Summer 2011 • ISSUE 78

acdm
association for clinical data management

DataMatters

NEWS & VIEWS

ARTICLES

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Guidelines for Contributors

Articles range from 700 words to over 2,000. Photographs, diagrams and illustrations help to break up large areas of text. News items can range from 80 – 400 words to include photographs if relevant. Profiles can range from 300-600 words, and photographs will enhance these pages.

Photographs – We need good quality digital images taken at the highest resolution possible. With digital photography the more mega pixels the camera has, the better.

Illustrations – Charts and diagrams drawn in Excel or Word will normally need to be redrawn for the printing process. If images are embedded in Word documents they need to be supplied as separate jpegs as well.

Preferably, articles should be sent via Email or CD. Plain ASCII text is best, but many WP formats can be imported. Contact the Editor for help if you are unsure.

All articles should be sent to the Editor in good time for the copy deadline. Articles may need to be edited to fit the constraints of publishing, with full text available on request. All articles are subject to editorial approval.

The opinions expressed within this newsletter are those of the individuals concerned and not necessarily those of their employers or of ACDM. All advertisements included with it are done so independently and the Editor reserves the right to refuse any, which, in his opinion, do not conform with ethical advertising standards.

Designed and Produced by Character Design
Tel. 01981 541154 • info@characterdesign.co.uk

NEWSLETTER DEADLINES AND PUBLICATION DATES

If you would like to submit an article to the Newsletter or include an advertisement, then the following dates will help you plan:

Issue	Copy Deadline	Publication
Autumn	19 September 2011	7 November 2011
Winter	9th December 2011	6th February 2012
Spring 2012	16th March 2012	7th May 2012

ACDM eShots

ACDM notices can be included in our twice monthly eShots sent around the 1st and 15th of each month. ACDM advertisements should be emailed to the ACDM office 6 working days in advance.

ACDM ADVERTISING

You can now advertise with the ACDM in the following ways:

- eShots are informative email communications sent to all registered members and non-members, highlighting relevent news and events from the ACDM and across the industry. Your advertisement will be included at least twice a month.
- *Data Matters* features articles on industry news and issues and ensures your advertisement will be viewed by an active audience of more than 1,200 data management professionals.
- Web Site *www.acdm.org.uk* now provides prime banner advertising space as well as the classifieds section where your advertisements cannot fail to be noticed.

Not only will your advertisement reach all ACDM members but also the wider community of data management and other professionals who access the website directly or click through from our eShot.

ACDM ADVERTISING RATES

Effective from 1st February 2010

Newsletter

Full Page Colour* £300
Half Page Colour* £200

Web Advertising (under recruitment or services)

One month* £150
Renewal per month (no changes) £100
Annual advert (up to 6 updates) £700

Website Banner advert – Home page

One month £200
Renewal per month (no changes) £100
Annual advert (up to 6 updates) £700

Website Banner advert – other pages (excluding home page)

One month £150
Renewal per month (no changes) £100
Annual advert (up to 6 updates) £700

eShot advertising

One month (eShot sent at least twice a month) £150

* bulk discounts available – please contact the ACDM office for details (Tel: +44 (0) 1727 896080, email: admin@acdm.org.uk)

Download the latest advert specification sheet from the adverts section of www.acdm.org.uk

All items, excluding membership and publications, will be subject to VAT

CONTENTS

Pushing, pulling or dare I say synchronising

I was recently having dinner with a former colleague of mine from my Brookwood Statistics Limited days. As we had not seen each other for at least ten years we were catching up on what had happened to old acquaintances as well as changes in the industry.

He, now working for an IT giant, mentioned that greater than 90% of us have an integrated Electronic Health Record (EHR) in the UK – apparently higher than the US where it all started! This figure was a surprise to me as newspaper headlines suggest that the government's NHS portal project had failed and cost the country millions of pounds.

This made me wonder when data managers will see the full benefits of EHR either by data being pulled from, pushed to or dare I say synchronised with clinical data management systems. So I did my own research on the matter and concluded that perhaps we were a long time off this vision if the following headlines are anything to go by:

- The Times ; Published: 06 July 2009: Ethics could sink Tory plan for Google or Microsoft health records
- The Times; Published: 19 March 2010: New patient medical records database 'contains life-threatening errors'

There are real practical issues to resolve – the biggest, I think being how you standardise data stored in different languages. The second is the ethical and security concerns as there is no shortage of people who get their kicks from hacking into systems.

However I do not despair, as medical records have come a long way since my childhood. Back in the day, you needed multiple hospital appointments to allow your medical records to catch up. And there were times that you did the chasing up yourself by visiting the records department in the basement several buildings from where you needed to be.

I for one will like to see many of these concerns openly debated as there are real advantages to patient safety and the wider society to have controlled access to EHR in clinical trials. The current process relies heavily on recall by investigators and patients.

Fred Daniels, ACDM Chair

JC Amos poster winners

Laurence Ghafar, Mervyn Maurimootoo, Roche

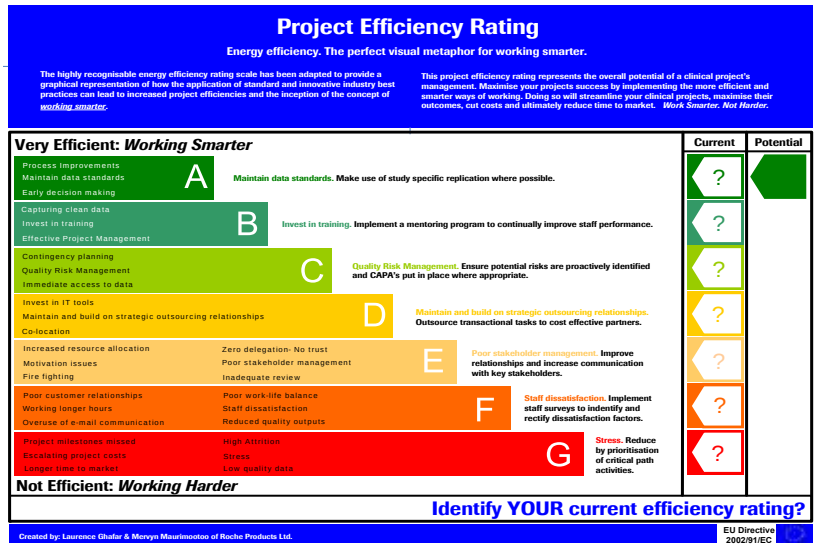
Innovation and working smarter has always been at the forefront of the Roche culture. We are actively encouraged to reach beyond boundaries and experiment, with unconventional approaches and solutions always being rewarded. The prospect of being innovative was a huge motivational factor in our decision to enter the competition.

Producing a design that reflected the concept of working smarter was a real challenge. Furthermore we wanted the design itself to be not only innovative and creative, but one that had the ability to influence, inspire and encourage others to think about working smarter.

We first translated the notion of working smarter into working more efficiently. This led to a brainstorming session culminating in our decision to utilise the popular energy efficiency rating scale as a template for the content of our final design. We believed that the use of a standard, recognisable symbol that everyone could relate to would best deliver our objectives.

The key project management principles and industry standards that lend themselves to the idea of working smarter were then embedded into the efficiency template. Together we hoped that these converged to produce a poster that was highly original in concept, instantly recognisable and most importantly provoked and encouraged individuals to think about how they can work smarter in their current role.

Winning the competition was a great personal achievement for us both. The exposure that has come from winning has meant that the poster has gained really positive feedback from our colleagues within Roche. The whole process was an enjoyable and positive experience and we would certainly recommend and promote this to anyone thinking of entering future competitions within ACDM



FDA's Guidance on Patient Reported Outcomes in Clinical Research

In December, 2009 the FDA issued its finalised Guidance on Patient Reported Outcomes (PRO) measures, capturing the FDA's current thinking on PRO data capture in clinical research. The final Guidance intended to help sponsors understand what the agency will look for when reviewing NDAs that include the collection of PRO data and included suggestions on how sponsors can best support claims in product labeling with study results measured by PRO instruments.

In this White Paper, members of invivodata's ePRO Inspection Team review our experiences in supporting and participating in ePRO regulatory inspections by the U.S. Food and Drug Administration (FDA), European Medicines Agency (EMA), specifically BfArM (German Federal Institute for Drugs and Medical Devices), and the Japanese Pharmaceutical and Medical Devices Agency (PMDA), and outline best practices for ensuring smooth regulatory inspections of ePRO data collection systems.

Follow the link below to read the full white paper:
www.invivodata.com/epro-resources

Are you interested in promoting and developing the professional status of clinical data managers worldwide?

If so the ACDM Training Committee needs you!

See page 13 for more information

Senior Forum – "You're Never Too Old To Learn"

Senior Forum
Committee

This was my first ever Senior Forum meeting, and having been in Data Management for over 21 years I was wondering what I would learn. The meeting was entitled 'Cost Effective Continuing Professional Development (CPD)', hosted by Gail Kniveton at i3. An initial presentation by Gail provided us with the framework of what CPD is, together with information on how to apply this to team members. This was followed by a presentation on the Evaluation Equation by Bob Melville, Learning and Development Consultant at PAREXEL. Bob led an insightful discussion on evaluation of training, highlighting a number of methodologies (e.g. Kirkpatrick's 4 Levels, CIRO (Context, Input, Process, Product) and Phillip's 5 Levels) and measures such as Key Performance Indicators (KPIs) to evaluate training.

After a short break we split into groups in order to discuss a Case study for Leadership CPD. Having been presented with the challenges within the organisation, we were then asked to consider alternatives for leadership training such as "3 day away training sessions" as well as more efficient and compliant training. This session allowed participants to talk about their own experiences, and share thoughts and ideas which were presented back to the whole group. Gail then provided a solution that i3 Statprobe had presented in a recent article.

The final part of the meeting was a summarisation of the afternoon's presentations, and considerations for ACDM and Senior Forum support for CPD. The networking continued after the meeting finished, with participants enjoying a meal and drink in a nearby restaurant.

So, in answer to the question, 'Did I learn anything', the answer is a resounding yes. I learnt a lot more about Continuing Professional Development, and how complex a subject it is. I also discovered ways to make it more effective and compliant for leaders and team members. And finally, I learnt how interesting and informative a Senior Forum meeting is, with a great opportunity to hear from colleagues about the way things work in their own companies.

I look forward to the next one!

Paul Fardy – 21 June 2011

ACDM 2011 Course Schedule

Autumn				
Course	**Trainer**	**Date**	**Time (GMT)**	**Location**
CDISC SHARE Project Update	tbc	Wed 7 September 2011	12:00 – 13:30	Webinar
Level One Certificate in CDM – Part 1 of 8	Cliona O'Donovan	Tues 13 September 2011 (Part 2 – 11 Oct 2011, Part 3 – 8 Nov 2011, Part 4 – 13 Dec)	12:00 – 13:30	Webinar
Therapeutic Area Training – Oncology	Jane Depledge	Wed 21 September 2011	12:00 – 13:30	Webinar
Project Management for CDM	Adam Baumgard	Tues 27 September & Wed 28 September 2011	09:30 – 16:30	Moor Hall Conference Centre, Thames Valley
Data Management for Non Data Managers	Susy Laws	Wed 5 October 2011	12:00 – 13:30	Webinar
Therapeutic Area Training – Pain	Jane Depledge	Thurs 6 October 2011	12:00 – 13:30	Webinar
CDISC for Data Managers: How to make sense of the standards revolution	Lauren Shinaberry	Wed 12 October 2011	09:30 – 16:30	Moor Hall Conference Centre, Thames Valley
Understanding the Roles of Other CR Professionals	Susy Laws	Wed 19 October 2011	09:30 – 16:30	Moor Hall Conference Centre, Thames Valley
Winter				
Course	**Trainer**	**Date**	**Time (GMT)**	**Location**
Preparing for a Regulatory Inspection from a Data Management Perspective	David Baker	Wed 16 November 2011	12:00 – 13:30	Webinar
Recent Developments in GCP & Regulations from a Data Management Perspective	Cliona O'Donovan	Tues 6 Dec 2011	12:00 – 13:30	Webinar

If you would like to attend a Webinar but are not available at the scheduled date and time then we may be able to run additional sessions – please contact us at training@acdm.org.uk to discuss. ACDM events can be booked online at www.acdm.org.uk

CALL FOR SPEAKERS

ACDM Annual Conference 2012
Whittlebury Hall, Silverstone
11-13 March 2012

The ACDM 2012 conference is to be held at Whittlebury Hall from 11-13 March 2012, near Silverstone. The theme of the conference is FUTURE FIT.

We are looking for speakers to cover how we can all ensure our careers, technologies and working strategies are fit for purpose and the future. Particularly we need fitness regimes to support the following:

- ★ **Recession proofing our business / Career planning & development**
- ★ **Inspection readiness**
- ★ **Cloud computing**
- ★ **Technology advancements / Managing Change**
- ★ **Phase IV Trials / Adaptive Trials**

REMEMBER you don't have to be a Data Manager to speak at, contribute or attend the conference!

Please let the ACDM know if there are any additional topics that you would like to speak on or hear about – they don't have to fall into the themes above.

Please submit synopsis for papers to admin@acdm.org.uk by 1st September 2011.

Debate:
We are keen to receive suggestions for the Debate at the 2012 conference. What is the most controversial topic you would like to debate with your industry colleagues? Please send suggested topics to admin@acdm.org.uk.

Team Break-Out Sessions/Hot Topic panel
We welcome receiving suggestions for the Break-Out sessions at the 2012 conference. What topics are you interested in discussing with your industry peers? Do you want to facilitate/chair a Break-Out session? Please contact us at admin@acdm.org.uk.

Handling Scan Data

A Data Management Perspective

Speaker: Alex Franklin, Principal Clinical Data Scientist, GSK
Event: ACDM Annual Conference

Alex began her talk by providing a brief background on the use of images and the current image handling process. Historically, medical imaging has driven endpoints in many therapeutic areas and radiographic images are used in approximately 70% of Oncology studies to demonstrate efficacy.

However, the current process used to manage these images and obtain appropriate review is expensive and inefficient. This process involves a large project management overhead together with four high level steps:

- Setup
- Collation
- Read
- Transfer

The presentation then provided a detailed look by focussing on issues, costs and quality associated with this process which is very close to everyone's hearts. GSK has traditionally utilised 3rd parties to conduct the above process which was seen as unsustainable due to high costs e.g. Setup costs for an imaging CRO are ~£99k/ $160k.

There are two principal reasons why study teams are required to undertake central collection:

- Regulatory requirements – Independent assessment
- Quality Assurance – Ensuring quality data acquired

As the aim is to have a central repository of quality assured and complete data, GSK examined each stage of the image handling process to seek improvements:

- Quality (scan data, eligibility, automated QC)
- Speed (electronic transfer, accessibility of data)
- Cost (read costs, removal of duplication of tasks, electronic transfers)

This resulted in GSK creating two models for scan collection and review that also offer flexibility for other studies based on protocol requirements. These are:

- Collect and Hold Model
- Hybrid Model (IRC involved)

Medical imaging is a complex area which many teams have found difficult to optimise. One of the major reasons is the lack of practical internal support to ensure trials are set-up optimally from an imaging perspective. This has resulted in the birth of the **Vesalius group**, a group of internal scientists who are available to offer advice to teams embarking on imaging work.

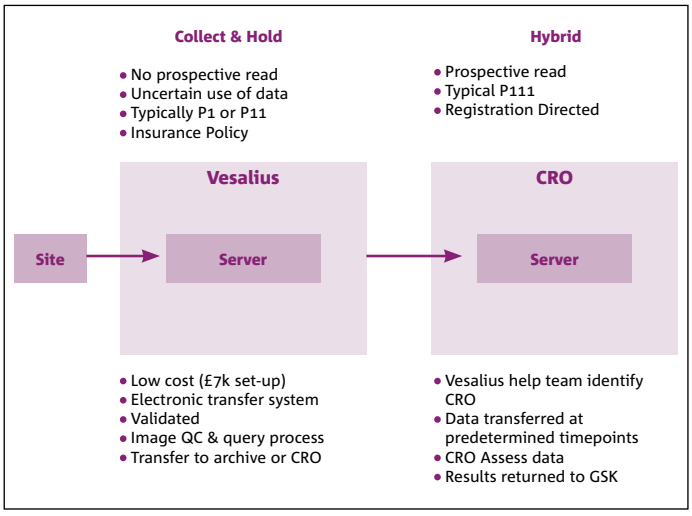
Collect and Hold Model

The collection and hold model allows scans to be archived and provides immediate availability if required at a future date.

Hybrid Model (IRC involved)

The Hybrid model allows scans to be sent to IRC company for review as and when required. The data can be archived upon read completion.

Both models can be adapted depending on protocol requirements e.g. baseline scans can be sent to the vendor to confirm eligibility status followed by subsequent scans being conducted using the collect and hold model. This would have the advantage of an automated process and electronic transmission of scans which would allow speedy confirmation of eligibility being provided to sites.



Overall Summary of benefits

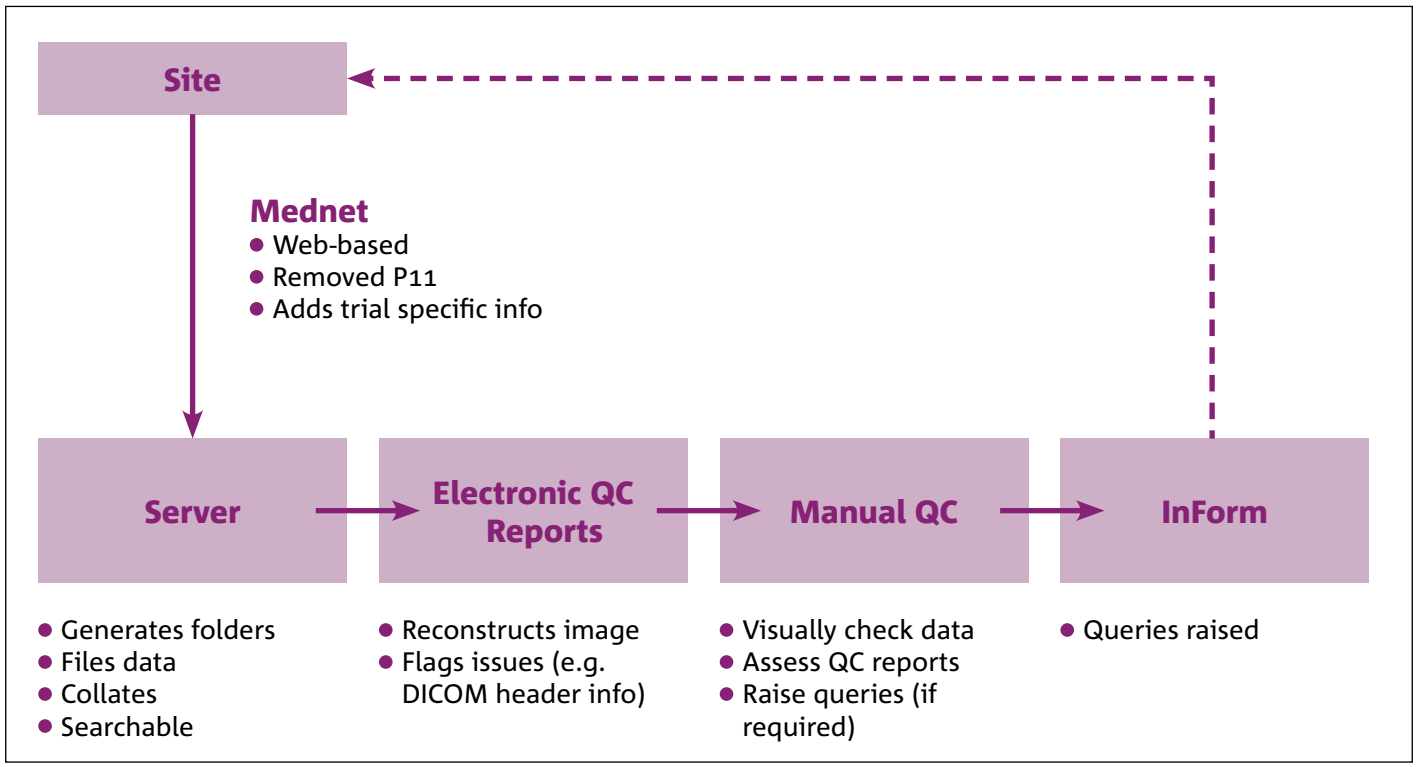
Quality
- Electronic anonymisation
- Automated QC (DICOM Headers)
- Standardised process
- Central location for queries

Speed
- Fast set-up time (approx 1 month)
- Immediate scan transfer available

QC on demand
- Last Subject Last Visit (LSLV) to Database Release (DBR) much quicker

Cost
- Removal of duplicated processes

Ease
- Easier process than previous for Study teams and sites



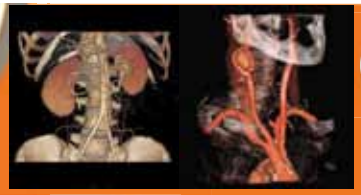
Alex also highlighted that the future of these new image processes is looking very positive as the process can be applied to other therapeutic areas where images are being used such as ECHO, MUGA, PET, MRI and Photos. Most importantly, images are readily accessible and retrievable if the regulators require information about an image

The audience found this presentation very interesting and were still talking about it the next day. In fact, the Chair mentioned the following in his closeout speech 'Had I known about the costs of handling images, I would have setup my own private image company for GSK….'

Nazma Ahmed
Principal Clinical Data Scientist, GSK

> MEDICAL IMAGING IS A COMPLEX AREA WHICH MANY TEAMS HAVE FOUND DIFFICULT TO OPTIMISE

Vesalius



Clinical Imaging = Vesalius

Success = (Speed*Quality*Service) > (Cost*Time)

Situation

Many trials use radiographic endpoints

- Where this is assessed locally by sites, open to bias and substandard acquisition quality. Critical in PoC/C2PIII where an ill informed decision can be made on poor data. Agency mandated for registration trials
- Often (especially for registration trials) an imaging CRO is contracted to manage the data centrally resulting in increased complexity and significant expense

Solution - Vesalius

The Vesalius team are GSK scientists available to help teams optimise their imaging strategy by providing the following support during protocol development and study set-up:

Scientific Consultancy - Provision of expert input concerning imaging endpoints and modalities

Operational Consultancy – Developing the optimal operational set-up to deliver quality data at low cost

Operational Solution - The study team are provided with a number of options and recommendations. We are then available to support teams during study set-up and conduct

Vesalius has been in existence for ~2 yrs and we are currently working on over 30 imaging trials (testimonials below)

Contacts: General - John Farrell
Scientific - Christopher Foley
Operations - Danielle Ledger

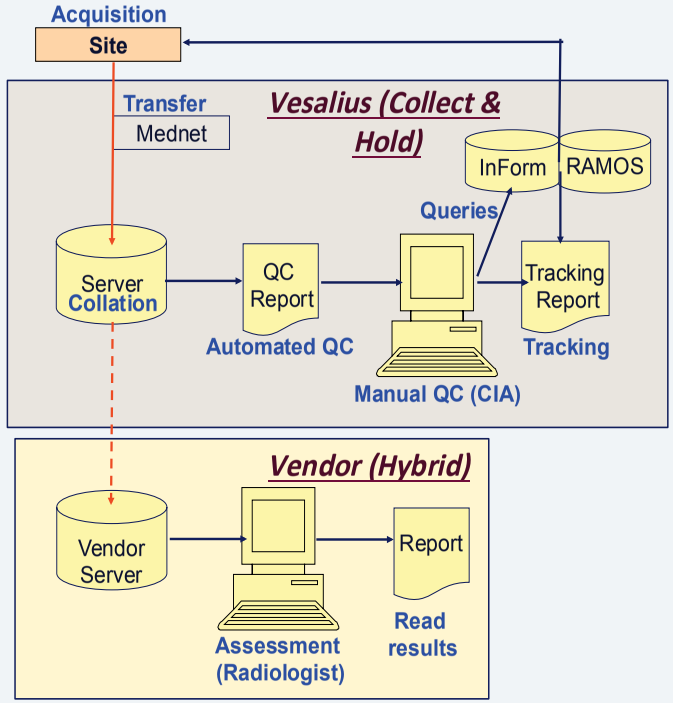
Website – Live end March (CPSE Community) Mingle- Clinical Imaging

Options for teams

- "Collect & Hold" – Low cost (~£7K set-up) providing QA and centralised collection (enables later analysis)

- "Hybrid" As above, add independent review via vendor

- Fully Outsource – Vesalius can support vendor selection and optimisation



The internal system

- Sites log into a webservice (Mednet) and transfer their data electronically into GSK
  - No requirement to install software
  - No transmittal forms*, transmittal data captured within scans electronically (*poor completion equates to 50% of queries generated by vendor systems, so we don't use them)
  - Embedded SPII (pt name) removed before data leaves site
- Data automatically loaded into server at GSK, compiled into cases
- Software runs against data. QC report generated which is reviewed by the team Clinical Imaging Associate (CIA)
- CIA raises queries in InForm (if required)
- Tracked objectively using acquisition date (Inform)
- Data held until required by team ("Collect & Hold") or pushed onto a CRO for Independent review ("Hybrid")

... it's more than saving money....

- Recent assessment. A trial using the internal system received 77% LESS imaging queries compared to an outsourced trial
- CT/MRI scans often have patient names embedded in hidden fields. Our system removes this SPII automatically
- We use electronic transfer (higher adoption than any vendor) which means data arrives immediately vs 3 days via courier
- A trial has a dedicated contact (CIA) who will coordinate all imaging aspects (set-up, QC, documents, validation, etc.)
- They can attend monitor TCs/SCM and respond to team queries immediately and access GSK internal systems
- Flexibility, a team were recently hit by an unplanned IA. We tripled resource on the trial to support the team with no additional cost to the study

QUALITY. SPEED. SERVICE.

"With regard to flexibility, resource allocation and communication, I was impressed with the organization and ability to accommodate the extremely aggressive timelines of the interim analysis.""I only have positive things to say regarding working with the GSK Internal Imaging team" "we estimated that we saved at least £3.4 M" "The Imaging team are very approachable, efficient " "Cost considerations aside, the main (and most important advantage to the study team) is with respect to communication " "I think the team's resource allocation, and particularly expertise and flexibility have been excellent in helping the PhII team meet its timelines for the interim analysis/IDMC deliverable." "available to discuss outstanding issues with the team whenever it was requested."

SIMPLIFY. EMPOWER. DELIVER.

Site eArchive Logistics

Authored by Greg Gogates, VP of Quality Management and Regulatory Affairs, CRF Health.

Introduction

Electronic clinical source data entered by Investigators and Patients are frequently stored on remote database servers. These databases are either under the control of the Sponsor or entrusted to a Trusted Third Party (TTP). CRF data is either derived from other site source data or entered into remote databases by investigational staff. PRO (Patient Reported Outcomes) data is mostly electronic using remote databases. It is important to note that this is source data that is "owned" by Investigators and must remain under Investigator control.

During the active clinical trial, they retain ownership by means of authorised access and online change control processes. Online access is shutdown once the trial is complete. To retain Investigator access to source data, XML, PDF, or paper copies of this data must be migrated to each Investigator as the "official GCP" source, ensuring that the chain of custody is not broken. The data is then considered "migrated" to the official Sponsor and Investigator(s) GCP copyholders. There is no regulatory position for the remaining TTP custodian database copy. This source data, stored at each site, becomes the legal official archive for the agreed-to retention period. This allows SDV to be performed between the Sponsor and Investigator copies as is required by regulations.

The transmittal of the eSource data, while seemingly straightforward, can be wrought with difficulties. These range from the chosen long term archive format to the logical and physical security while in transport.

Data Formats

The migrated data should be in the original context so that anyone can understand both the data points and the visit flow. The acceptable regulatory archival formats are:

Paper

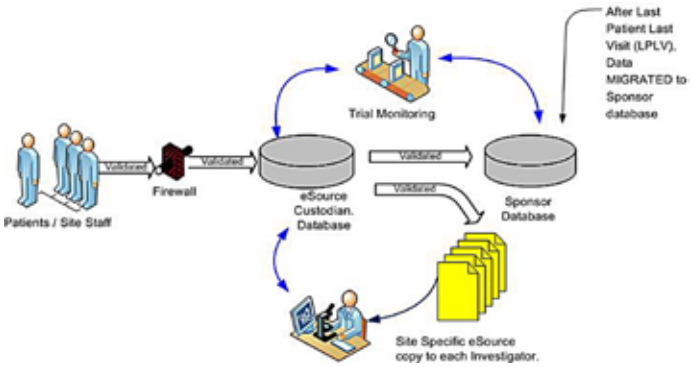
This is the incumbent format. It is a flat-file format that must be manually indexed to ensure readability. It is a straightforward process to print and courier to each location.

PDF/A

This is a NARA (National Archives and Record Administration) acceptable archival format for PDFs. It is the electronic version of flat-file paper. This format is acceptable for eCTD submissions.

TIFF

This is a NARA acceptable uncompressed image data that results in large electronic file sizes but retains all pixels. This is typically used for images. It too is flat-file and must be indexed to the appropriate visit.



XML

This is a NARA acceptable relational schema that represents each site | patient | visit. The schema maintains the relationships allowing the user to navigate to the exact data point in question. The eCTD schema accounts for XML and requires formatting in the published schema. At this point the eCTD schema does not require or support ePRO data. Requested and submitted ePRO data must be provided in PDFa format.

Media

There are various ways to transmit eSource data to both the Sponsor and Investigator(s).

On-line data transmission

This is the most efficacious but requires knowledgeable recipients. This works well for Sponsor IT departments since they understand how to exchange PKI (Public Key Infrastructure) tokens. It can also be done using encrypted attachments, sending the unlock password by separate means. This does not currently work well for Investigators as not all of them will have the resources to manage it.

CD / DVDs

This is the most common method currently used. The data is burned onto "medical grade" media which ensures long life. There is concern that CDs will shortly become obsolete.

USB or SD memory cards

These are becoming more commonplace. It is important to break the tab after recording to ensure that they are read-only.

In all media cases it is important to choose a medium that will ensure the future viability to read the information. It is also important to have a plan in place to refresh the media at

the sites in the event that the readers become unsupported or obsolete by future computing systems.

Archive Creation

The Database eSource export function must be part of the software validation process to ensure the right records are extracted for the correct site. It is important to add QC to the manual process of extraction, burning the media, and printing the labels. Independent persons should be employed to check the media and label against the content. An attestation record of who created and who checked the copy provides good objective evidence and provides a certificate of compliance (C of C) that can be included in the site package.

Media Protection

Media is nothing more than flat file or relational electronic paper. The information is recorded on read-only media to ensure that it cannot be changed. A situation could arise where someone could copy, change and re-record the material onto new media but this can be averted by creating a hash of the file contents. It will produce a code that will only match the exact contents. If changed, the hash algorithm can be re-run and the codes will not match! These hash values could be provided to both GCP copyholders to check at a later date. Other methods such as custom labelled media thwarts counterfeit data.

Physical Security in Transport

Paper and CD / DVDs should be shipped via courier. Some concerns have been given to the ability to modify eSource if not encrypted. Remember this is no different than paper which is not encrypted and could be modified with a copy machine. It is not recommended to encrypt because there is no way to ensure the recipient maintains the de-encryption keys or that the decryption tools will run on future computer operating systems.

Loss During Transport

Loss of eSource clinical data is no different than losing paper records. No privacy information is typically included in the dataset. Only site / subject IDs and visit data. Once lost, that specific copy can be noted as null and void in the study records. The original holder can then make a copy that is re-sent along with a note of the lost item.

Inability to Deliver

Sometimes the Investigator source data cannot be delivered due to unforeseen circumstances.

Death, Move, Default, just gone! This is not dealt with well within the regulations. The only recourse is to denote the inability along with justification. The sponsor then maintains the copy.

Archive Package Contents

Each archive package should contain:

- The archive media with all of the data.
- A description on how to view it.
- A system description of how the data was collected.
- An introductory letter stating that the data was held secure during the active trial period and was collected on a computing environment that met all predicate regulations.
- A copy of the archive creation attestation.
- A return – receipt return form indicating site acceptance of the archive media. This can be faxed or mailed back to the sponsor.

Acceptance by Sites

The site now has all of the needed information to maintain the trial source data. The courier delivery logs are proof that the packages were received but not that the Investigators can both read and understand the content. To ensure that the sites agree and acknowledge, include some form of return-receipt or fax-back form. These receipt forms should be kept with Sponsor study records.

Third Party Storage

Sites sometimes cannot be entrusted to maintain their source data copies. This tempts Sponsors to maintain them on the site's behalf but this will render a loss in the Investigator custody! The use of HASH algorithms remedies that thought, as long as the HASH values are stored outside of Sponsor domains.

Summary

- Export the data onto long term media.
- QC the exported material.
- Include full set of information to the Investigator.
- Do not lose the custody of the Investigator role.
- Assure site acceptance of the archive.

> **"THE TRANSMITTAL OF THE ESOURCE DATA, WHILE SEEMINGLY STRAIGHTFORWARD, CAN BE WROUGHT WITH DIFFICULTIES. THESE RANGE FROM THE CHOSEN LONG TERM ARCHIVE FORMAT TO THE LOGICAL AND PHYSICAL SECURITY WHILE IN TRANSPORT.**

Are you interested in promoting and developing the professional status of clinical data managers worldwide?
If so the ACDM Training Committee needs you!

The purpose of the Training Committee is to develop and execute a data management focussed training strategy that meets the changing needs of the ACDM membership.

To do this effectively we need more committed people like you who are ACDM members and understand the professional development needs of data managers to join us. If you are able to commit a minimum of 10 hours per month to committee activities such as identifying new training offerings, and trainers; reviewing training materials and undertaking marketing activities we would love to hear from you.

As well as working hard to ensure the Training Committee meet their goals and actions being a member of an ACDM committee provides you with a fantastic opportunity to work with industry colleagues and to develop new relationships.

To learn more or to volunteer your time contact the Training Committee at training@acdm.org.uk

RTI(h)(s)™ RTI HEALTH SOLUTIONS®

Job Opportunities

www.rtihs.org

Data Management Director – Manchester, UK

Responsibilities

General Data Management Responsibilities:

- Works collaboratively with colleagues and takes a technical lead to develop, evaluate, validate, implement, and maintain data collection systems and technology (either internally developed or subcontracted)
- Coordinates the evaluation and selection as well as oversees the performance of subcontractors providing data collection and management support
- Develops and maintains data management policies, guidelines and procedures (SOPs, training manuals, etc) and complies with standard operating procedures (SOPs)

Project Specific:

- Works with project teams to design CRFs and eCRFs for data acquisition and data entry
- Develops and maintains auditable data management project documentation (e.g., DMP, Quality Plan, annotated CRFs, Data Entry Conventions)
- Develops test cases and performs user acceptance testing of data capture and management systems
- Ensures database accuracy according to departmental operating procedures
- Performs a QC review of the data and coordinates corrections to the database with the study sites
- Performs independent reviews of data management deliverables following documented guidelines

Qualifications

Education and Experience:

- Master's or Bachelor's degree in health information management, clinical, biological, or mathematical sciences or related field
- 8 years of data management experience in a professional environment, preferably within a clinical or medical data environment or pharmaceutical company
- Direct experience working across European countries
- Experience managing multiple simultaneous projects
- Knowledge of FDA and EU/EMA regulations with respect to data quality and data privacy for the conduct of observational studies in the US and Europe. Thorough knowledge of the relevant ICH and GCP guidelines

Knowledge, Skills, and Abilities:

- Substantial working knowledge of multiple clinical data management systems and electronic data capture systems (e.g., InForm, Medidata Rave)
- Ability to effectively apply knowledge and skills in a highly organised fashion while adhering to regulatory guidelines, SOPs, and client expectations
- Good written and verbal communication skills in English
- Ability to speak additional European languages (desired)
- Must be able to set and meet timelines or be able to recognise and schedule changes in response to project demands
- Ability to maintain a high degree of confidentiality with study data and client's proprietary information

International Study Director – Manchester, UK

Responsibilities

General Management Responsibilities:

- Ensures consistent use across projects of study tools and training materials and compliance with standard processes, policies, and procedures
- Coordinates the evaluation and selection as well as oversees the performance of subcontractors providing data collection and management support
- Works closely with data management functions to develop and maintain data collection and management policies, guidelines, and procedures (SOPs, training manuals, etc.)
- Represents European data collection operations in cross-functional meetings

Project Specific:

- Manages and co-ordinate efforts of cross-functional project teams to support milestone achievement and to manage study issues and obstacles
- In collaboration with technical teams, leads the development of proposals and budgets for the design and implementation of observational studies in Europe
- Advises study teams and participates in study design and protocol development activities:
  - Performs tasks related to protocol management from study startup to database lock for both paper-based and EDC studies and those managed internally as well as those contracted to vendors

Qualifications

Education and Experience:

- Bachelor's degree in a life sciences, nursing, or a health-related discipline required; Master's degree preferred
- 8-10 years experience managing and 4-5 years leadership experience in multi-national clinical and/or observational study operations at an outcomes research consulting, CRO, or pharmaceutical company
- Working knowledge and understanding of applicable European and country-specific regulations
- Experience with clinical or observational study document preparation for protocols, consent forms, and ethics committees
- Working knowledge of multiple EDC systems and ability to train sites on protocols and proper use and technique of various systems
- Knowledge of FDA and EU/EMA regulations with respect to data quality and data privacy for the conduct of OS and clinical trials in the US and Europe. Thorough knowledge of the relevant ICH and GCP guidelines

Knowledge, Skills and Abilities:

- Good written and verbal communication skills in English
- Ability to speak additional European languages (desired)
- Must be able to set and meet timelines or be able to recognise and schedule changes in response to project demands

Equal Employment Opportunity

Salary commensurate with experience and excellent benefits package provided

Application Process

To apply to this position, go to **www.rti.org/careers** and apply on line for position number 13481 or 13483 or contact the following:

Janet Bullock
jbullock@rti.org
1-919-485-5572

Kelly Hollis
khollis@rti.org
1-919-541-5842

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LEADING RESEARCH...
MEASURES THAT COUNT

SEPTEMBER

7
ACDM Webinar
CDISC SHARE Project Update
Webinar

11-14
SCDM
2011 Annual Conference
Marriott Baltimore Waterfront, Baltimore, US

13
ACDM Webinars
Level One Certificate in CDM – Part 1 of 8
Webinar

21
ACDM Webinar
Therapeutic Area Training – Oncology
Webinar

27-28
ACDM Training Course
Project Management for CDM
CIM, Cookham

27-30
BARQA
2011 Annual Conference
Marriott Royal Hotel, Bristol, UK

OCTOBER

5
ACDM Webinar
Data Management for Non Data Managers
Webinar

6
ACDM Webinar
Therapeutic Area Training – Pain
Webinar

OCTOBER

11
ACDM Webinar
Level One Certificate in CDM – Part 2 of 8
Webinar

9-15
CDSIC
CDISC Interchange North America 2011
Renaissance Harborplace Hotel, 202 Pratt Street, Baltimore, MD 21202

12
DIA
5th Annual Clinical Forum
Congress Center Basel, Messeplatz 21, 4058 Basel, Switzerland

12
ACDM Training Course
CDISC for Data Managers: How to make sense of the standards revolution
CIM, Cookham

13-14
TOPRA
The 8th Annual TOPRA Symposium
Rome, Italy

19
ACDM Training Course
Understanding the Roles of Other CR Professionals
CIM, Cookham

26-28
ISoP
11th Annual Meeting
Harbiye Military Museum, Istanbul, Turkey

NOVEMBER

8
ACDM Webinar
Level One Certificate in CDM - Part 3 of 8
Webinar

16
ACDM Webinar
Preparing for a Regulatory Inspection
Webinar

DECEMBER

6
ACDM Webinar
Recent Developments in GCP & Regulations From a Data Management Perspective
Webinar

13
ACDM Webinar
Level One Certificate in CDM - Part 4 of 8
Webinar

JUNE 2012

24-28
DIA
48th Annual Meeting
Pennsylvania Convention Centre, 1101 Arch Street, Philadelphia, PA 19107

OCTOBER 2012

21-26
CDISC
CDISC Interchange North America 2012
Renaissance Harborplace Hotel, 202 Pratt Street, Baltimore, MD 21202

ACDM events can be booked online at www.acdm.org.uk

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Email: admin@acdm.org.uk

ACDM membership can be applied for via the internet at www.acdm.org.uk, or call the ACDM Office for an application form.

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For BARQA events: **www.barqa.com**
For CDISC events see: **www.cdisc.org**
For CR-CSV events: **www.cr-csv.org**
For DIA events: **www.diahome.org**
For eClinical Forum events: **www.eclinicalforum.com**
For ICR events: **www.instituteofclinicalresearch.org**
For ISoP events: **www.isoponline.org**
For MHRA events: **www.mhra.gov.uk**
For PSI events: **www.psiweb.org**
For SCDM events: **www.scdm.org**
For TOPRA events: **www.topra.org**

acdm
association for clinical data management

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