Clinical Trials

The Handbook

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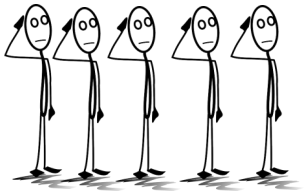
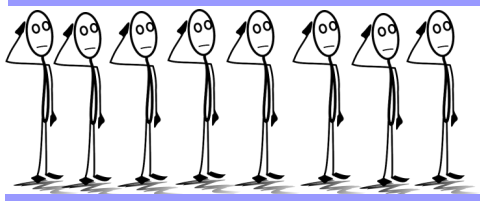
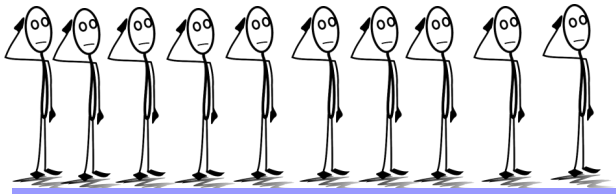
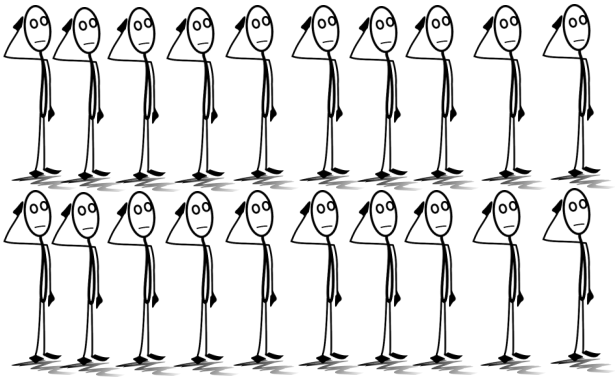
Clinical Trials or Clinical Research?

From our understanding, the difference between a clinical trial and clinical research is very minute. Simply put, a clinical trial is part of clinical research. The objective of clinical research is to test the effectiveness of medication, treatment and other diagnostic tools and a clinical trial is a means of achieving the goals and aims of clinical research. For example, a researcher or professors clinical research may be in tropical medicine and the clinical trial might entail the testing of a particular vaccination for a tropical disease. A clinical trial works in various phrases depending on how subjects respond to the medication being administered. Usually a clinical trial consists of five stages from phase 0 to phase 4. Additionally, much preclinical studies take place before the main trial. A brief overview:

Phase 0	Description
	These are the first human trials to gather preliminary data on what the drug does to the body and what the body does to the drug. Sub therapeutic levels of the drug is given i.e. a dose less than what is required to have a therapeutic effect.

Phase 1	Description
	The treatment is tested in a small group of people (roughly 20 but can go up to 80) to evaluate its safety in terms of optimum dosage range and side effects.

Phase 2	Description
	The treatment is tested on a larger group of people to further evaluate its safety and so forth..

Phase 3	Description
	The treatment is tested on even larger groups of people to establish effectiveness, side effects and essentially double check.

Phase 4	Description
 	Post marketing surveillance to monitor the safety of the treatment once released to the market.

Both clinical research and clinical trials involve mass amounts of data collection and data is extremely sensitive and personal therefore has to be handled with care. A quick glance at some of the forms required:

⇒ CRF forms: Case (or clinical) report forms collect participant data and results of each phase of clinical trials.

⇒ Consent Forms for participants.

⇒ PRF forms: Patient report forms collecting general patient data.

⇒ Ethics forms.

⇒ Various documents, depending on the type of research.

Having excessive amounts of paper to deal with and the manual processing of it can make one feel a little overwhelmed and can also cause delays in research, errors in data collection, inaccurate data and these delays adversely impact data analysis and reporting.

How it can feel trying to deal with all the paperwork

Fortunately, there is a way out of this. The Liverpool School of Tropical Medicine perform large amounts of clinical research in studying tropical diseases. Their then latest project was running two networks in Malawi to process multiple users across the two sites, however, this was proving to be difficult. Their primary pain point was getting the data from paper forms and documents onto their database. The current method was very time consuming as they utilised double data entry, meaning it is typed twice with a third person managing discrepancy in the two entries.

DCC installed and trained staff in the system which was to be implemented for this project and everything ran smoothly, much to their delight. An ethos DCC apply when collaborating with clients is to understand the nature of their project as this allows us to dip into our toolkit and give them exactly what they need rather than a 'generalised, out of the box solution', which in turn leaves our customers happy and satisfied. Liverpool School of Tropical Medicine are a testimony to that, the following is taken from the feedback given to us (names of individuals and software has been taken out):

'DCC has a really good knowledge of how the system works, both from a frontend perspective and in terms of backend shortcuts. We were able to trial a number of different possible solutions until we got to the correct one, whereas if we didn't have DCC there it may have taken us a lot longer to get to the solutions we need.'

'Normally, if an issue can't be found in the knowledge base then you could be stuck for a couple of days before someone comes back with a solution. We can consult the knowledge base ourselves and exploit that resource, but DCC's knowledge and understanding of how software works is a far more valuable, useful service.'

Ending with: '*Ultimately, though, we'd definitely recommend DCC's services to other companies in the clinical research and healthcare sectors.'*

Understanding the nature of the data

DCC have a firm understanding of the nature of clinical research and clinical trial data. For example, we know that the clinical/case report form is no ordinary form, they can be between 30-100 pages long, need the to be completed using a specific method, hence are complemented with detailed instructions that need to be followed, moreover, a patient is handing over sensitive data which must be accurate and the appropriate sections also need to be completed. Universities may possess a CRF template that a team of researchers use as part of their trials. Of course, depending on the type of research, questions or sections in the CRF that are not required will be removed. It is also possible that personnel who are to complete the CRF's receive training in doing so before the trial begins as there is method to recording data accurately as well as developing an understanding on how to deal with corrections. The high emphasis placed on completing the CRF's properly displays the importance of it. Generally a CRF will contain the following pieces of information:

⇒ Inclusion/exclusion criteria

⇒Eligibility review

⇒Baseline data and demographic information

⇒Trial specific data

⇒Trial medication administration

⇒Trial assessment

⇒Study completion

⇒Concomitant medications table

⇒Adverse events

⇒Principle investigators sign off

These CRF's are more difficult than I thought!

On a trial by trial basis, the sections/information may differ, however, this covers broadly the make up of a CRF. Now, lets take closer look at some of the questions to explain the importance of accuracy. Starting with the more basic information/questions such as date, initials, screening number, sponsor number and other demographic and personal details, will be required to be in a certain format or are compulsory, additionally some may require a single or multi-response. Furthermore, CRF etiquette will need to be adhered to such as using the correct abbreviations and units of measurement. There is also a method to depict missing data, how to correct data and how to state on the CRF that information given is only partially known. Delving into the core of CRF, case specific questions will also demand adherence to guidelines on completion and recording data. Although, all this information is usually detailed on the instruction page, there is always the possibility of forgetfulness or human error that result in instructions not being followed at the stage of recording the data onto the CRF's and the manual input of data into a database. Data automation and the use of business rules and validations can address these problems. Firstly, data automation is the process of scanning each CRF and, via a specialist data capture software, extracting the relevant data and exporting the data directly to a database. Data automation thus brings many time saving benefits as time is not spent manually inputting mass amounts of data from CRF's. Secondly, an instruction page can only help produce accurately completed CRF's to an extent. The use of business rules and validations can further ensure formatting demands are met. At the design stage of a CRF, the specialist data capture software builds in these rules and validations. For example, you may want the date and time in a specific format or certain other trial specific information or measurements to be depicted in a certain way or even a way of validating a patient/subject number, sponsor number or other patient/trial details, business rules and validations ensure the format you want are enforced. The business rules and validations come into effect whilst the CRF's are being scanned and prepared for automation. Throughout data extraction any break in a rule of validation will be flagged and thus be correcting or be placed under exceptions handling.

Contact us and arrange your free onsite assessment. The purpose of the assessment is to help, advise and guide you on how data capture technologies can assist your clinical research specifically and the benefits reaped as a result.