
SAGACITY
December 2010
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Scientific Archivists Group
Promoting Excellence in Records Management

Scientific Archivist Group Committee

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Entries in Blue are the executive positions

About The Scientific Archivists Group

The aims of SAG are:

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

To achieve these objectives the Group will:

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

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

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

For further information visit our website

www.sagroup.org.uk

Inside this issue

Letter from the Editor Gail Dams

As you read this another year will be drawing to a close and I am sure that we will all be getting ready to look forward to a new year and the challenges that this brings.

Reflecting on this year for a moment it has been an interesting one to say not least just for the Scientific Archivists Group. For the first part we had the postponed Spring Conference which tested the skills of the committee and in particular Liz Hooper to the limit. Sincere thanks go to all those who stepped up to the mark and made it such a success in the end, it was well worth the effort. Additionally Richard Pennicard has put an immense amount of work into researching and providing details for the group to become a limited company he further then investigated and looked into the tax systems which culminated with information on how to get your tax rebate from your subscription, details are on the website, again very many thanks to Richard for this.

As you can see Sagacity and the flyers for the Autumn Conference took on a new look. The Committee felt that we really needed literature that reflected our enthusiasm and the positivity that we all have. I do hope you like the new 'look' it brings into the 21st century!

This brings me nicely to the content. In this issue we were fortunate enough to have articles ranging from GCP-RMA relevant communications guidance document relating to retention times for clinical data to an article from Richard for the conversion to a limited company.

Please endeavour to review the details for the Spring Conference and the topics that we are aiming to cover – interest for all I hope. You will notice that we have not printed a 'Newbie' conference attendance article because this time we wanted a different perspective; consequently we are/were looking to gain feedback from one (volunteer) of our existing delegates. Jackie English (volunteered) from Antisoma. Jackie being one of our regular attendees seemed an ideal volunteer to give all of us feedback and a different approach that reiterates to everyone the benefits of why it is useful to attend to more than just the odd one or two conferences. The feedback should allow individual to underline the importance of what SAG is all about and further to encourage companies to buy in and allow their staff to attend SAG conferences. At the end of the day it is a benefit for the individual as well as the company, we just need to convince all that SAG attendance can be promoted as a "win, win" situation.

In conclusion, many thanks to all those that submitted articles for both issues of Sagacity this year, to those who gave their time to speak at the conferences and who generally work hard to help the Scientific Archivists Group the success it is.

Have a great Christmas and here's to a fabulous New Year!

Cheers
Gail

Letter from the Chair
Chris Jones

Welcome to another edition of Sagacity. Writing the letter for the December edition is a cue for me to start thinking about Christmas (I can see the look of horror on the faces of those of you who long ago prepared yourselves for the festivities!).

Since becoming chair, each year I've been able to reflect back on a positive year for the group, and I'm pleased that 2010 has followed the same pattern.

The membership of the group is steady - the members who left due to retirement or career changes, have been replaced by new members. The committee are exploring ways to promote the group, to help grow the membership in the future.

We held two successful conferences, despite the ash cloud induced postponement of the Spring event and relatively late speaker changes both times. The conferences were successful due to the expertise of the committee and the enthusiasm of the speakers and attendees. My personal thanks to everyone involved. Our recent Autumn conference in Birmingham was memorable for two reasons – the absence , for the first time in many years, of Liz Hooper our conference organiser due to work commitments and for having a presentation on Health and Safety that was both informative and enjoyable to sit through!

Looking forwards - 2011 will be an busy year for the group. Included in this edition of Sagacity you'll see the plans for converting the SAG to a Limited Liability Company. This is an activity that the committee have discussed at length, and which we feel is important for the future of the group. As we go through the process of conversion, we will consult regularly with the membership. If you have questions or feedback about the conversion, please contact our treasurer Richard Pennicard, who has collated all the relevant information.

Another important piece of work planned for 2011 is the working party on electronic archiving , announced at the October conference. Tim Stiles will be leading this project, which is currently in the planning stage. Last but not least, it is the group's 30th anniversary in 2011. The committee are currently looking at ways to celebrate this milestone, based around the Autumn conference.

Thanks again to all our members for your support of the group this year. Season's greetings to you all – and best wishes for 2011.

Best Regards
Chris

Committee Positions for Election

Dear Members,

Due to the current vacancies and members currently coming to the end of their term of office, several Committee positions will be open for election/re-election at the AGM which will be held during the Autumn 2011 Conference. Anyone wishing to volunteer as a Committee Member must have the support of their Management to attend Conferences, Committee meetings outside of the Conferences and be prepared to take an active role within the Committee on behalf of the Group Members.

Such nominations should be made in writing indicating the position you are applying for, candidates being proposed by a full member/seconded by a full member of the Group and received on this occasion by the Secretary (Julia Crisp) by August 2011

Should more than one nomination be received for the Executive Committee position, or should the number of nominations for Ordinary members exceed the number of places on the Committee, the Secretary or Vice Chair will circulate the necessary papers for the conduct of a ballot vote to all full members prior to the AGM.

One Executive Committee position for election
Term of office 3 years.

- Chairperson

Five Ordinary Committee positions for election
Term of office 2 years

- Conference Organiser
- Publications Editor
- Membership Secretary
- Committee Member
- Committee Member

For your information A brief summary the Job Descriptions for each of the above positions are listed below, please don't hesitate to contact any of the Committee Members if you have any questions or need further information.

Committee Members Job Descriptions

General duties performed by all Committee Members include:

- Be prepared to attend committee meetings
- Actively partake in discussions during the committee meetings
- Suggest conference speakers – agree conference, workshop themes
- Research relevant topics and investigate possible authors.
- Help with any housekeeping task at the conference e.g. preparation of the room, circulating handouts etc.
- Circulate/Network during the conference to ensure that the members have all the information they need – especially new members
- Gather information from the members that would be useful when planning future conferences – to fulfil the member's needs.
- Feed to web liaison any useful web sites
- Help promote SAG

Chairperson – additional duties

- Chair the committee meetings.
- Support and encourage the committee members in their roles.
- Host the conference member's session.
- Welcome and introduce the speakers at conferences.
- Chair the SAG member's session.
- Produce a letter from the chair for SAGACITY.
- Respond personally or redirect any questions or requests for information to the relevant SAG expert.
- The contact on the SAG website.

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Committee Positions for Election

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Publications Editor – additional duties

- Commission articles, liaise with authors on timelines, review content for Sagacity
- To include but not limited to committee biographies, new members and retiring members, letters from the Chairperson and Editor, minutes from the members session following conferences, notification of next conference, any advertisements, copy of the application form
- Agree with committee the date for publications
- Liaise with prospective advertisers
- Agree on size, cost and amount of issues to be inserted
- Agree on format to be received
- Design and edit the journal, conference materials and other publications
- Liaise with committee regarding agenda and content of the delegate flyers for twice yearly conferences
- Design and produce delegate registration forms
- Liaise with printer and proof read flyers
- Design delegate hand outs for conferences
- Collate and insert speaker presentations
- Ensure the Secretary has electronic copies of speaker presentations to be loaded onto the laptop prior to start of the conference
- Print and bind required amounts and either courier or take to conferences
- Print delegate badges and either courier or take to conferences
- Liaise with committee and printer regarding any publications produced by membership
- Ensure copyright is gained if necessary and the distribution has been made to appropriate institutions eg British Library
- Act as group point of contact for the printer
- Ensure sufficient copies of publications are printed and distributed as required
- Liaise with Membership Secretary with regard to address labels for sending copies of Sagacity, membership directory, conference flyers and any further publications
- Send and invoice any additional copies of SAG publication requests ensuring a copy of the invoice is sent to the Treasurer

Conference Organiser – additional duties

- Agree with the committee the location of the next meeting (usually 12 months ahead)
- Research possible venues and gather as much information as possible e.g. pamphlets.
- Liaise with committee who will decide on an appropriate venue, format, agenda, meals, workshops and or visits.
- Liaise with the agreed company or hotel or combination where the conference will be taking place.
- Contact agreed speakers to confirm their commitment, timings, travel, accommodation, meals etc.
- Produce and post covering letter and booking form to accompany conference flyer.
- Liaise with the appropriate person who is producing the conference handout, supply the relevant information on the speakers and their presentations as soon as available.
- Keep an updated list of members attending the conference and forward monies to the Treasurer
- Update members at the conference

Membership Secretary – additional duties

- Update SAG membership database
- Send renewals and reminders as appropriate
- Send welcome pack consisting of welcome letter, membership card and copy of most recent journal.
- Check date for extended membership i.e. October
- Send cheque/monies to Treasurer
- Notify the Website co-ordinator to issue a password.
- Canvas reasons for non-renewal e.g. job moves, company moves and mergers.
- Update members at the conferences

Members Page

General Updates and Information

E-archiving
Working party request - Tim Stiles

As we all know e-archiving is a topic that is becoming more and more important to the future of company business and may of course impact on our positions (if it hasn't already). Tim is currently putting together a working party to produce a document to provide information and assistance as we move forward to tackle the "new science" of e-archiving.

Consequently, if anyone would like to be involved in this working party then can you please contact Tim with your interest or if you require more information before committing yourselves to what will be I'm sure a very interesting task.

Welcome to our New Members

Bernard Eichinger	Ricera Biosciences S.A.S.
Alieu Amara	University of Liverpool
Holger Koschel	Nycomed GmbH
Guy Clark	Synexus Ltd
Estelle Nunes	Merck Sharp and Dohme
Gillian Gittens	Phlexglobal Ltd
Grant Hutchinson	Kellys Storage Ltd

Membership renewal 2011

Just a gentle reminder that by now you should have received your membership renewal for the coming year, payment is required by the end of January.

Best Wishes on your Retirement

Brenda Harris Schering Plough

May I take this opportunity on behalf of the Scientific Archivists Group to wish you a happy retirement. And to thank you for all your support over the years.

Tax update

Registration with HMRC

Richard Pennicard

SAG is registered with Her Majesty's Revenue & Customs as a professional body under section 344 of the Income Tax (Earnings and Pensions) Act 2003 with effect from 6 April 2010. This means that members become automatically entitled to a tax rebate for their membership fees and if their membership fee is paid by their employer, it is not treated as a taxable benefit.

SAG's name will be added to the HMRC's list of approved bodies later this year. If members wish to obtain a tax rebate before then, they should explain to their local tax office that the group has only recently been approved, quoting reference T1644/28/2009/JEM. As further support, a copy of the letter of approval has been posted in the member's section of the web site.

Call for Articles

Should you like to submit an article on a topic you feel would be of interest to our members, please contact the editor by e-mail ***sagacity@sagroup.org.uk*** or telephone **01933 319906** and speak to Gail.

GCP-RMA

Relevant communications Guidance Document & GCP-RMA Paper on Relevant Communications

Liz Hooper and Russell Joyce

Relevant Communications Guidance Document

Introduction

1. This document is intended to supplement the ICH Guideline for Good Clinical Practice section 8.3.11 "Relevant Communications Other Than Site Visits".
2. In particular, to provide guidance on how to decide whether a communication is 'relevant' or not.

What is a communication?

1. A communication may comprise a letter, email, telephone contact, fax or meeting minutes.
2. Some forms of 'communication' are ICH-GCP documents in their own right, e.g. a letter from a Regulatory agency giving approval is not filed as correspondence but as 'regulatory approval'.
3. All communications (including emails) should be business like and not contain personal information. They should be professional, courteous, not chatty, only discuss study matters and one study per piece of correspondence.

What is relevant

1. Communications that document any agreements or significant discussions regarding:
   - trial administration;
   - protocol violations;
   - trial conduct; and
   - adverse event reporting.
2. When deciding whether an email message constitutes a record, the context and not just the content of the email message needs to be considered. The types of e-mail that may need to be included as a record could pertain to:
   - substantial discussions/exchanges;
   - information distributed to groups of people expected to take action or to comply with instructions, or to raise their awareness of a critical situation, etc.; and
   - agreement(s) to proceed.
3. E-mail messages could provide supporting reasons(s) for a particular course of action being followed. This means that it is necessary to capture not only the e-mail related to the final decision but also any discussions that might indicate the reason(s) for the decision having been reached. For example:
   - The decision-making process around whether or not to include a patient into the study, the background discussion of the issues and the manner in which these are addressed might have taken place via e-mail and should therefore be captured and retained safely as part of the record of the decision.
   - Communications that document processes that were followed or decisions that were made where there is no SOP/Policy to support that process or decision, or when the existing SOP/Policy was not followed; and
   - Exceptional/study related circumstances that may occur will require retention of related communications. The Study/Project Manager (that is, the person who is responsible for the study) must assess relevance on a case-by-case situation.
4. To ensure legal admissibility, preserve provenance and integrity, and to capture header metadata, e-mail messages should be saved in their native format (e.g. MS Outlook e-mails should be saved as a .msg file). This holds true for both the initial e-mail and for each subsequent receipt and response. The reason is that when using the "Reply" or "Forward" function, header information is embedded into the response as alterable text and may therefore be changed. When converting to other formats e.g. Portable Document Format (pdf) or Extensible Markup Language (xml) ensure, there possible, that the header metadata is retained.

What is not relevant

1. Communications related to a decision captured elsewhere in a formal document held within the TMF need not be kept e.g. attendance at teleconferences, which is captured in meeting minutes.
2. Ephemeral (transient/temporary) communications should not be kept. Ephemeral documents are defined as documents of a trivial nature and therefore not business-critical) or of such short-term value that they do not support or contribute to the decision making process or any outcomes. These records are generally only needed for a few hours or a few days e.g. an email invitation to a meeting. In broad terms, ephemeral documents include:
   - documents of a routine or trivial nature;
   - documents that duplicate (or extract) information already held elsewhere; and
   - documents with little or no value as a record of compliance (or non-compliance) with Good Clinical Practice.

Location of Relevant Communications within the TMF

1. Relevant communications should be filed in the TMF in a way that allows for ease of retrieval. Three approaches are suggested;
   - File all communications in one dedicated "communications" section in the TMF.
   - File communications according to the subject to which they relate eg communications related to drug supplies are filed with other drug supply records (rather than in a separate communications section).
   - Use a hybrid system, filing some communications according to the subject to which they relate (e.g. for those areas considered to be of critical importance such as Regulatory, Ethics etc.) and filing other communications in an "Additional Communications" section.
2. Where using a "communications" section either for all correspondence or according to the hybrid system, we recommend subdividing by "Internal communications" , " Third Party Communications" and (if relevant for CROs) "Sponsor Communications".
3. Subdivisions such as these enhance ease of retrieval when faced with a large number of communications. Whichever option is chosen it should be remembered that regulatory inspectors require trial document to be "readily available, upon request, to the competent authorities". The filing system should therefore facilitate easy and rapid location of document requested by the competent authorities.

GCP-RMA Paper on Relevant Communications

The GCP – RMA originally started life as a working party of the European Forum for GCP in 1992 and ran a session on Records Management at the inaugural conference of the EFGCP at the European Parliament in 1993. The aim of the working party was to look at Records Management and particularly Trial Master Files across Sponsor, CROs and investigator sites to establish standards and best practice. A paper on Retention of Clinical Trial Records at Investigator sites was published through EFGCP in 1993.

The group left the umbrella of EFGCP in 2001 and established itself as an independent Association. It has members working within Clinical research as Records Managers or archivists, from many of the leading pharmaceutical companies, all working within Europe. Members are not accepted from outside Europe.

It is still a very small, specialised Association, with only about 30 members. However, the small size works in the Association's favour as it operates through regular discussions and meetings, rather than via newsletters and journals. For example, there are monthly telephone conference calls to discuss relevant topics e.g. recently issued guidelines or legislation; upcoming conferences, training courses and meetings; issues of specific interest to individual members. There are also face to face meetings, usually two per year. The format of the meetings is based around discussion and the free exchange of experiences and ideas. The Association endeavours to track any relevant legislation or proposed legislation and working papers to comment on the proposals from a Records Management point of view. For example, they recently provided comment to the New Zealand Ministry of Health regarding proposed GCP guidance. All members agree to a non-disclosure clause to encourage frank debates.

There have been several small work streams looking at specific Records Management problems, which when finalised are added to the group's web-site. The website is www.gcp-rma.org. In addition to publishing position papers on this website, the Association has published papers in a number of professional journals. The following paper was produced two years ago by a working committee led by Sarah Hitching of Chiltern International.

GCP Records – Keep Them Forever

Eldin Rammell

One of the key responsibilities of an archivist or records manager is to help define the most appropriate retention period for each record series for which he/she is responsible.

There are a wide variety of methods that can be used to appraise records and set retention periods (for example, see **Managing Records: A Handbook of Principles and Practice**, Shepherd & Yeo, 2003). Whichever method is used, it should take account of the value of the content to the organisation, any legal requirements for record retention and any regulatory requirements for record retention. The challenge for managing records related to clinical trials on medicinal products is that the regulatory framework is not always fully understood. This brief article is intended to provide clarity regarding the GCP regulatory requirements for record retention. To determine which regulations are pertinent, I shall review the primary regulations in a chronological manner.

"The challenge for managing records related to clinical trials on medicinal products is that the regulatory framework is not always fully understood."

Prior to the introduction of Good Clinical Practice guidelines, the most common retention period in place was 15 years although only a period of 5 years was mandated by European Directive 75/318/EEC. GCP was first published in Europe in 1995 as **CPMP/ICH/135/95 Note for Guidance on Good Clinical Practice**. It was approved by the CPMP in July 1996 to be effective for any studies commencing after 17 January 1997. These guidelines state:

> *The sponsor should retain all sponsor-specific essential documents in conformance with the applicable regulatory requirement(s) of the country(ies) where the product is approved, and/or where the sponsor intends to apply for approval(s).*
>
> *The sponsor-specific essential documents should be retained until at least 2 years after the last approval of a marketing application in an ICH region and until there are no pending or contemplated marketing applications in an ICH region or at least 2 years have elapsed since the formal discontinuation of clinical development of the investigational product. These documents should be retained for a longer period, however, if required by the applicable regulatory requirement(s) or if needed by the sponsor.*

And for the investigator:

> *Essential documents should be retained until at least 2 years after the last approval of a marketing application in an ICH region and until there are no pending or contemplated marketing applications in an ICH region or at least 2 years have elapsed since the formal discontinuation of clinical development of the investigational product. These documents should be retained for a longer period, however, if required by the applicable regulatory requirements or by an agreement with the sponsor. It is the responsibility of the sponsor to inform the investigator/institution as to when these documents no longer need to be retained.*

The minimum period is therefore 2 years following project discontinuation/termination or 2 years after the last marketing approval in one of the ICH member countries.

ICH GCP was embedded into European legislation with the issue of the GCP Directive, 2001/20/EC on 4th April 2001. This Directive does not however provide any specific requirement with regards to record retention other than requiring compliance with the principles of good clinical practice. The Directive states:

> *The detailed guidelines on the documentation relating to the clinical trial, which shall constitute the master file on the trial, archiving, [...] shall be adopted and revised in accordance with the procedure referred to in Article 21(2).*

In other words, Directive 2001/20/EC states that records shall be retained in accordance with the principles of ICH GCP and that more detailed guidance will be forthcoming. It took a further 5 years for the guidance to appear!

Directive 2001/83/EC, otherwise referred to as the Clinical Trials Directive, was issued on 6 November 2001. The main area of relevance for us is Annex I (Analytical, Pharmacotoxicological and clinical standards and protocols in respect of the testing of medicinal products). Part 4 of Annex I concerns requirements for clinical documentation and includes the following:

Archiving

The marketing authorization holder shall make arrangements for archiving of documentation.

a) *The investigator shall arrange for the retention of the patient identification codes for at least 15 years after the completion or discontinuation of the trial.*

b) *Patient files and other source data shall be kept for the maximum period of time permitted by the hospital, institution or private practice.*

c) *The sponsor or other owner of the data shall retain all other documentation pertaining to the trial as long as the product is authorized. These procedures shall include:*
   - *the protocol including the rationale, objectives and statistical design and methodology of the trial, with conditions under which it is performed and managed, and details of the investigational product, the reference medicinal product and/or the placebo used,*
   - *standard operating procedures,*
   - *all written opinions on the protocol and procedures,*
   - *the investigator's brochure,*
   - *case report forms on each trial subject,*
   - *final report,*
   - *audit certificate(s), if available.*

d) *The final report shall be retained by the sponsor or subsequent owner, for five years after the medicinal product is no longer authorized.*

The requirements of this Directive were superseded however on 25th June 2003 for trials that support marketing applications with the issue of Directive 2003/63/EC. This newer Directive specifically states that the old Annex I contained in Directive 2001/83/EC is now replaced by the Annex contained in 2003/63/EC for covered studies. This new Annex I states:

> *Marketing authorisation holders must arrange for essential clinical trial documents (including case report forms) other than subject's medical files, to be kept by the owners of the data:*
>
> - *for at least 15 years after completion or discontinuation of the trial,*
> - *or for at least two years after the granting of the last marketing authorisation in the European Community and when there are no pending or contemplated marketing applications in the European Community,*
> - *or for at least two years after formal discontinuation of clinical development of the investigational product.*
>
> *Subject's medical files should be retained in accordance with applicable legislation and in accordance with the maximum period of time permitted by the hospital, institution or private practice.*

It is usually interpreted that the above paragraphs apply to the records **at the investigator site** because (a) they specifically mention case report forms, (b) they specifically mention subject medical files, and (c) the phrase "must arrange for" is used, implying someone other than the sponsor. Thus, the minimum retention period for investigator trial records in support of marketing applications is 15 years, but longer if bullet 2 or 3 go beyond 15 years.

> *The documents can be retained for a longer period, however, if required by the applicable regulatory requirements or by agreement with the sponsor. It is the responsibility of the sponsor to inform the hospital, institution or practice as to when these documents no longer need to be retained.*

This paragraph highlights the need to check any other applicable regulatory requirements (including any issued subsequent to 2003/63/EC). Annex I continues:

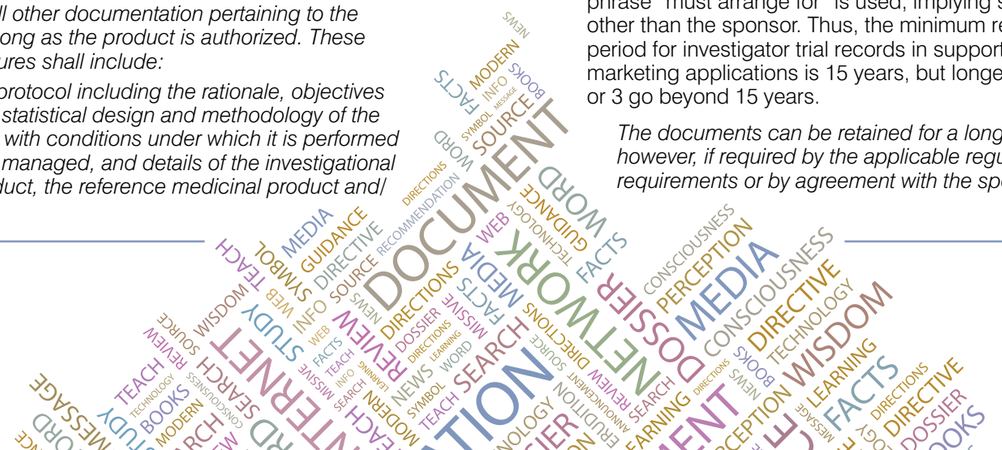
> *The sponsor or other owner of the data shall retain all other documentation pertaining to the trial as long as the product is authorised. This documentation shall include: the protocol including the rationale, objectives and statistical design and methodology of the trial, with conditions under which it is performed and managed, and details of the investigational product, the reference medicinal product and/or the placebo used; standard operating procedures; all written opinions on the protocol and procedures; the investigator's brochure; case report forms on each trial subject; final report; audit certificate(s), if available.*
>
> *The final report shall be retained by the sponsor or subsequent owner, for five years after the medicinal product is no longer authorised.*
>
> *In addition for trials conducted within the European Community, the marketing authorisation holder shall make any additional arrangements for archiving of documentation in accordance with the provisions of Directive 2001/20/EC and implementing detailed guidelines.*

It can therefore safely be concluded that 2003/63/EC specifically widens the scope of records required to be retained beyond just the minimum list of essential documents.

These paragraphs requires the sponsor to retain any document that could be interpreted as being trial-related – *"all other documentation pertaining to the trial"*- for as long as the product to which it pertains is authorised for sale. The examples quoted in the Directive include document types which are not specifically included in the minimum list of essential documents in ICH GCP Chapter 8 (for example, written opinions on the protocol and procedures). It can therefore safely be concluded that 2003/63/EC specifically widens the scope of records required to be retained beyond just the minimum list of essential documents. This interpretation forms the basis of the DIA TMF Reference Model, for example. This Directive again refers to "implementing detailed guidelines" which were not available for another 3 years.

Some additional clarification was provided with the issue of Directive 2005/28/EC on 8th April 2005, included in Chapter 4 (The Trial Master File and Archiving). Article 17 of Directive 2005/28/EC states:

> *The sponsor and the investigator shall retain the essential documents relating to a clinical trial for at least five years after its completion.*



GCP Records – Keep Them Forever *Eldin Rammell*

(continued)

This is the absolute minimum retention period, irrespective of whether or not the trial supports a marketing application or the product is discontinued/terminated.

> *They shall retain the documents for a longer period, where so required by other applicable requirements or by an agreement between the sponsor and the investigator.*

Directive 2005/28/EC does not therefore change any of the requirements in earlier Directives with respect to trials that support marketing applications; the requirement to retain *"all other documentation pertaining to the trial as long as the product is authorised"* still stands.

The "detailed guidance" referred to in Directive 2005/28/EC and 2001/20/EC was issued in July 2006 as part of the European Commission's "Rules Governing Medicinal Products in the European Union, Volume 10, Clinical Trials, Notice to Applicants". Chapter 5 of this guidance includes "Recommendation on the Content of the Trial Master File and Archiving". Section 7 provides requirements for record retention as follows:

> *Directive 2005/28/EC Article 17 and 18 sets out the requirements for retention of the essential documents and medical files. The requirements of Annex 1 to Directive 2001/83/EC (as amended by Directive 2003/63/EC) shall be complied with concerning clinical trials submitted in support of marketing authorisations.*

In other words, as far as retention periods are concerned, the long-awaited detailed guidance only confirms retention times already stated. However, the guidance does confirm that the sponsor must obtain the investigator's agreement to retain their trial records until told by the sponsor that they are no longer needed and that this agreement must be confirmed in writing:

> *The sponsor should inform the investigator(s)/institution(s) in writing of the need for record retention and should notify the investigator(s)/institution(s) in writing when the trial related records are no longer needed. The sponsor should obtain the investigator's/ institution's agreement to retain the trial related essential documents until the sponsor informs the investigator/institution these documents are no longer needed. The sponsor and the investigator/ institution should sign the protocol, or an alternative document, to confirm this agreement.*

Of course, in addition to the European Directives and European Commission guidance documents, we need to ensure compliance with national and local legislation. In the UK, for example, the Medicines Act 1968 provides the legal basis for clinical trials and Statutory Instrument 2004, No. 1031 (The Medicines for Human Use (Clinical Trials) Regulations 2004) implements the requirements of Directives 2001/20/EC and 2001/83/EC. This was amended in 2006 by Statutory Instrument 2006, No. 1928 with the insertion of regulation 31A regarding the trial master file and archiving. This regulation states:

> *The sponsor and the chief investigator shall ensure that the documents contained, or which have been contained, in the trial master file are retained for at least 5 years after the conclusion of the trial.*
>
> *The sponsor and chief investigator shall ensure that the medical files of trial subjects are retained for at least 5 years after the conclusion of the trial.*

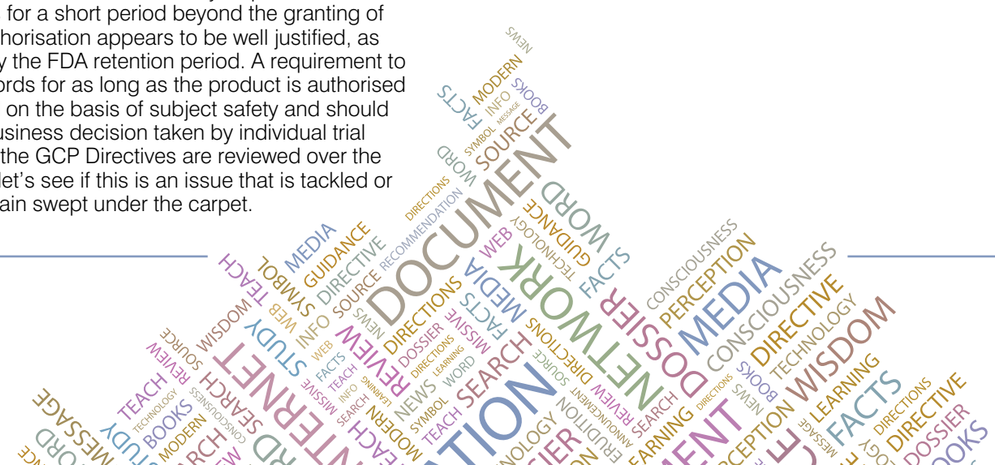
Again, this is a minimum retention period irrespective of whether the trial will support a marketing application. The longer retention period required by 2003/63/EC will still apply for trials that support marketing applications.

It is important to check with national retention requirements in all areas where a product may be marketed to ensure compliance with any local requirements, for example, a minimum retention period of 25 years in Canada. In addition, a sponsor may choose to extend the minimum retention period mandated by the various applicable legislation and regulations for a number of reasons including research purposes, historical value and risk mitigation (to support potential litigation).

It should be noted that this summary applies to medicinal products for human use, as defined by 65/65/EEC, 75/318/EEC and subsequent legislation. The retention requirements for clinical trial records for advanced therapies, diagnostic reagents and devices, including in vivo devices, are regulated by a number of additional Directives and regulations, including 93/42/EC, 98/79/EC, 2007/47/EC and Regulation 1394/2007.

"... the retention requirements for clinical trial related records are fairly clear ..."

In conclusion therefore, whilst it takes a little practice to negotiate the directives and regulations, the retention requirements for clinical trial related records are fairly clear, at least in Europe. However, it still remains that the mandatory requirement to retain records for *"as long as a product is marketed"* appears to be an overly conservative retention period. The rationale for GCP is to ensure that *"the rights, safety and well-being of trial subjects are protected"*. A mandatory requirement to retain records for a short period beyond the granting of marketing authorisation appears to be well justified, as exemplified by the FDA retention period. A requirement to retain the records for as long as the product is authorised is not justified on the basis of subject safety and should surely be a business decision taken by individual trial sponsors. As the GCP Directives are reviewed over the coming year, let's see if this is an issue that is tackled or one that is again swept under the carpet.



Conversion to a Limited Company

Richard Pennicard

The committee has been looking further at the cost and process of converting SAG to a limited liability company (technically a company where liability is limited by guarantee). It also considered whether to apply to be registered as a charity; however it was felt this would require us to change our objectives and working practices beyond what would be practical.

At the moment the membership as a whole is liable for debts that SAG may incur. The worst case scenario is if SAG were found to be negligent and damages awarded exceeded our insurance cover. In these circumstances, all SAG members would be required to share the cost of the damages awarded. Limited liability limits the amount that members would pay out to what is guaranteed in the articles of association – normally £1

The downside of conversion to being a limited company would be an increase in our administrative costs. The cost of conversion could be up to £500 – though this could be reduced if the group did some of the work ourselves, e.g. rewriting our constitution as a memorandum of association. Annual running costs could rise by up to £500/year and we would have to file tax returns: at least initially until we were accepted as a not-for-profit organisation. Our annual accounts would have to be filed at Companies House and would be open to public examination.

At present, our constitution states that on dissolution, the group's assets will be divided among the current membership. This would have to be changed as the groups assets will be needed by the new company. It may be necessary to change this section of the constitution in advance of voting for the conversion.

The proposal was approved in principle at the members' session at the conference in Basel. Following that, the committee has put together a draft timetable for the conversion. This may be subject to change depending on what professional advice we get. Our current thinking is to have the final vote on the conversion at the AGM at the next Autumn conference, but we may be able to bring the vote forward to a general meeting at the Spring conference. In either case, the vote will be a postal ballot so that members unable to attend the conference will still be able to vote.

The timetable currently planned is:

- Get a complete costing of the proposal
- Draw up draft articles and memorandum of association to replace our current constitution. These would have to comply with the laws regulating the governance of limited liability companies while preserving our current aims and objectives, and also as much as possible of the way we currently run our affairs.
- Consult members about the draft articles of association and incorporate feedback into the final version.
- Once details are finalised, set up shell company, with bank account and make all other necessary preliminary arrangements.
- At the next AGM, put resolution to members to dissolve SAG and transfer its assets to the new company. This would be done by a postal ballot of all members as currently provided for in our constitution.
- Immediately afterwards, hold first AGM of the new company to elect a board of directors (equivalent to the committee), appoint auditors, etc.
- Enjoy the benefits of limited liability.

If you need further information, or have any questions on any of the topics in this article, please contact me at treasurer@sagroup.org.uk

Scientific Archivists Group
promoting excellence in records management

AUTUMN CONFERENCE

14th & 15th OCTOBER 2010

at Jury's Inn BIRMINGHAM

Autumn Conference

Attendee Experience
Jackie English *Antisoma*

October 2010, Birmingham

I work for Antisoma Research Limited and I have been with the Company for seven and a half years. Initially I supported a number of Departments but soon joined the Clinical Department as a Clinical Administrator on a permanent basis. I am now Clinical Project Assistant and responsible for Archiving all documentation relating to Clinical Trials.

I attended my first Scientific Archivist Group Conference in April 2007, which I found really interesting and provided a lot more insight into Archiving instead of just putting documents into a box and forgetting about them which most people think is the case. I did not realise there was so much to learn about Archiving and how important it was to Clinical Trial documents.

In 2006, the Clinical Department had an MHRA Inspection and I was interviewed on more than one occasion regarding Archiving and I think it was only then that it struck me how important Archiving was. It was suggested by the Head of UK Clinical Department that I became a Member of the Scientific Archivist Group, which I duly did and since 2007 I have attended every Conference except one which I was unable to attend due to personal reasons.

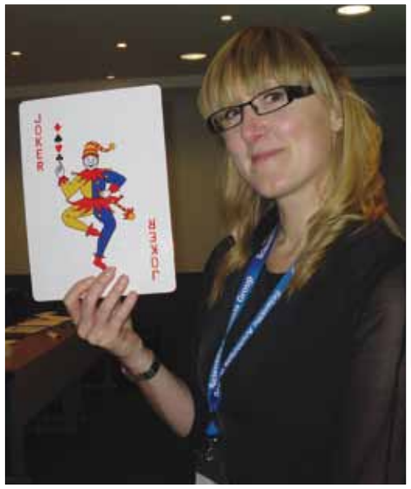
The workshops that are run are always informative and it is good to hear other people's views and their experiences, and also the opportunity to interact with people from different Companies. There are always a number of excellent speakers who are available and willing to answer questions during and after the sessions. It is vital that one keeps good records regarding the Archiving of documents so if need be, documents can be easily identified and retrieved in a timely manner from the Archive. I believe I have learned a tremendous amount from attending these conferences and it has been a great help to me in the position I hold at Antisoma. On numerous occasions, MHRA Inspectors have spoken at the conferences and every time one learns something new about what is expected.

I would like to take this opportunity to thank the Committee Members for all their hard work that goes into the organising of these Conferences, which are always professionally run. I know a tremendous amount.

Autumn Conference

Presenters and Delegates Networking Photo Gallery

October 2010, Birmingham



Autumn Conference

AGM and Members Session

October 2010, Birmingham

1. **Constitution Update**

   The Chair informed the group that the constitution was reviewed at the July committee meeting and no changes were suggested.

2. **Committee Positions**
   - The group was updated on who had taken the positions which were up for election this year.
   - Executive positions are for a three year term, the following people were unopposed
     Vice chair – Mary Paul
     Treasurer – Richard Pennicard
   - Ordinary member positions are for a two year term, the following person was unopposed
     Ordinary member – Russell Joyce
   - European Liaison – Britta Krusemeyer has agreed to take up this position for a further two year term.
   - The Chair informed the group that in 2011 the terms of the chair and five ordinary members comes to and end. More information will be shared with the membership in due course

3. **Treasurer Update**
   - The Treasurer handed out copies of the 2009 reviewed accounts and gave a summary to the group.
   - Current account: £4221.03
   - Deposit account: £28185.84
   - Euro account: €6243.79
   - We have applied to become a limited company, further information will follow
   - Membership fee will stay the same for 2011 at £50/€80
   - The Treasurer invited questions:

   Q) Are we going to be able to use a credit card to pay for membership fees and conferences.

   A) This requires enhancements to the SAG web site, the requirements for this and the costs are being developed in partnership with our web site developer

4. **Membership update**
   - The membership secretary gave the statistics for the groups membership

- We have had membership cards in the past but have decided in 2010 that certificates of membership would be better, as people can add these to their work files
  - The membership directory is now published on the SAG web site rather than being sent out as a hard copy. This was decided as it would save the group money, it could then be quickly and easily updated and every member would have access
  - Renewals will be emailed out in November 2010
  - Date for receipt of payment should be by the end of January 2011
  - Reminders will go out in February 2011
  - Non responders will be treated as non renewals at the end of March 2011, this will enable an accurate membership directory for 2011 to be published in April

5. **2011 Spring Conference**
   - The group were informed that the spring 2011 conference would be held in Bournemouth at the Royal Bath Hotel on 12th & 13th May 2011 at a cost of approx £285 or €340
   - Potential topics: *ISO15489 workshop part two*
     DEFRA
     Lab books

6. **Electronic archiving working party**
   - The Chair informed the group of the committee's decision to put a working party together to write a set of guidelines on e-archiving. Tim Stiles has volunteered to lead the working party
   - The Chair gave a brief outline of the scope
   - The group was asked how they felt about this and if anyone would be interested in being part of the working party. The response was very positive and two people came forward at the meeting
   - The group was asked to inform any member of the committee if they were interested and their name would be given to Tim. In addition, an email will be sent to all SAG members to outline the scope of the working party, and requesting those with an interest in participating to contact Tim.
   - Depending on the level of interest not everyone who comes forward will be part of the working party
   - The committee will decide how to publish and disseminate the output of the working party.

   Questions

   Q) Will preclinical be included
   A) Nothing is out of scope at present

   Q) Do we know what the time commitment will be
   A) Not at this point

   Ideas
   - Validation should be in the scope
   - There should be a balance between technical and non technical on the working party
   - The full lifecycle should be considered, including destruction.

7. **AOB**

   Q) Has anyone had experience with human tissue act
   A) It has a 30 year retention period. The facility has to have a licence. The 30 years start when the human tissue is used.
   - Inspections are most commonly now conducted at the full time of 27 months.

SCIENTIFIC ARCHIVISTS GROUP

Promoting Excellence in Records Management
Web Site: www.sagroup.org.uk
E Mail: saginfo@sagroup.org.uk

MEMBERSHIP APPLICATION FORM FOR CALENDAR YEAR 2011

Full membership is open to individuals with an interest in Archiving, Document and Records Management

Please return completed registration form, together with payment to:

R Pennicard, SAG Treasurer,
c/o Selcia Ltd,
Fyfield Research and Business Park,
Fyfield Road, Ongar,
Essex, CM5 0GS,
U.K.

Payment can be made either by:
- Cheque (£50 Sterling) – made out to **Scientific Archivists Group**
- BACS transfer (£50*) to our Sterling bank account
- BACS transfer (€80) to our Euro bank account

*£55 for payments from outside of the UK to our Sterling account, to cover bank charges.
Bank details are shown below.

SAG is approved by HM Revenue and Customs under section 344 of the Income Tax (Earnings and Pensions) Act, for income tax relief in respect of annual membership subscriptions. A copy of the HMRC letter is in the members area of the SAG website.

PERSONAL DETAILS

Name	
Job Title	
Company Name	
Address	
Tel No. Fax No.	
E Mail Address	
Discipline (tick those that apply)	GMP ☐ GLP ☐ GCP ☐ GPvP (pharmacovigilance) ☐ Other (please specify) ☐ .....
How did you hear about the group?	

Bank details for BACS payments

Sterling Payments		**EURO Payments**	
Natwest Bank Plc		Natwest Bank Plc	
Acc No:	92106293	Acc No:	550/00/64500632 NXNBBNDK-EUR00
Sort Code:	01-09-69	Sort Code:	01-09-69
BIC:	NWBK GB 2L	BIC:	NWBK GB 2L
IBAN:	GB68 NWBK 0109 6992 1062 93	IBAN:	GB85 NWBK 6072 0264 5006 32

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Scientific Archivists Group
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SPRING CONFERENCE

MAY 2011 - BOURNMOUTH

Topics to include:

- E-archiving Initiative
- E-discovery
- Implementing Records Retention Policies
- Business continuity Planning

In Addition

- Records Management Workshop (to include retention analysis)
- Member Session
- Conference Dinner

Other topics to be determined

SAG Conference Grant

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

An amount to be set aside will be reviewed and decided upon by the Committee on an annual basis. The fund will be used on the basis of a written request from individual members a minimum of 2 months prior to the conference. The request must be sent to the Group Secretary and the Chairperson. The Committee will discuss each case on its merit and, if justified, will allocate a sum from the fund, based on an amount to cover an individuals conference fees only. Once the monies set aside for any one year are used up no further requests will be considered until the following year.

All applications will be treated in confidence.

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All enquiries regarding advertising must be addressed to the Editor.

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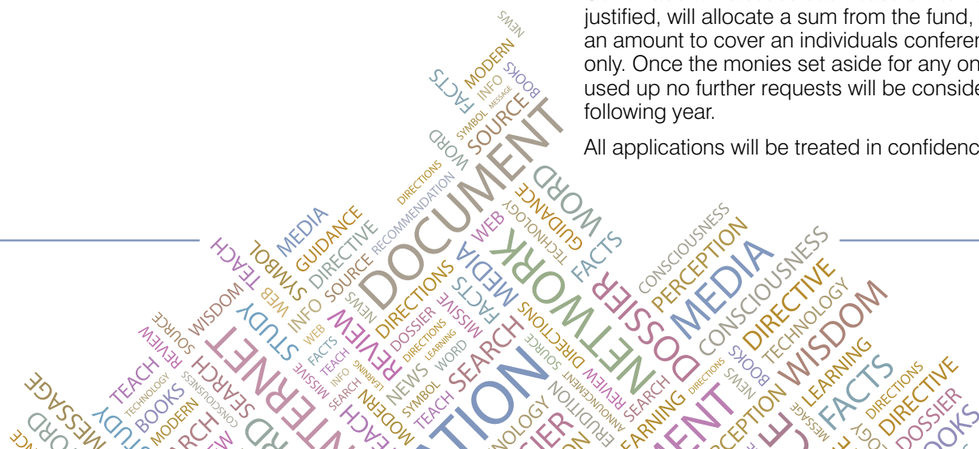
Please send an original copy to the Editor and a further copy to the Treasurer to enable an invoice to be raised.

The advertisements carried by Sagacity are entirely independent of any endorsement by the SAG Committee.



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