

USEFUL WEBSITES TO HELP YOU IN YOUR DAILY ROLES...

ABPI website www.abpi.org.uk/default.asp. A good place to find things like the CT agreement standard, and EU templates for two way and tripartite CT agreements.

Timezones converter www.timezoneconverter.com. Really helpful when working on international studies, arranging TCs, or contacting local CRAs and Project Managers.

Translations, free, quick phrase translations from www.babelfish.yahoo.com. Invaluable when working on EU/international studies.

Contact databases, there are many of these but the most useful for the UK are:

• **R&D Forum** – www.rdforum.nhs.uk which has a list of all the R&D addresses & contact details as well as guidelines for the IRAS applications.

• **The website for the Ethics Committees** – www.nres.npsa.nhs.uk/, another useful resource.

The Voice does not claim responsibility or ownership for the content on any of these websites. Individuals should make their own decision as to whether to use them.

Common Clinical Definitions

The clinical research industry is very precise about the meaning of key words. Here are some definitions to help you through the terminology maze ...

Investigator	The person responsible for the conduct of a clinical study at the study site. If the study is conducted by a team of individuals at the study site, the investigator is the responsible leader of the team and may be called the principal investigator. For more information refer to ICH E6 1.34.
Essential Documentation	The term used to describe documents which either individually or collectively permit evaluation/assessment of the conduct of a clinical trial and the quality of the results/data produced.
ICH	The abbreviation used for the International Conference on Harmonisation of Technical Requirements for the Registration of Pharmaceuticals for Human Use.
Monitor	The term used to describe a person who has been trained to oversee (monitor) the progress of a clinical trial and to ensure that the clinical trial is conducted in accordance with the protocol, standard operating procedures, GCP and applicable regulatory requirements. The monitor is also known as the Clinical Research Associate (CRA), or the Clinical Research Scientist.
Quality Assurance (QA)	All those planned and systematic actions that are established to ensure that the trial is performed and the data are generated, documented, recorded and reported in compliance with GCP and the applicable regulatory requirements.



PERSONAL PROFILE ETHICS COMMITTEE ADVISOR, BY NICOLA RAND

What does your current role involve?

As Ethics Committee Advisor my role is to support the medical department with submissions to the REC (Research Ethics Committee) and R&Ds/PCTs for all studies.

Initial study applications to the RECs and the submission of any safety updates have very strict timelines. As soon as I know a new study is coming and all the documentation is complete, I need to book it in with the relevant REC and send the full application within four days for it to be reviewed at the next REC meeting for approval. Working closely with the project manager, the medical advisors, CTAs and the internal chief investigators is essential in order to meet these strict timelines.

How did you get into this role, what were you doing before?

I began working for my current client as a CTA with the intention of moving into a CRA role when the time was right. I saw the Ethics Advisor position and thought it would be a good move in order to learn more about other aspects of clinical studies.

How do you view the regulation changes?

The IRAS process is still new and everyone is learning as they go. Once it becomes more familiar it should definitely improve the

ethics application and submission process and in particular it should decrease timelines for approvals. Anything we can do to support R&D departments and improve study timelines to get FPFV in quicker will help the industry to keep studies within the UK.

What do you enjoy about the role?

This is a great role because it is so varied, challenging and interesting. There is a big learning curve in trying to understand how it all works, keeping on top of the current process while everything in the R&D area is changing as well.

Tips for people doing ethics submissions?

The NRES (National Research Ethics Service) is a fantastic resource. They provide you with regular updates on process changes and are good at answering questions. It is also worth developing a communication link with the REC coordinators, making sure they have what they need. As part of my training a member of the NIHR (National Institute for Health Research) visited our office to explain the changes.

Last but not least keep a regular eye on the websites, they are a valuable resource for the most up to date information. Good sites are: www.rdforum.nhs.uk; www.nihr.ac.uk; www.nres.npsa.nhs.uk.

theVoice

for clinical trial administrators everywhere

Issue 7 Spring 2010

EDITOR'S NOTE

Welcome to Issue 7 of The Voice. There has been a slight delay in finishing this issue of The Voice but you can be reassured The Voice is still around!



A topic that won't be far from your mind is training. While there is always a need to update and develop new skills and knowledge, which method do you choose, that is both cost effective and delivers the right result? In this issue of The Voice, we look at some different types of training and pose the question, do they work.

In this climate of doing what we can to get drugs to market in ever shorter timescales, we look at the IRAS system and the CSP system that are used for gaining NHS permission to conduct clinical research studies; and how they could shorten approval timelines.

We hope you enjoy reading this issue of The Voice, and if you have a topic you would like to hear more about, or you would like to get involved, then contact us at thevoice@phlexglobal.com.

Facilitation and administration of The Voice is by Phlexglobal Ltd on behalf of the CTA community. The Voice is produced bi-annually and distributed to secretaries, administrators and clinical trial administrators working in clinical research.

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IRAS – what does it all mean? Integrated Research Application System

IRAS is a single, integrated research application that has been designed to capture information that needs to be submitted by researchers to obtain the relevant permissions and approvals to enable them to conduct health and social care research in the UK.

A key aspect of the new system is that you only need to enter the data once, as all the required applications are filtered automatically from the initial data set and all fields that need to be completed are populated as this information cross-populates. No more time spent completing different forms from several different websites and having to keep track of them all.

When the application process is complete, the researcher will open the relevant tab to display

the completed application before printing it off and submitting to the appropriate department.

Further information, on-line help and guidance to support users through all stages of the application process can be found on www.myresearchproject.org.uk. The website has a useful Update section for recent news, for example information regarding an update to improve the options for importing data from EudraCT into IRAS for clinical trials of IMPs.

Clinical Research in the NHS

Clinical Trial Administrators (CTAs) in the pharmaceutical, biotech and medical device sectors have always been aware of the regulations governing clinical trials within the commercial sector. Over recent years, the management and running of clinical studies within the NHS has had to become more structured and in line with regulations.

UK CLINICAL RESEARCH NETWORK Comprises 4 CRNs

NIHR Clinical Research Network Coordinate and manage NHS clinical studies run by 25 Clinical Local Research Networks (CLRN) across the UK	Scottish Clinical Research Networks
CRC Cymru	Northern Ireland Clinical Research Network

The NHS is an enormous entity with large numbers of clinical studies being run across England. In order to manage the sheer volume of studies, the UK Clinical Research Network Coordinating Centre, now called the National Institute for Health Research Clinical Research Network Coordinating Centre (NIHR CRN CC), has been created.

Across the UK there are four Clinical Research Networks (CRNs) working together as the UK CRN with a primary role to deliver high quality clinical research studies. The role of the NIHR CRN CC is to support clinical research and help facilitate the conduct of trials and other well-designed studies within the NHS.

In the same way the commercial sector is continually looking for ways to reduce the time taken to get a drug to market, the NHS is also looking at ways of streamlining procedures. Reducing the time it takes a research project to be ready to recruit patients into the study is key in bringing new treatments to the NHS.

Within the clinical research industry, maintaining patient safety is paramount. Before any studies can take place either in the commercial and non-commercial (NHS, and academia) environments, approval needs to be obtained. For pharmaceutical or biotech led studies this is done by submitting Ethics Committee submissions and other relevant applications through the Integrated Research Application System (IRAS). For the NHS, there is a new Coordinated System for gaining NHS Permission (CSP) which is also linked to the IRAS system.

The CSP is a single system to standardise and streamline the process for reviewing applications and gaining NHS permission for clinical research studies in England. Within the CSP there is a consistent and comprehensive set of NHS research governance checks for all new studies. The goal being to streamline and rationalise processes resulting in a reduction in NHS R&D approval times. For further information, please look at www.ukcrn.org.uk.

THERAPY AREA

Neurosciences, By Martina Whawell

The Neurosciences therapy area covers a wide range of different conditions, falling into two main categories, Neurology and Psychiatry. Neurology covers conditions which have a definable physical cause relating to the brain and/or nervous system. Psychiatry covers any form of mental illness which cannot be attributed to a physical cause.

A major focus across the industry in Neurosciences at present is Alzheimers, a condition that causes a gradual degeneration of the structure of the brain, causing the cells to die. It is a progressive disease and the effects are irreversible, at present the only treatments available just slow down the degeneration. Pharmaceutical companies are working to find the breakthrough treatment that can actually prevent progression of the disease altogether.

Due to the complexity of many of the conditions that fall within the Neurosciences therapy area, the studies can often be quite large in terms of number of centres and recruitment targets. A CTA working in this therapy area needs to be extremely organised, keeping on top of several sites and dealing with large amounts of documentation. The types of studies can vary greatly from mental illnesses where all of the assessments are based on questionnaires, to physical conditions involving various physical assessments. Some will involve a lot of paperwork being sent to site, with large CRFs including multiple questionnaire assessments; others will involve equipment such as ECG

machines. The CTA therefore needs to be flexible and able to adapt to a variety of studies with very different models.

Like any therapy area, it is useful if the CTA has an understanding of the conditions and treatments that fall within Neurosciences. However, as it covers such a wide range of conditions, a CTA cannot be expected to develop detailed knowledge in all of these areas. Some companies may choose to assign a CTA to focus on a particular condition and enhance their knowledge in that specific area. Other CTAs may be expected to work across a large variety of studies where a basic but broad knowledge of the different conditions will be more beneficial. Further information about this therapy area is available from www.sfn.org.

KEY TERMS WITHIN NEUROSCIENCES:

Neurological conditions:

- **Parkinson's Disease** – nerve cells in the brain are lost, affecting movement in the body
- **Epilepsy** – recurrent seizures caused by a sudden burst of electrical activity in the brain
- **Multiple Sclerosis** – the substance surrounding the nerve fibres throughout the central nervous system becomes damaged, affecting the transfer of messages from the brain to the rest of the body

Psychiatric conditions:

- **Various forms of depression including Seasonal Affective Disorder and Social Anxiety Disorder**
- **Bi-polar Disorder (or manic depression)** – severe mood swings ranging from extreme happiness to intense depression
- **Schizophrenia** – psychotic episodes involving hallucinations and delusional thoughts

AUDIT AND INSPECTION – THE SAME OR DIFFERENT?

An Audit is a systematic and independent examination of trial related activities and documents. The objective of the exercise is to determine whether the evaluated trial related activities were conducted and the data recorded, analysed and accurately reported according to the protocol, sponsor's standard operating procedures (SOPs), Good Clinical Practice, and the applicable regulatory requirements. (ICH 1.6)

An Inspection is the act by a Competent Authority of conducting an official review of documents, facilities, records, quality assurance arrangements and any other resources that are deemed by the Competent Authority to be related to the clinical trial and that may be located at the site of the trial at the sponsor's and/or contract research organisation's facilities or at other establishments which the Competent Authority sees fit to inspect. (EU Directive 2(l) & ICH 1.29)

The primary aim of an inspection is to establish whether those involved in the conduct of clinical trials have adequate quality systems in place which are effective, complied with, continually improved and compliant with GCP and the law.

For anyone who has been through or is about to go through an inspection, it can be quite a daunting prospect. The key to remember is that inspections take place to make sure that subject welfare is maintained. Everyone working in this industry is expected to follow the regulations, be compliant and the inspections help to point out to companies where they may be falling down and where they could improve.

If you are due to be interviewed, here are a few top tips. Think before you answer and keep your answers clear, brief and accurate. Listen to the inspector and ask for clarification if you don't understand the question. Above all, be professional, be prepared and remember to stay calm!

The Training Challenge which method?

We all attend training to develop our abilities and knowledge in a particular skill or subject area. In this climate of constant change, evolving regulatory guidelines, modified management structures and reformation within health services; it is crucial that clinical research and healthcare professionals are kept up to date within the field (i.e. knowledge) and are adequately trained to work effectively (i.e. with skills).

The role of the CTA in particular involves a significant amount of training. Not just one-off training, but regular updates to maintain knowledge levels. The pace of change in the clinical research industry means that it is never too long before you need to attend the next training course.

But with so many different types of training courses available, how do you choose which one will suit you best and meet your needs? The traditional approach has been classroom based, with a teacher imparting knowledge, information and skills to students sitting at

their desks. However technology advances means that methods have changed considerably so that now it is possible to update or obtain new skills or knowledge from the comfort of your own home.

Web Based Training vs LMS Training, Tina Rickard

I participated in a **web based training course** which took place over three mornings using net meeting. We were sent the presentations beforehand so we could make notes or if there was a problem with the net meeting we could still follow the slide show.

The training course was for a large number of CTAs spread across six countries. The content of the training was excellent but it was hard work looking at the screen, concentrating on the slide show. Also, when the trainer asked a question you couldn't be spontaneous as you had to key #6 before you could reply. I missed the participation and interaction you get with the other delegates and the trainer.

I prefer the **on-line LMS (Learning Management System)**, which is really easy to use. You register for the training when it suits you and notification is sent when training has been allocated. There is a time period to complete the course and reminders are sent when the deadline is approaching.

The LMS system can be used either in the traditional read and sign option, with a set of questions at the end of the course requiring a pass mark. Alternatively there are module systems, where the student needs to pass each module before completing the next one.

A CLOSE RELATIONSHIP

CTAs and CRAs, By Martina Whawell

Historically, Clinical Research Associates (CRAs) were expected to conduct all of the administrative tasks associated with maintaining a site throughout a clinical study. This was in addition to their primary role of monitoring the study to ensure ICH GCP standards are being adhered to. However increasing workloads and the increased emphasis on quality of data within the industry, put too much pressure on the CRA.

The role of the Clinical Trial Administrator (CTA) emerged to support the CRA and take responsibility for many administrative and logistical tasks including: checking, tracking and filing documents; preparing documents such as financial disclosures for the CRA

to take to site; setting up Investigator Site Files and Pharmacy files; sending study materials to site.

The CTA now plays a crucial role in the study team, and must have very good communication channels with the CRA to ensure that each understands the other's requirements. In a good partnership the CTA will already know the dates of their CRA's site visits and will be prepared with the relevant documentation for them to take to that particular site.

During study start-up and close-out the CTA and CRA will work closest together, due to the amount of documentation being generated and the critical timelines being worked to. They will also work particularly close together leading up to and during an audit when the CRA will often become involved in some of the CTA tasks, such as QC of the TMF. The CRA will rely on the experience and knowledge of the CTA to ensure the documentation is up to standard.

While there are fantastic prospects for a long-term career as a CTA, there is also the opportunity to progress into a CRA role if desired. The knowledge and experience gained as a CTA provides a strong basis for moving on to the CRA role. In some companies, it may be possible for a CTA to accompany a CRA on site visits in order to assist with QC of the Investigator Site Files. A CTA who understands the challenges and skills required to be a good CTA and how to work with a CRA will have a distinct advantage in working effectively as a CRA should they wish to follow that career path.

