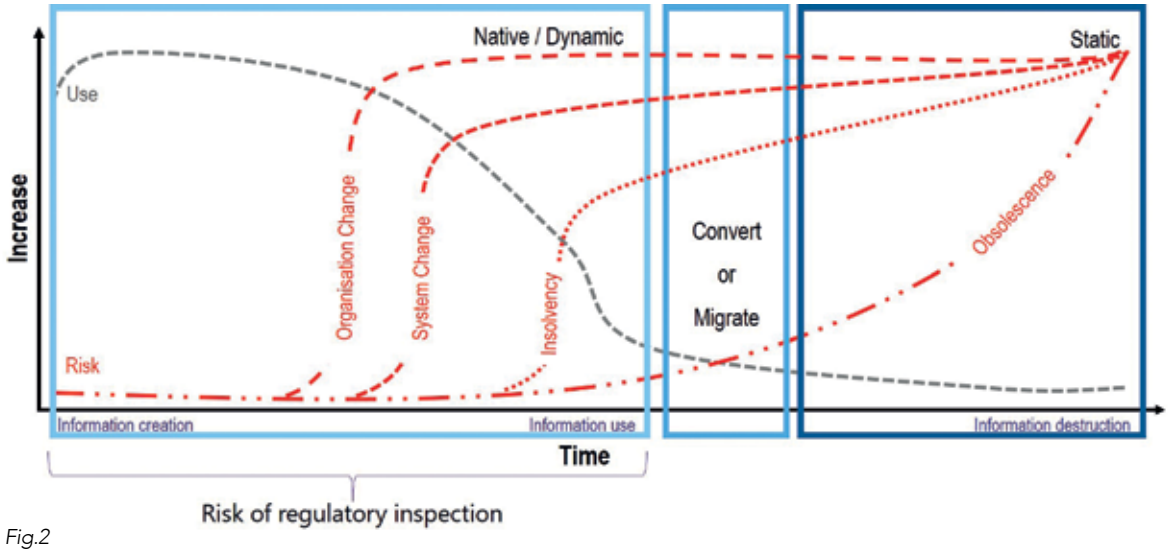

Fig.2

place, and the implications of file conversion is a complex one. As records managers/archivists, we need to understand that the review of data sources is a continual process that happens throughout the record lifetime. Decisions are often taken by our IT colleagues but we can offer advice in terms of ensuring alignment with regulatory expectations and preserving data integrity (see Fig.2).

4. File format migrations

If we become aware that the organisation is converting records from one file format to another for archiving, we need to ensure there is a good understanding of the regulatory requirements for a 'true copy' or 'certified copy' to be made. The EMA, MHRA and FDA have all issued very clear and consistent guidance on the generation of true copies, either by verifying and certifying individual copies of files or by using a validated file conversion process.

5. Authorised modification of audit trails

Organisations are not always aware that in limited circumstances it is acceptable for audit trails to be modified. For example, in the event of a computer error or failure. However, it is critical that an appropriate documentation trail is created and maintained to explain what the changes was and why it was needed.

6. Record preservation to avoid obsolescence

The topic of record preservation is a huge one and there is insufficient space here to cover this. It is also an area that can be extremely complex and consequently, it is not always clear where or how the records manager/archivist can provide input. My suggestions include:

- be proactive and partner with IT colleagues;
- encourage adoption of OAIS Reference Model (download a copy and take a read!); and
- influence your organisation's SOPs on system procurement and development to consider an archive strategy at the point of system selection / design.

As a takeaway, here is a brief action plan to consider:

☑ ACTION

- ☐ Read latest regulatory updates relating to data integrity
  - April 2016: FDA Data Integrity and Compliance with cGMP Guidance for Industry
  - May 2016: World Health Organisation Guidance on Good Data and Records Management Practices
  - August 2016: PIC/S Good Practices for Data Management and Integrity in regulated GMP/GDP Environments
  - August 2016: EMA Data Integrity Qs & As
  - March 2018: MHRA 'GXP' Data Integrity Guidance and Definitions
- ☐ Highlight any requirement that is specifically within scope of your role
- ☐ For each topic highlighted, identify one action you can take to improve current processes

About the Author: Eldin Rammell is Director, Expert Solutions at Phlexglobal Ltd. His role includes advising clients on trial master file strategy, processes and technology optimisation. In addition, he drives thought-leadership to further advance Phlexglobal's industry reputation and position. Prior to joining Phlexglobal, he was a freelance, records management consultant for 15 years, following a 17-year career as an archivist and records manager at Glaxo (now GSK) and Pfizer.

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