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ONrecord

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THIS ISSUE HIGHLIGHTS

HEALTH SCIENCES RECORDS & ARCHIVES ASSOCIATION

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LETTER FROM THE CHAIR

LETTER FROM THE CHAIR

Eldin Rammell

We have already completed a full year as the re-branded Health Sciences Records and Archives Association (HSRAA). It has been a great start for us with our new identity.

During this past year we have delivered 7 workshops, with over 100 attendees in total. Three of these were located in the UK but the remainder were in other countries, including our first in the USA. We also ran our one-day training course 'GxP-Regulated Archives and the GxP Archivist' in Birmingham, having brought delivery of the course in-house. This now combines the GCP- and GLP-focussed material into a single programme, allowing attendees to learn from a broader knowledge base of regulations. We were also excited to offer this same programme as a series of one-hour webinars and are nearing completion of this first series. Only 25% of the attendees are UK-based and over 30% US-based, so achieving our objective of improving accessibility.

We were also encouraged to see attendance at our annual conference increase once again. As previously mentioned, we had a few logistical issues with the venue but the general feedback was overwhelmingly positive. We agreed to introduce some limited commercial sponsorship for our next conference and I'm very pleased to report the acceptance of Formpipe, Phlexglobal and Montrium as sponsors for our 2019 conference in May. We're heading back to the St. Andrews Hotel in Cardiff, the venue for our 2015 conference but this time securing a conference room twice as large! So, we are relying on you to spread the word about the conference. This is truly a great opportunity to meet up with colleagues old and new, to hear some great presentations, and get involved in interesting and stimulating discussions. Please let colleagues know about our bursary programme this year. This provides funding for colleagues with limited budget for conference attendance. Don't forget that you can also get a great discount by booking early and once our block of hotel rooms sell out, they're gone! Checkout the conference page (page 25) for more details.

You'll read further on in the journal about our new committee members. We've already had a few meetings since they joined in October and I'm excited about the further changes we're planning over the coming months. As a volunteer-led association, we're entirely dependent upon the goodwill of our committee members so a huge "Thanks" to you all.

As always, my door is open for suggestions for HSRAA. If you have ideas, please get in touch. We have had quite a heavy slant towards GCP-related activities over the previous year so I'd like to shift the balance back this coming year. But I'll need your help!

Eldin
chairperson@the-hsraa.org

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

- the Editorial Team publications@the-HSRAA.org
- the Conference Programme Organiser, events@the-hsraa.org

LETTER FROM THE EDITORIAL TEAM

Dora Endreffy

LETTER FROM THE EDITORIAL TEAM

Dear Reader.

Welcome to ONrecord

First of all let me wish everyone a Happy New year!

The past year has been a very exciting one for The HSRAA as well it has for Archivists, Records Managers, TMF experts and anyone having an interest in managing records and data.

Firstly, HSRAA has made a big leap forward by receiving an unexpectedly high number of nominees for committee membership. This was the best Christmas present ever. It proves that the HSRAA is a respected, contemporary association in which people are keen to partipate to keep it current and relevant. The pre-2018 committee members are very proud to have been able to make joining such an attractive prospect and warmly welcome our new colleagues.

And it is, indeed, a very warm welcome. Like most, I was struggling to balance the demands of HSRAA tasks with my everyday employment and family responsibilities. It is not always easy to

- devise new ideas for training;
- research topics of interest for ONrecord;
- keep the HSRAA website current;
- stay abreast of regulatory news to keep you all informed;
- to develop, revitalise, and deliver HSRAA training courses; and
- in general, to maintain the interest in HSRAA and enhance its reputation.

Of course, none of that would be worthwhile if we had no members, so thank you for being a member of the HSRAA!

The other excitement in 2018, of course, was GDPR which has presented us all with new challenges to resolve. GDPR "gave us the shivers" before May and even sometime after. However, in my recent discussions with others, I wonder what the fuss was all about. For years, Records Managers have been trying to convince senior management and business leaders in general of the importance of managing records properly and consistently. The information security requirements of GDPR have given us much-needed leverage to focus on the records management and achieve long-held aspirations.

Looking at GDPR, its requirements list that records must be

- up to date and accurate;
- managed in a secure, confidential manner;
- maintained in alignment with clear stated liabilities and accountabilities;
- and be subject to
- consent rules;
- data retention requirements;
- collection minimized for specified purpose; and
- lawful and transparent record management processes

So, hand on heart, is that not sufficient reason and an opportunity finally to embark on that long-desired project to better enforce improved management of your records?

In this edition, we shall try to summarize the most important lessons we have learned as a profession during the first half year of GDPR implementation.

In the meantime, we all look forward to meeting you in person at the conference in Cardiff in May 2019.

Dora

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.

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.

Please note that members' rates for conference and training events are only available to those who are current members at the time of booking. HSRAA will not refund the difference, nor any loss of early-bird discount, caused by late renewal.

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	Role
Emily Chambers	Astrazeneca	Nonclinical Submissions Administrator
Claire Thompson	Clarity Compliance Solutions Limited	Business Development Manager
Andrea Moss	Gentronix Limited	Business Administrator / GLP Archivist
Mine McPherson	PsiOxus Therapeutics Limited	Quality Associate, Archivist
Daniele Dedominici	PSI CRO AG	Document Center Assistant
Hobson Lopes	Regeneron	Sr. CDA, TMF Lead
Darshan Patel	AUTOLUS LTD	Clinical Trials Administrator
Marie-Christine Poisson-Carvajal	Pfizer	Head of TMF Operations
Ashley Cole	Eisai LTD	Senior Associate
Neelam Taj	Quotient Sciences	Documentation & Archiving Coordinator
Roxanna Boyd	TAURX Therapeutics Ltd	Records Specialist
Stephanie Cherbuin	Debiopharm International SA	Document Management Specialist
Karen Roy	Phlexglobal	Chief Strategy Officer
Kristen Cahill	Sarepta Therapeutics	Head of TMF Operations
Catherine Hoet	DigiDyco	Business Manager
Bob Thompson	Reckitt Benckiser	GxP Archivist
Rachel Bannister	Reckitt Benckiser	Archives Assistant

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*).

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

The electronic Records Special Interest Group is about to publish its third white paper, "A Guide to the Use, Management and Archiving of Electronic Signatures", a project the SIG began some 2 years ago. It will be great to be finally publishing the document. The archiving of digital signatures is a a complex subject and so it's proved a long and interesting journey. The document:

- includes a history of the adoption and acceptability of digital signatures,
- considers different technologies, and
- provides guidance on implementation strategies and
- examines records management aspects of different varieties of electronic Signatures.

We hope the document is of interest and look forward to receiving your comments and feedback.

In the new year we shall be looking at one or more new topics of research and other activities that the SIG could initiate, so this would be a good time to join if you can find time and are looking for career development opportunities outside of your regular employment. The eRecords SIG membership hovers around the 12-14 mark with a core of around 5 regular attendees at its monthly telephone meetings.

We welcome any interest in joining the group. You don't have to be an expert on electronic records or have technical knowledge; all you really need is to be prepared to spend an hour or two each week doing something different, developmental and constructive for the life sciences and healthcare community. Please contact me if you are interested and I shall provide more information on what we do and answer any questions that you have.

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

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).

Good Clinical Practice Special Interest Group

Alex Dingenouts

MHRA GCP Symposium 2018

Sarah Howard represented HSRAA on the MHRA GCP Symposium held on 6th September 2018 in Leeds. This year's Symposium was focused on quality systems and associated corrective and preventative actions. The sessions looked at the impact these actions have on the compliant conduct of quality clinical trials research, with a focus on case studies from an inspection perspective.

eTMF and Audit Trials Guidance

The SIG team is working to finalise this guidance document intended to assist understanding of the regulatory requirements for audit trials when transferring TMF data between different eTMF systems.

The guidance focusses on recommendations for how to align with these requirements.

Relevant Communications Guidance

In 2019 we shall be looking to update the existing HSRAA TMF relevant communications guidance, which was first published in 2009 (see *https://the-hsraa.org/resources/publications/white-papers-gcp-sig*). If you would like to contribute to that project, please contact me.

New Members

We are always open to accept new members interested in contributing to the SIG. If you work in the GCP area and would like to participate in discussions and work streams in this area, please contact me to join this group. We look forward to having you on board!

Alex Dingenouts
GCP SIG Chair
alex.dingenouts@astellas.com

PHARMA AI REQUIRES A NEW APPROACH TO GOVERNANCE

The adoption of Atrificial Intelligence (AI) by pharmaceutical companies demands a new, agile governance layer

PHARMA AI REQUIRES A NEW APPROACH TO GOVERNANCE

Tim Wright and Anthony Bott, Pillsbury Winthrop Shaw Pittman LLP

The convergence of big data, cloud computing, artificial intelligence (AI) and its subsets, machine learning and deep learning, offers pharmaceutical companies the potential to realise many exciting benefits. You will have heard the well-worn saying: "Half the money I spend on advertising is wasted; the trouble is I don't know which half". With drug research, the wastage is more like 80-90% — traditional drug discovery employs biochemical screening, scrutinizing millions of natural and synthetically-derived chemical compounds to identify molecules that have drug-like properties. But the number is so huge (a trillion trillion trillion trillion trillion possible compounds) that, despite technological advances, drug discovery has only become more expensive and protracted.

Now scientists hope to change the game by combining lessons from previous drug research with the vast amounts of experimental data that has already been produced by the scientific community to drive AI-powered drug design. As a result, AI may enable better predictions, resulting in focused sets of compounds for screening during the early stages of drug discovery, or new uses for previously tested compounds towards treating diseases. This will help speed up drug discovery, reducing wasted research and clinical trial failures. The quicker a new drug can be brought to market (i.e. shortening the time from initial filing to regulatory approval), the longer it stands to benefit from its patent. This in turn should help to stem the trend of rising drug prices. AI adoption also promises to improve product quality and make manufacturing processes more efficient.

AI – the future of pharma?

A recent report by the House of Lords' AI Select Committee (https://bit.ly/2qCcP7G) highlighted significant opportunities, with "the impact of artificial intelligence on … the healthcare system … likely to be profound"— through more efficient research and development, the adoption of better methods of healthcare delivery, and more informed clinical decision-making. Patients will also be more able to manage their own health needs.

AI is not new but we are only now starting to see its benefits. And although AI adoption has been slower in the pharma sector compared with some other industries, there is already a wide range of use cases, notably in radiology and oncology diagnostics and drug discovery and development, where computer models are being used to identify novel targets for cancer therapy. Other successful implementations include platforms and applications that deliver virtual patient coaching, digital surgery platforms, surgical robots, predictive medicine and treatment protocols, adverse event detection, regulatory reporting, and quality assurance. AI is being used in clinical trials to identify possible early stage failures, and it is also making its way into supply chain operations and helping to optimise manufacturing processes, through new approaches such as continuous manufacturing, process analytics and advanced process control.

Data sharing – risks and benefits

AI and machine learning rely on having access to a lot of data. BERG, a pharma start-up, which has developed AI software to analyse the transformation of cells from healthy to cancerous, utilised data from the 2003 Human Genome Project as well as the over 14 trillion data points in a single cell tissue. Using this process, BERG aims to develop new drugs that can return cells to a healthy, pre-cancerous state.

In a crowded market, drugs companies are seeking to differentiate their drugs and treatment therapies, leading to a multitude of collaborations between big pharma, CROs, the large tech titans, government institutions, regulators, academia and a wide range of AI based start-ups. The temptation to over-share datasets, without adequate rules of engagement and protocols in place first, can be strong. The Royal Free London NHS Foundation Trust's 2015 partnership with DeepMind is a case in point.

DeepMind partnered with the Royal Free to develop an app to assist diagnosis of acute kidney injury. To aid its development, Royal Free had provided DeepMind with personal data from around 1.6 million patients. The Information Commissioner's Office subsequently investigated, ruling that Royal Free had failed to comply with the Data Protection Act 1998 when it provided the data to DeepMind. Although the app did not use artificial intelligence or deep learning techniques, DeepMind's involvement highlighted a number of the potential issues involved in the use of patient data to develop AI.

The Data Protection Act 1998 has since been replaced by the General Data Protection Regulation (GDPR) and with it comes the risk of far greater fines and sanctions for getting it wrong. Data sharing requires a cautionary approach, not least since government and regulators are struggling to catch up. Obstacles that still need to be addressed include data

governance and privacy of medical records, transparency (or lack thereof) of algorithms. In this context, where machine-to-machine communication is set to grow exponentially, the implementation of data exchange standards, such as those published by the International Organization for Standardization and the International Electrotechnical Commission, will become increasingly important. The Select Committee's report recommends a universal code of ethics for AI, and calls for an appropriate legal and regulatory framework for AI developers and users: "maintaining public trust over the safe and secure use of their data is paramount to the successful widespread deployment of AI and there is no better exemplar of this than personal health data."

A new approach to governance

Over the past decade or so, responding to the regulatory challenge, big pharma has implemented strong governance controls across the enterprise, with top-down management and decision-making meaning that it is sometimes difficult to reverse course. Because of the need, in many cases, to pool large datasets, or where collaborating with a start-up, success may well depend an intensely collaborative, agile approach, enabling a much more rapid response to market pivots. Mirroring cross-industry collaborations in other sectors, such as the coming together of consortia of banks and technology providers to pilot, test, develop and implement blockchain use cases for the finance industry, collaborations between pharma and technology firms call for new approaches to the handling of issues such as data sharing, ownership of deliverables and other intellectual property, defining success, and the monetization of the outputs.

Procurement and legal functions will need to collaborate closely with their business teams to develop and adopt new governance layers specifically targeted at AI adoption (focused on areas such as legal, regulatory, information governance, intellectual property, and reputational risk); without such an approach, businesses risk uncovering issues too late in what is often a fast-moving process. Governance approvals will need to be flexed – current regimes are often most closely linked to spend thresholds that may not be triggered by the new approaches. Different nuances may need to be considered when data sharing, as between say R&D (crown jewels) and manufacturing (operational processes). And beneath the governance layer, a new contract toolkit is needed. Traditional frameworks such as ownership of intellectual property and risk transfer (i.e. liability and indemnity), tried and tested in binary relationships such as manufacturing services agreements, don't necessarily lend themselves to commercial collaborations and partnerships. Agreements covering things such as non-disclosure, collaboration, partnering, and data sharing will need to be adapted to manage the unique challenges that AI poses, and to reflect a new more agile way of working and partnering with third parties.

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https://www.pillsburylaw.com/en/

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MHRA GCP SYMPOSIUM

Sarah Howard, Head of Regulatory & Quality Governance, hVivo

MHRA GCP SYMPOSIUM

I attended the MHRA GCP Symposium on 5th September 2018. The purpose of the symposium is for GCP inspectors from the MHRA to present to industry on current hot topics and any new or problem areas they are finding during inspections. Examples of recent inspection findings are presented.

Following the opening address, there were 6 presentations throughout the day and panel sessions where the inspectors answered questions that were submitted to them both in advance and during the day. The presentations were on the following topics:

1. Quality Systems, Serious Breaches & CAPA –What does inspection experience tell us? Jason Wakelin-Smith, Lead Senior GCP Inspector
2. Computer systems validation processes for eSystems; including case studies of Serious Breaches in this area, Balall Naeem GCP Inspector
3. RSI – CTFG Guidance Update & Case Studies, Dr Maria Beatrice Panico, Medical Assessor, Clinical Trials Unit and Jenny Martin, Lead Senior GCP Inspector
4. Joint FDA & MHRA Unblinding Session including case studies, systems & CAPA, Dr Jean Mulinde, Senior Advisor, DCCE, FDA and Gail Francis, Expert GCP Inspector
5. IMP Management – Quality systems, Root causes and CAPA, Mandy Budwal-Jagait, GCP Inspector
6. Forward Look: Inspection Conduct & Processes, Paula Walker, GCP Operations Manager & Senior GCP Inspector

Quality Systems, Serious Breaches & CAPA –What does inspection experience tell us?

This presentation went through the basics of what an inspector expects to see ahead of an inspection and the sources they use to prepare for inspection which include the submitted dossier, intelligence, previous inspection history and review of any reported serious breaches. Inadequate CAPA responses are common and examples were provided. The presentation then gave guidance on how to produce an acceptable CAPA response.

During inspection, how previous inspection CAPAs were managed are reviewed as the inspectors use this as an indicator to how you deal with other quality issues that arise including serious breaches. Ie if you don't bother to complete and manage a CAPA from a MHRA inspection, then you probably aren't bothering with other issues either. CAPA responses should avoid a 'sticking plaster' approach and instead look for a root cause. Examples of 'sticking plasters' presented included adding a line to a SOP which gets taken out again at a later revision, and retraining staff with no consideration as to how sick or absent staff will also be trained on their return to work.

If an inspector finds a CAPA has not been completed, they will not trust the organisation to complete the CAPA next time but instead request quarterly updates on progress. If CAPAs are not going to be met or need to be changed, the lead inspector must be updated. It is not acceptable to not complete a CAPA and this will result in an upgraded finding at the next inspection. The organisation must be able to present evidence of completion of CAPAs from the last inspection even if it is different staff.

From a records management perspective, the importance of maintaining the evidence from previous inspection CAPAs is key. For organisations where there is a large time gap between inspections, consideration needs to be given to where this file is stored for easy retrieval when required.

Computer systems validation processes for eSystems; including case studies of Serious Breaches in this area

This presentation covered how inspectors look at validated computerised systems, expectations from vendors and case studies. MHRA are now inspecting software vendors independently as well as Sponsors and CROs.

Case studies presented emphasised the importance of a vendor performing a study specific build having access to the correct version of the protocol (and any amendments). In the first case, an IRT vendor had not received the protocol and dosing instructions provided did not match the protocol. Subjects were mis-dosed resulting in a critical finding. In the second case, only a draft protocol had been received and the study design changed in the final protocol. This resulted in an arm of the study being activated prior to regulatory approval which resulted in a critical finding.

Core system development essential documents were summarised which include URS, validation documentation, release notes, bug tracking, helpdesk documentation, code production and review systems, documentation justifying key development decisions such as ignoring a bug for an extended period, evidence that required coding standards have been followed.

Any study specific system builds need to be able to be reconstructed from the documentation in the TMF and all aspects including coding and automated testing needs to be GCP compliant

with a clear trail of who performed each task. Inspectors have seen examples of 'a developer' did something rather than a clear audit trail demonstrating accountability by one person. Vendor selection documentation, evidence releases comply with the current protocol, and documentation of any testing needs to be filed.

The desire for 'Agile technology' was recognised but this still needs to follow a clear framework and documentation needs to be in place.

Audit trails must be easily accessible.

A MHRA CSV blog will be issued shortly.

From a records management perspective, maintaining all of the required documentation is key and ensuring this is readily available within the TMF as evidence of full validation.

RSI – CTFG Guidance Update & Case Studies

There is always a session on safety during a MHRA inspection which will include management of Reference Safety Information (RSI), SAE processing including expectedness of events, SUSAR reporting, flow of information between groups, training, DSUR production. RSI is still a hot topic with Major or Critical findings given at most inspections. Inspection findings include no awareness of RSI, no control over RSI, incorrect RSI used, multiple versions of RSI used. Reasons for non-compliance provided by organisations included different interpretations of CT-1 and CT-3 guidance, poor procedures and using medical judgement.

MHRA have previously issued a blog on the topic and are soon to release a position paper and a further blog to assist organisations with compliance. CTFG issued a Q&A document in Nov 2017 to ensure a harmonised approach across the EU. The document confirms that RSI serves as the basis for expectedness assessments of suspected SARs for reporting of SUSARs and annual safety reporting.

Any change to the RSI is always a substantial amendment and can only be implemented after approval from MHRA. RSI (and the IB) should be updated annually based on the DSUR.

The presentation involved showing example RSIs and asking the audience to vote using interactive technology as to whether the RSI was deemed as acceptable. Most people got it wrong but as the reasons for RSI not being acceptable were explained, more people answered correctly as the examples progressed. An example IB was provided and questions asked about whether certain events would be considered SUSARs.

From a records management perspective, it needs to be ensured that RSI is defined somewhere within the trial documentation.

Joint FDA & MHRA Unblinding Session including case studies, systems & CAPA

Protecting the blind is important to maintain integrity of the data, especially for subjective assessments. This presentation gave 22 examples found during inspection where the blind was broken inadvertently and 1 example of where there were robust processes to maintain the blind. The potential to unblind would be an inspection finding. The severity of the finding would depend on the potential impact this could have.

The examples included IMP preparation where numbering patterns of batch or kit numbers may permit staff to guess treatment groups, differing physical presentation of IMP and placebo, comparing expiry dates to the CofA in the site file, documentation inadvertently

...continued

MHRA
Regulating Medicines and Medical Devices

included in shipments of IMP, using the same staff to prepare and randomise IMP who made the clinical assessments, IRT configuration issues, poor CRF design, laboratory results where abnormalities can be attributed to a particular treatment group.

From a records management perspective, a risk assessment to consider how the blind may be inadvertently broken is key as well as ensuring any documents such as shipment records that may accidently reveal the blind aren't filed in the TMF.

IMP Management – Quality systems, Root causes and CAPA

52 serious breaches related to IMP have been reported to MHRA since 2014 including mis dosing, use of expired IMP, wrong IMP used, overdose, and storage deviations. This presentation went through two case studies where IMP management failed.

Case study 1 was an overdose. The MHRA were notified of a death due to an overdose so conducted a triggered inspection. The IMP was tablets that came in 3 different strengths each of a different colour. However, the lowest and highest dose colour were very similar. The tablets were provided in blister packs in an envelope. Only the envelope was labelled and not the blister packs. Patients were dispensed IMP in bulk and not related to the dose they should be taking. The patient who died had been taking the highest dose tablet (5mg) instead of the lowest dose tablet (1mg) over 18 days. No robust risk assessment had been performed at the start of the study and actions identified had taken 2.5 months to complete in which time the patient died.

Case study 2 was on a trial in the emergency department. A triggered inspection was conducted following reporting of a Serious Breach. The IMP was stored in the emergency department rather than the pharmacy and was given to a non trial patient in an emergency situation. This was however a placebo. A very similar previous serious breach for this drug had been reported where a non trial patient had received active IMP. The CAPA put in place had not been effective to prevent this second case to occur. There was a lack of sponsor oversight and impact assessment across trials. Critical inspection findings were given to the sponsor and the site.

Both interesting case studies but probably not of direct relevance to records management!

Forward Look: Inspection Conduct & Processes

This presentation looked at the changing environment the MHRA are working in and what we can expect to see from MHRA going forwards. Protocols have become more complicated with numerous arms. More complex technology has mean that inspectors need more time at inspections. In the last few years, eTMF, ePRO, IRT, eCRFs have become commonplace. MHRA stopped requesting an annual compliance report in 2016 as it was no longer adding value to them to decide who to inspect. During 2016 and 2017, MHRA conducted a scoping exercise with CROs and pharma in which hVIVO took part.

Current information used to determine inspection frequency includes reported serious breaches, past inspection history, and whistleblowers. The format of inspection has not changed and still consists of a request for a dossier to be completed in advance along with requests for some documents. An onsite visit is conducted although some Office Based Inspections have taken place for which the inspection fee is reduced. It is planned to continue with Office Based Inspections in parallel with on site inspections. A new Guidance on how to complete the pre inspection dossier has been issued.

MHRA continue to collaborate with other regulators and since the symposium, have issued a new HRA/MHRA Guidance on e-consent.

From a records management perspective, it is clear that access to electronic systems data during inspections is key and will continue to be a challenge.

Panel Session

Example Questions with responses were as follows:

Do IT vendors need GCP Training? Yes

Can process maps be used in SOPs? Yes they can be incorporated if useful

Can emails be used for documenting decisions? Yes and file in the TMF

Do internal QA auditors need to be blinded? No they are independent so can be unblinded.

How are audits selected? Use a risk based approach, document the risk and decision. Justify changes if other things take priority and mean the audits aren't done, eg serious breach investigation.

Do we need to update QMS for the EU Clinical Trials Regulation? No as this isn't effective yet. Still don't know when this will be as not until 6 months after the portal is available.

How do we handle conflicts between GCP and GDPR? There isn't a conflict of you select *the correct lawful basis which isn't consent.*

["Note from ONrecord Editor" "Whilst this report is specific to GCP issues and an MHRA perspective, many of the principles are applicable across the GxPs and also represent the views of other regulatory agencies."]

OVERCOMING INFORMATION GOVERNANCE INERTIA

OVERCOMING INFORMATION GOVERNANCE INERTIA

George Parapadakis, Director of Business Solutions Strategy, Alfresco Software IncCoalition

Making information governance a high priority in the enterprise is a tall order. It is fair to say that perceptions around IG and its predecessor, document management, are that of back-office IT functions that reside "out of sight and out of mind" in a faraway data center. Hot tech concepts like DevOps, cloud, internet of things and digital transformation grab more headlines than IG, which is often perceived as being "not close to the business." As such, it frequently gets pushed to the back of the line when it comes to IT prioritization.

Nevertheless, IG is challenged by sprawling amounts of siloed agency data, with petabytes of unknown information floating around on servers, driving ever-increasing storage costs while inhibiting access to current, accurate and legally-compliant data across the enterprise. What's more, a robust IG policy is essential to enable digital transformation, as well as many of today's advanced technologies designed to drive agency missions forward.

The most basic drivers for IG revolve around security, data privacy and legal compliance. Many organizations do enough in the area of IG to just "get by" and meet basic requirements, Alan Pelz-Sharpe, founder of the research and consulting firm Deep Analysis, pointed out in a recent webinar. Those that do not address IG are typically saddled with vast amounts of unstructured, redundant data that increases work cycles and operational cost. In addition, bad data and lack of accountability can lead to wrong decisions. What's more, the lack of an IG policy limits the implementation of machine learning, artificial intelligence and blockchain programs due to a lack of clean data.

Robust IG policies can deliver much more than risk avoidance to the enterprise; according to Pelz-Sharpe, the overall IG goals should include bringing order to IT platforms, data and corporate information; preventing chaos; and saving time and money. The purpose of good governance is not to stay out of trouble but to run an efficient set of managed and controlled services for the enterprise, he noted.

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'Just enough' IG is not really enough

With respect to information governance, compliance-driven thinking is strategically incorrect, Pelz-Sharpe said. Taking control of data and information assets decreases the volume of content, lowers storage costs and streamlines information management. In addition, visibility into more accurate information provides the basis for better decisions that impact the enterprise.

Unfortunately, most IT managers have little control, and despite potential IG benefits, a sprawling amount of siloed and ungoverned data exists. According to one Deep Analysis client, "We have over 1 billion documents in our system and no way of knowing what is of value and what is not."

A senior administrator of a U.S. city described his challenges with disconnected, independent city departments now under pressure to work together more efficiently. Many of these departments have been around for generations and become fiefdoms, resulting in numerous disconnected silos with no central control. Pressure from citizens and top officials is finally forcing departments to figure out a more unified method of city government, one in which citizens or officials can make one call and get correct answers to their questions, no matter how many departments are involved. Today that's a pipe dream, but government officials, citizens and businesses alike are demanding change. The first step to deliver this unified system of information management is to apply governance.

Breaking governance inertia: Getting started

For an organization that eventually decides to tackle IG, Pelz-Sharpe recommended attention to three key principles: focus on the relevant, let information govern itself and automate the process.

To focus on the relevant, create a heat map of the highest-priority IG issues. IT should first evaluate what information is most at risk, assess the size of the problem and address the highest impact priorities first, like the risk of data privacy breaches. For example, an agency might prioritize any documents containing personally identifying information and apply tight governance to those. On the other hand, marketing data might be a lower priority, given its reduced risk profile even if temporarily ungoverned. The heat map offers an interesting and surprisingly quick exercise and can change how enterprises view their information assets as well as offering new insights into how to balance risk.

The concept of letting information "govern itself" is based on the idea that not every information asset is of equal value and that it is difficult to manage everything equally well. Some types of information, such as contracts, are clearly very important, while other documents are less so. That is why it is useful to identify the most important types of information, define simple and defensible rules around those information assets and apply automated rules to those assets, including retention, disposition, compliance, access and discovery. The final part of this step is to monitor, audit and adjust the rules as needed to support the agency mission and meet compliance requirements.

The third key element of overcoming IG inertia is automation through process. Because information does not live in a void and business processes interact with information, a significant amount of effective governance can be achieved by applying simple, automated and defensible rules. Enterprises should include governance controls in process design to allow the system to drive implementation rules, keeping in mind the many benefits of automation, including reduced risk, greater consistency and decreased operational overhead.

The bottom line: IG is about enabling competitive advantage

The time to break free from information governance inertia is now. Huge increases in data volume will continue and agency resources will continue to be constrained. Governance initiatives should be aligned with business strategies, providing a foundation for digital transformation and other advanced technologies designed to serve the agency mission. By starting with three relatively simple IG principles -- focusing on the relevant, letting information govern itself and driving automation through process -- today's agencies can leverage IG to bring order to chaos, gain insight into "black boxes," reduce redundancy and increase efficiency.

About the Author: George Parapadakis is director of business solutions strategy at Alfresco Software Inc.

EMAIL CHARTER

EMAIL CHARTER

Chris Anderson and Jane Wulf

The Problem

We're drowning in email. And the many hours we spend on it are generating ever more work for our friends and colleagues.

The relentless growth of in-box overload is being driven by a surprising fact: the average time taken to respond to an email is greater, in aggregate, than the time it took to create.

This is counter-intuitive because it's quicker to read than to write. So you might assume a typical email takes a few minutes to write, but only a few seconds to read. However, five other factors are outweighing this.

1. The act of processing an email consists of much more than just reading. There is
   - scanning an in-box,
   - deciding which ones to open,
   - opening them,
   - reading them
   - deciding how to respond
   - responding -- which may well involve writing an email of similar length back g) getting back into the flow of your other work. So the arrival of even a two-sentence email that is simply opened, read and deleted can take a full minute of your available cognitive time.
2. Many emails contain open-ended questions that can't rapidly be responded to e.g. "What's your opinion on all this?" "How should I move forward?" Easy to ask, hard to answer.
3. Many emails are sent to multiple recipients. It takes no time to add another cc, but each additional recipient multiplies the total response time demanded.
4. Many emails contain additional text that has been copied and pasted from other documents or a lengthy thread that is simply being re-forwarded.
5. Many emails contain links to web pages or videos. Easy to add a link. But it may take minutes to view it.

Now consider that the amount of time people are spending on line is increasing. It is, after all, a seductive place to hang out. As social creatures, it's the most natural thing in the world to want to use that time to reach out to others. What is more the range of 'distractions' online is growing every year. And it's easy (and often wonderful) to share them with our friends and colleagues. Just copy a link, paste and send... and boom, the world's cognitive capacity takes another hit!

The result of all this is a deadly upward spiral. Every hour you spend writing and sending email is probably consuming more than an hour of the combined attention of your various recipients. So without meaning to, we're all creating an ever growing problem for each other.

An email inbox has been aptly described as the to-do list that anyone in the world can add an item to. If you're not careful, it can gobble up most of your working week. Then you've become a reactive robot responding to other people's requests, instead of a proactive agent addressing your own true priorities. This is not good.

This phenomenon can be thought of as a potent modern tragedy of the commons. The commons in question here is the world's pool of attention. Email makes it just a little too easy to grab a piece of that attention. The unintended consequence of all those little acts of grabbing is a giant rat's nest of voracious demands on our time, energy and sanity.

...continued

The Solution

We can reverse this spiral only by mutual agreement. Hence the eMail Charter.

1. *Respect Recipients' Time*

This is the fundamental rule. As the message sender, the onus is on YOU to minimize the time your email will take to process. Even if it means taking more time at your end before sending.

2. *Short or Slow is not Rude*

Let's mutually agree to cut each other some slack. Given the email load we're all facing, it's OK if replies take a while coming and if they don't give detailed responses to all your questions. No one wants to come over as brusque, so please don't take it personally. We just want our lives back!

3. *Celebrate Clarity*

Start with a subject line that clearly labels the topic, and maybe includes a status category [Info], [Action], [Time Sens] [Low Priority]. Use crisp, muddle-free sentences. If the email has to be longer than five sentences, make sure the first provides the basic reason for writing. Avoid strange fonts and colours.

4. *Quash Open-Ended Questions*

It is asking a lot to send someone an email with four long paragraphs of turgid text followed by "Thoughts?". Even well-intended-but-open questions like "How can I help?" may not be that helpful. Email generosity requires simplifying, easy-to-answer questions. "Can I help best by a) calling b) visiting or c) staying right out of it?!"

5. *Slash Surplus CCs*

CCs are like mating bunnies. For every recipient you add, you are dramatically multiplying total response time. Not to be done lightly! When there are multiple recipients, please don't default to 'Reply All'. Maybe you only need to cc a couple of people on the original thread. Or none.

6. *Tighten the Thread*

Some emails depend for their meaning on context. Which means it's usually right to include the thread being responded to. But it's rare that a thread should extend to more than 3 emails. Before sending, cut what's not relevant. Or consider making a phone call instead.

7. *Attack Attachments*

Don't use graphics files as logos or signatures that appear as attachments. Time is wasted trying to see if there's something to open. Even worse is sending text as an attachment when it could have been included in the body of the email.

8. *Give these Gifts: "EOM" & "NNTR"*

If your email message can be expressed in half a dozen words, just put it in the subject line, followed by EOM (= End of Message). This saves the recipient having to actually open the message. Ending a note with "No need to respond" or NNTR, is a wonderful act of generosity. Many acronyms confuse as much as help, but these two are golden and deserve wide adoption.

9. *Cut Content-less Responses*

You don't need to reply to every email, especially not those that are themselves clear responses. An email saying "Thanks for your note. I'm in." does not need you to reply "Great." That just cost someone another 30 seconds.

10. *Disconnect!*

If we all agreed to spend less time doing email, we'd all get less email! Consider calendaring half-days at work where you can't go online. Or a commitment to email-free weekends. Or an 'auto-response' that references this charter. And don't forget to smell the roses.

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This article is available online @ *http://www.emailcharter.org/*

DATA, DATA AND MORE DATA – THE CURSE AND THE KEY TO THE FUTURE

Simon Carlile, Professor of Neuroscience, Sydney University

Healthcare is THE biggest driver in our economy based on fraction of GDP –it provides a huge range of employment opportunities, technological development and clinical research and, at the speculative end, investment in start-ups and new business models. As the impact of the Web has demonstrated, the reach and impact of technological change can be profound. Likewise, it is difficult to think of an area of healthcare that is not already, or will not be affected soon, by current and near future developments in technology.

Data is at its core. This goes well beyond the medical records of a particular patient and is increasingly extending into many aspects of an individual's life and behaviour. Technologies such as body worn, environmental and proximity sensors with spatial (GPS) and commercial tracking (credit and debit card) will add to data such as genomic analysis and more traditional medical records of the individual. IBM has estimated that over the course of a lifetime, the quantity of individual healthcare data generated will reach 1100 Terabytes (Figure 1). By 2020, total medical data will double in size every 73 days.

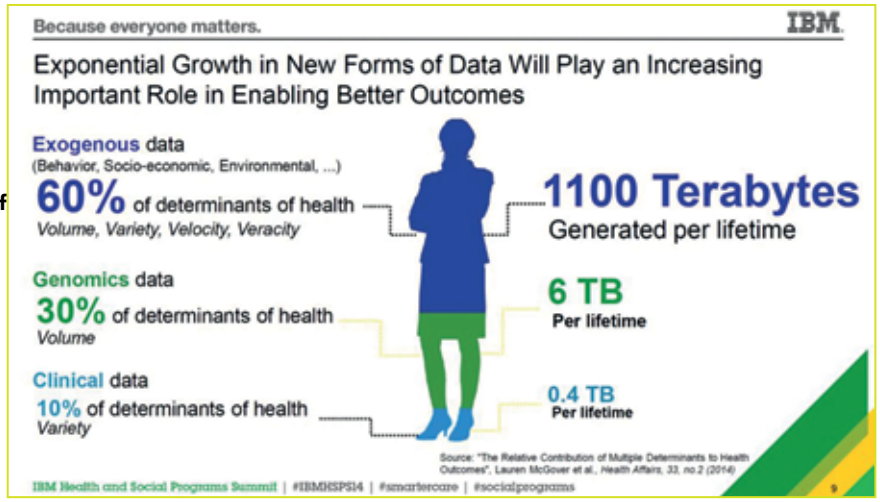

Figure 1: In 2015 IBM estimated the amount of healthcare data that would be acquired over the course of an individual's life time. Critically, what currently constitutes clinical data, represents only about 10% of that data and other sources relate to the individual genomic and environmental data (see also Relative contributions to health).

Like any great river, this torrent has many headwaters. Much of the current medical records and the systems that create them, are being laboriously migrated from analogue to digital. Such information provides an important foundational input and specific government initiatives (e.g. The US Affordable Care Act) have motivated data integration as a means of increasing healthcare efficiency and improved outcomes by better supporting continuity of care. Automation of medical test data entry not only decreases the labour burden but enhances data accuracy.

Since the early 2000s, body-worn sensor technologies have become more prevalent – initially in the domain of fitness and physical training monitors, but now broadening to consumer electronic devices (including smart phones, watches and ear-bud headphones). The Global Wearable Devices Market is expected to exceed more than US$51.60 billion by 2022 at a CAGR of 15.51% – healthcare is identified as a significant driver. Currently these sensor technologies include microphones and cameras, GPS trackers, motion and altitude sensors and optical sensors for blood flow and O2 saturation.

Other near term technologies that are very likely to find their way into body worn sensors include a range of environmental and body chemistry sensors (e.g. blood, sweat and tears), electrophysiological sensors for cardiac, skin conductance, muscle and brain activity as well as other environmental sensors (sound, light and other radiation levels), RF and other beacon receivers and proximity detectors (capacitance, microwave, ultrasonic and infrared).

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The capability and use-cases for these sensors will evolve over time in ways that are hard to imagine from where we now stand. For instance, microphones are currently used as inputs to communication and speech recognition systems to drive search, commerce and text based communications. There is also significant R&D aimed at completely different use cases such as speech and voice quality analysis as a means for judging mood, stress levels and as a diagnostic tool for a range of neurological and cognitive problems. In another example, motion sensors were originally employed to track physical activity over time (and to a lesser extent sleep duration and quality) but now they are used to drive automatic fall detection systems in the elderly and also provide important information for disambiguating other data (for say cardiac monitoring) and calculating VO2 max (a key indicator of physical fitness and respiratory function).

Most likely, it will be novel combination of many different types of sensor data that will provide for some of the most reliable (and possibly surprising) means of monitoring the endogenous (inner) and exogenous (external) environments. Individual streams of data contain noise (variations that don't reflect the specific state being monitored) and combining multiple independent data streams can provide high quality and highly specific information. For instance, a robust measure of emotional state can be obtained by combining optical blood flow data, electrophysiological information (from skin conductance, muscle and brain activity), and voice quality and speech analysis. Any one of these alone provides ambiguous information.

As the Internet of Things becomes more pervasive, interoperability and data from environmental sensors will also provide an important data feed to better define the moment-by-moment environmental context of the individual. The quality of the physical environment – sound levels, light levels, concentrations of key chemicals and pollutants, and presence of pathogens or other disease vectors, will contribute to the stream of exogenous data (see Figure 2). Another key data stream includes purchasing behaviour from credit and debit cards, on-line purchasing and EFTPOS activity which can illuminate among other things, what we consume and when, our physical and social activities and the levels of stress and comfort in our lives.

The analysis firm IDC estimates that by 2025 the annual data growth on the internet will be about 160 zettabytes (10 to the power or 21) but only a fraction (~1%) of that will be stored. Of course, it's not the quantity of the data per se' that is of interest (although working out where to put it, how to access and manipulate it are not trivial problems), it is how such data can be transformed into useful information not the least because presumably that's what will be stored rather than the raw data itself. AI and machine learning will play THE key role in this process. In fact, it inconceivable how such massive streams of data can be managed and mined for important information without such technologies.

Today, AI and machine learning are already making significant contributions to skin cancer diagnosis, drug discovery, genomic interpretation, cancer clinical trial matching and management and beginning to have impact in the delivery of bedside clinical care. Although far from universal, the successes are sufficiently positive to be driving much change in what are traditionally very conservative discipline areas – but one where many also recognize the need for change (see The Healthcare Context). There are however, important limitations with these technologies that need to be incorporated into our understanding of their likely impact(s) in the medium term. In the next blog we will take a deeper dive into the application of machine learning in healthcare to understand not only the potential power of these systems to mine the deluge of data that are emerging but the dangers of sampling bias and bias by design.

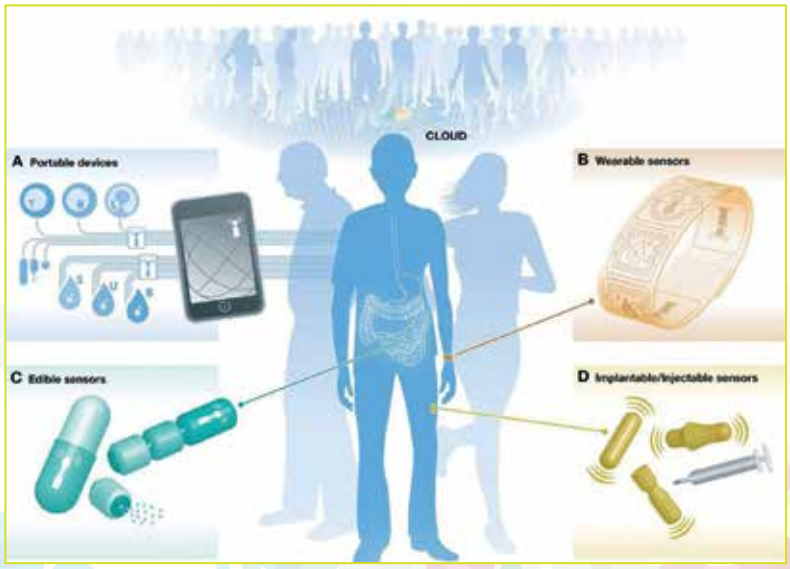

Figure 2: In 2016 the Journal Molecular Systems Biology had an editorial issue which included a review of bio-degradable and bio-compatible internal (ingested and implanted) sensor technologies.

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HAPPY HALF-YEAR GDPR! A GLOBAL OVERVIEW OF THE LAST SIX MONTHS

Dora Endreffy, Global Records Manager, ICON plc

Before you continue reading I would like to highlight that the data and information I am using is based on research and all references are listed at the end of this article. .

So, now let's get into this.

I have already highlighted in my editorial letter that GDPR has been the buzz word for some time now and continues to be the buzz word for at least the next few years to come. I have also stated previously that, in my view, if one has been maintaining records in a consistent manner, using common sense, most of the requirements should not come as a surprise.

We should all have been aiming at knowing what sort of records we have, where we have them, and whether there is any point or legal requirement requiring them to be kept. It doesn't hurt to know where they are and to make sure that a mouse doesn't eat them or they don't get wet. On that baise, surely, one ought also to check on old records once in a while to make sure they are still OK.

Here we are: a simple records management strategy in a nutshell, using common sense only. This simple strategy in itself will probably help you comply with 60% of GDPR requirements.

"But not everyone has common sense", I hear you say. And I agree wholeheartedly. Common sense is a variable concept. But before we decide what it is, let's look at some of the broader news in the world of GDPR to see if that helps.

Global effects of GDPR

The number of country specific privacy regulations are gradually increasing, especially in those countries that have traditionally been loosely regulated. The health research sector has come into focus in some of the new regulations e.g.

- Irish Data Protection (Health Research) Regulations 2018
- India's Personal Data Protection Bill
- Chile's Privacy Bill Initiative
- New Zealand's Privacy Bill
- Brazil's General Data Protection Law and
- China's new regulations.

It will be interesting to see how these new laws contradict each other.

The term "demonstrable compliance" has been introduced as a new legal standard because actions speak louder than words in this case. This was a requirement that most of us have probably encountered during the increased number of audits in 2018.

With an increased awareness on individual privacy, the enquiries on personal data management and retention have substantially increased in all areas and the world has seen a number of massive fines.

- Merck 2017 - cyber issue - $300m
- Facebook– $134b with an initial hit to market valuation (-24%)
- The US Securities and Exchange Commission breach in 2016
- The Yahoo breaches in 2013, 2014 & 2016 resulting in fines of $35m, $350m & $45m
- The Equifax fine of £500,000 from the ICO for failing to protect the personal data of 15 million Britons.

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The main lesson learned from these examples is that there is still a lot of confusion around the interpretation of some of the articles in the GDPR regulations. Even though the European Data Protection Board (EDPB) has published its guidelines on the territorial scope of the GDPR (Article 3) on 26th November 2018 this is still open for public consultation.

The new guideline attempts to provide clarification on the boundaries regarding (for example)

- what constitutes an establishment in the EU
- the conditions of appointment of an EU representative for non-EU controllers and processors.

However, there are many areas that remain open to interpretation that will no doubt be the cause of further findings and data privacy law suits.

GDPR Breaches

I have always loved this picture, which I found on the internet. I have used it in many of the training sessions I have given both at ICON and elsewhere.

Over the last 6 months, it has become rather obvious that most of the companies and even state institutions must shape up to meet the new expectations. It is also very obvious that having a regulation such as GDPR is great.

Facebook and Google have been "the talk of the town" recently for not able to justify the reasons for the extent of their data collection and consequent retention or any profit oriented use of that data. But think of that near €500.000 fine on a Portuguese hospital in July 2018 for two violations of the EU General Data Protection Regulation (GDPR).

According to numerous news items, the majority of companies around the world are failing to fulfil subject access requests (SARs) in time, so contravening one of the most important provisions boosted under GDPR. Under Article 15 and Article 20 of the new data protection laws, organisations must return the information they hold on a user or customer on request within one month. But research shows just 35% of EU-based companies are fulfilling SARs within the legal timeframe; outside of the EU, that figure increases to 50% of companies.

The Data Breach Reports filed only in the UK soared to 8000 in 2018, which is interesting. Just how many breaches were swept under the carpet before? Might someone be using your personal data somewhere without you knowing so?

Lesson Learnt about misuse or abuse of GDPR

Delgates at the HSRAA Brighton conference in 2018 may remember the debating sessions: I volunteered to be the person arguing AGAINST the benefits of GDPR. Though I disagreed with the statement, it made me research and consider the possible flipsides of GDPR. There was a point where the "the path to hell is paved with good intention" comes to play when talking about GDPR.

One of my favourite news pieces on GDPR misuse comes from Germany. In a town in Bavaria, children had been writing letters to Santa. The letters were then put on the town's public Christmas tree. This year, however, the tradition almost ended because it was felt that children's names and addresses should not be in the public square.

Another favourite instance was a request to indicate on a consent form that I approved of me having access to my own PPI.

So what are the lessons to be learnt six months in to GDPR implementation? That training and education are key to success? Absolutely. That no-one is quite there yet but that we are on the right track? I believe we are.

Let me close this article with a quote from one of my favourite books, Douglas Adams' "The Hitchhikers Guide to the Galaxy": "A common mistake that people make when trying to design something completely fool-proof is to underestimate the ingenuity of complete fools."

About the Author: Dora Endreffy is the HSRAA Publications Coordinator and Senior Manager for Quality and Compliance, Global Records Manager at ICON plc where she has specialist interests in- and responsibility for- the management of controlled documents, EDMS process management, the global records management programme control and development, GDPR readiness and support, eTMF audits, and CAPA.

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KRISTEN BRETZIUS, HSRAA TRAINING COORDINATOR

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

I was working at the Merck West Point site as a receptionist for their construction contractor. A project manager noticed my Excel and organizational abilities. He wanted me on his team, so he had a job created for me a Document Control Coordinator. My job was to ensure blue prints were archived and all validation documentation was in place. I also got the opportunity to receive GMP and GLP training and insight as we were building the labs. After a short hiatus from pharma, I took an entry level job at ICON (then Beacon Bioscience) as a Data Coordinator while I was working on my Bachelors of Legal Studies (BLS), PSI approached me through a recruiter and I was asked to come on as a Document Control Coordinator, there were 4 people in the US office at the time and though I really wanted to pursue law, I saw this as an enormous entry level opportunity where I could still study and learn about laws and regulations, but applicable to research and ethics, and boy, have I learned A LOT!

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

14 years+

3. What are you most passionate about professionally?

Promoting the importance the TMF as well as the people who maintain it.

4. What made you apply to become an Executive Member of HSRAA?

My desire to help set a global standard in GxP archiving and records management. I'd really like to see the US and CROs as well as non-EU countries all on the same page for the basics.

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

X Factor, but all the "most [insert adjective here] YouTube videos. I can watch people insult Simon Cowell for hours.

6. Bake Off or Master Chef? Both? Or neither? Why?

Bake Off because I can bake! I can also burn water!!

7. 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!

My epitaph: She did what she wanted and she wanted to make people happy. Wisdom: You can make changes to an infrastructure more easily from the inside than you can standing outside and throwing rocks at it. My track would have to be "Live Before You Die" by Social Distortion "So close your eyes and embrace your memories. Leave your troubles and your worries far behind. Stop contemplating and start celebrating. Yeah, you gotta live before you die."

8. You have a wonderful collection of paintings on the DeviantArt website with the tagline "I paint what I see, but sometimes, what I see isn't really there." Please explain!

When I look at a potential subject (mostly land and cityscapes) I see outlines of things that are not actually there. My mind places them there for balance and/or I think "hey, curtains would look ominous there" or "this place needs some snow!"

9. I see you undertook Legal Studies at Kaplan University. Did a career in the legal profession not beckon?

I wanted to be a law librarian, research case law and precedence for attorneys. I love the US Constitution, the way it was written and I find it very interesting how it's interpreted.

10. Rather famously George Bernard Shaw is alleged to have commented that 'England and America are two countries separated by the same language'. As an American citizen, are there any particular aspects of the English language that you find curious?

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Yes! Why in certain regions of the UK "th" is pronounced as an "f": other, mother, fifths, fourths. From the other side, why we (in the U.S) use the letter "z" where as in the UK it's grammatically correct to use an "s": customize, realize, socialize.

11. In your experience, can the same be said of American and English approaches to Records Management?

Not at all! In my experience in the US teams focus on the initial clinical deliverables, milestones and maintenance (First Site Initiate, FPI, databases, etc.) and it's very linear. Where as in the UK there seems to be a more circular all-encompassing approach. All the milestones and deliverables are also very important, however there is a very strong focus on the TMF as well. I see this as a difference in our regulations. The FDA is not as articulate on TMFs as the MHRA or EMA, and in an inspection situation the FDA focus will be on data, adherence to the protocol and sites (again, linear) whereas the MHRA will look at a wider array of information including in-depth review of TMFs and procedures. From a CRO stance, TMFs (in the US) are not likely to be inspected while in the CRO's possession. Any FDA inspection that would include TMF review would most likely occur after transfer to the client. On the contrary, MHRA will inspect a CRO and review TMF operations and potentially inspect a project during the clinical phase.

ASHLEY COLE, HSRAA MEMBERSHIP SECRETARY

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

I have been directly involved with Records Management and Archiving for over 7 years, it has been part of my daily tasks in some way or another since starting in the industry at 17.

2. What path brought you into Records Management / Archiving?

I originally started my career as a Document Scanner for a eTMF Service provider/ Vendor. I found what I was doing not only fascinating, but I enjoyed the main derivative, which was to ensure clinical research was conducted in a safe and methodical manner, as well as working with Paper or Electronic based eTMF's and ISF content, which would then be managed in such a way to assist with the reconstruction of the clinical trial.

3. What are you most passionate about professionally?

What am I most passionate about professionally? Harmonisation. Harmonisation of standards, processes and knowledge are the aims of my career.

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

Belly dancer, I've been told I have great hips.

5. Rugby or football? Both or neither?

Both, I enjoy football for the sport, however you can drink in the stands of a Rugby game, whereas you cannot in a football match.

6. Cats or dogs? Both? Or neither? Why?

Dogs always win. I need things to keep me occupied and amused. I feel dogs do that perfectly.

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

David Attenborough is a very obvious one. Would love to take him for a pint.

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

My Parents are my inspiration. They've shown me that you have very little to work with, but still produce the goods some way or another, whilst enjoying it.

9. I hear you enjoyed as a young man a potentially promising future as a rifleman. How did you develop an interest in shooting?

I joined Buckinghamshire Army Cadet Force at 13, where I was introduced to many different types of shooting. However I had a pretty keen eye for Target Rifle and Skeet shooting. By 15/16 I had participated in several global shooting competitions, and had the honour of representing the South East of England in a Skeet Shooting completion.

10. You share you name with the professional footballer Ashley Cole, member of Arsenal's revered "Invincibles" but also personally tainted by a number of controversies including the accidental shooting of a work experience student with an air rifle. You both love football and guns. Is that where the similarities end?

I think the real question is, where do these similarities start? I have noticed that there is an uncanny list of similarities that both Ashley and I share, from holding the No.3 shirt, sharing the same name, our love for Cheryl Cole. But I think you missed something critical out, I actually have the ability to hit the target with an air rifle, whereas I think the other Ashley has struggled in the past.

11. Is your love of cycling for road racing, track racing, or touring?

Neither, Down Hill Biking is my preferred way of getting from A to B. I would injure myself often, but that didn't stop me! Ironically, my current bike is a hand-made fixie bike (designed and built by me) that I use just to get to the shops and back at the moment. I aim to get a new Down Hill bike in the New Year.

BEN SAXTON, HSRAA MARKETING COORDINATOR

Ben heads up the Commercial side of the Formpipe Life Science division with the following responsibilities

- Securing new and recurring revenue.
- Account and partner performance.
- Marketing strategy and input to product development.

This wide ranging roles covers Northern Europe, Scandinavia and the UK with a small amount of responsibility within the US also.

With over 10 years experience of selling software solutions into the Life Science sector Ben is well used to recognising the challenges the client organisation will face as well as appreciating what is required to make a project successful. For the last 2 years he has been leading the Formpipe team on developing Long Term Archive for the private sector in the geographic regions mentioned above.

Away from work Ben is married with two young daughters, runs trial marathons, endures being a Sheffield Wednesday fan and on the rare occasion gets to play golf.

https://www.linkedin.com/in/saxtonben/

https://twitter.com/saxtonben

HOBSON LOPES, HSRAA FINANCE COORDINATOR

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

Much like my entry into pharma as a career, I've become involved in the Records Management/ Archiving area out of luck, chance, and opportunity. As a company, we were working towards becoming compliant with the requirement for an archivist and we thought that given my interest and specialties with inspections, that I would be the appropriate person to take that task on.

2. What do you see as the greatest challenges and opportunities in Records Management / Archiving in the life sciences and healthcare sectors?

Educating the industry on what is needed/ required is one of the greatest challenges and opportunities in Records Management/

Archiving in the life sciences and healthcare sectors. For as long as the pharma industry has been alive, there have been records that companies needed to keep. They didn't know why they needed to keep them at all times but they knew they couldn't just trash them. Still today, as regulations change, and more scrutiny is placed on the industry, what we are doing in this area is more important and I think the responsibility falls on us to educate our companies and inform our teams of the requirements and how it impacts them.

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

I think that my chosen job is part of what I was doing before entering pharma. Prior to my start in pharma, I was a freelance writer that worked for several popular websites and was able to interview some huge stars across several sports. While I wouldn't want to go back to the freelance writing industry, I have always been a big fan of baseball and growing up, my dream was to be the broadcaster for the Atlanta Braves from Major League Baseball. While that dream may not come to fruition, I can still say I had a good run with my freelance career.

4. What made you apply to become an Executive Member of HSRAA?

Being so new to the records management area and becoming a new member of HSRAA this year, I thought the best way for me to get a crash course in learning this aspect of the industry would be to become an Executive Member of HSRAA. With some of the most knowledgeable minds in this part of the industry, I can only help enhance my career with what I learn through this small group.

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

So I can probably equate this to the American versions, "Dancing with the Stars" or "The Voice/American Idol." For me, I would rather the singing version. In the States, the bro-mance between Blake Shelton and Adam Levine is hilarious and there have really been some incredible talents on that show.

6. Rugby or football? Both or neither?

Living in the United States, I would assume that the answer one would expect from me is neither, but I thoroughly enjoy both. I remember watching rugby highlight shows when I was growing up as I waited for something else to come on at 1 a.m. It's the only time that I would see rugby on TV in the States so maybe the television networks thought it was too violent? As far as football, growing up in a Portuguese household and having been born in Brazil, I was brought up on football. Every four years, I get my nicest Brazil jersey out for the World Cup and hope for good things, and throughout the year, I catch Champions League action and other leagues from around the world whenever I have a chance,

7. There's nothing I enjoy more than….

A relaxing night at home after a long day at work with my wife and our dogs. It's seems simple and probably cliché, but it really is the best recipe for me to keep my sanity in check.

8. What is your ideal holiday destination / film / book / TV show and why?

When I was growing up, we never had a holiday destination. We didn't vacation as a family and I was fine with that. My wife, Sarah, loves to travel and has been to more countries than I can remember so I knew that no vacations wouldn't fly with her. We take the same trip to Vermont every year between Christmas and New Year's Day. We go snowmobiling through the VAST trails, snowshoe throughout the area in which her family has a property and enjoy the fireworks at the local ski slope lodge up the street on New Year's Eve.

9. I see that you are a freelance writer for numerous websites, have authored several books including, "Men Cook Too" and "Top 25 Atlanta Braves Players of All Time", studied for a degree in professional writing and journalism at university, and are a member of BlogMutt. Do you find writing cathartic?

My interest in writing started when I first went into university with hopes of going into business. I didn't start my secondary education until four years after graduating high school, so I was in a different place in my life and realized that I had a real knack for writing. At first, I started writing about things I liked and then when I decided to make a freelance career out of it, I wasn't writing about only things I liked anymore. So the first part of my writing life, I would say it was cathartic for me but when it became my career, it lost that feeling for me. Still today, when I vacation in Vermont in the United States, I always bring a notebook so I can jot down some ideas and write a little so now that I don't have as much time to write, it gets back to being cathartic for me when I am there.

10. I assume from your Instagram account that you have a real affection for dogs?

My wife and I are big animal people. We have rescued two amazing dogs that we treat like our children. Our first dog, Zooey, just turned five. She is vibrant, full of energy, loves to play, and loves to cuddle. Our second dog, Peeber (which is named after the beer Pabst Blue Ribbon), is almost four and while he has recently started to allow us more freedoms, still doesn't like being as close as Zooey does. He is a special character and makes us laugh out loud at least a few times per day.

We hope you will be able to join us for our 2019 Annual Conference at the five-star St. David's Hotel, Cardiff, UK. This event will take place over Thursday and Friday 8-10 May 2019 and well include presentations, discussions, networking breaks and our conference dinner. The conference will be preceded by a choice of two half-day workshops.

Workshop A: Data Integrity

Leaders:
Russell Joyce, Heath Barrowcliff Consulting
David Thompson, Clarity Compliance Ltd

Workshop B: Data Protection for Archivists & Records Managers

Leaders:
Dora Endreffy, ICON Clinical
Reynold Leming, Informu Solutions

PHLEXGLOBAL RAISE YOUR STANDARD montrium Formpipe.

This event is the only global forum aimed specifically at Records Management and Archive management professionals working within the life sciences and healthcare sectors and a great opportunity to network with like-minded industry colleagues.

The conference will comprise fully interactive workshops presentations, debates, and round table sessions on regulatory requirements and updates, best practices, sector trends, technology developments, and innovations in the field of records and archive management.

Delegates will learn how to best to tackle the challenges of ensuring compliant practices; how best to develop strategies to improve, and optimise procedures, facilities, and technologies; and how best to introduce efficient and durable approaches by learning from inspirational and leading industry experts and peers covering a wide range of topics including

- Data integrity
- Digital archiving
- Inspection strategies
- General Data Protection Regulation
- Good data and information governance
- Artificial intelligence and machine learning

Hotel Information

The HSRAA has reserved hotel rooms at the five-star St. David's Hotel and Spa, Havannah Street, Cardiff, CF10 5SD, UK. The number of rooms we have at a special HSRAA rate is limited so please book early to ensure you secure a room.

Set on Cardiff Bay's waterfront, the St. David's Hotel makes a bold statement, with its glass-fronted façade, private balconies, floor-to-ceiling windows, and coastal setting.

Conference Fees

Early-bird Discount – Deadline 15th March 2019

	Non-HSRAA Member	HSRAA Member
Full conference*	£558	£492
Day delegate	£150	£132
1-night accommodation	£129	£129
Workshop	£135	£120

Standard Prices – From 16th March 2019

	Non-HSRAA Member	HSRAA Member
Full conference*	£744	£656
Day delegate	£200	£176
1-night accommodation	£129	£129
Workshop	£170	£150

** includes drinks reception & conference dinner (value £60)*

HSRAA Member Rates

HSRAA members can benefit from a discount on the standard conference fees. When booking online, please ensure that you are logged into the website and the prices will automatically adjust. If you are not logged in, you will be charged the standard rate and we will not be able to make adjustments subsequently.

The full conference rate includes two-nights' accommodation at the five-star St. David's Hotel on a bed and breakfast basis (single occupancy). It also includes the networking drinks reception and three-course conference dinner with wine. The prices reflect a discount for delegates booking for the full conference. The drinks reception and conference dinner may be purchased separately for day delegates wishing to attend or for guests, at £60 per person.

Please remember to book early as HSRAA only has a limited number of bedrooms blocked with the hotel. Once our deadline passes, we will need to release unoccupied rooms and they become available to the general public.

Sponsors & Bursaries

HSRAA is grateful for the generosity of its sponsors: Formpipe, Montrium, and Phlexglobal. These sponsors make it possible for HSRAA to deliver premier events, provide excellent networking opportunities, and to expand its impact in the life sciences and healthcare sectors through development opportunities.

Thanks to sponsor funding, HSRAA is able to offer for this conference two bursaries to eligible applicants. Please follow the links on the HSRAA website to see the eligibility criteria and to download the application form.

Queries

If you would like to know more about the conference, please contact

- the Conference Administrator *conf-admin@the-hsraa.org*
- the Conference Programme Organiser *events@the-hsraa.org*

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