My experience while involved in a clinical trial study

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Being part of a clinical trial team was certainly one of my goals in life, so when my application and interview were successful, my dream came true.

The particular clinical trial study was sponsored and driven by an international entity. The Clinical Research Site already existed and the team comprised of medical practitioners, nurses and technical support members. The pharmacists who joined this team contributed significantly to and added enormous value to the study.

One of the prerequisites for this study was that there had to be a Pharmacist of Record (PoR)/Responsible Pharmacist and an Associate Pharmacist running the pharmacy. My role as the PoR was very stimulating and contributed to my experience in a new field.

The list of suggestions and tips below certainly worked for me and could make a valuable contribution to you as well.

- Before commencing a clinical trial study, attend a basic Good Clinical Practice (GCP) course. This will aid in giving insight into how a clinical trial is set up to run effectively. Also, attend and participate in as many sponsor(s)-driven training session(s) as you can.
- During these training sessions, you will be collaborating with other Clinical Research Sites. Take their contact details and create a WhatsApp group for the pharmacists which can serve as a network platform for asking advice and raising questions. Establish contact via email as well.
- Ensure that you know and fully understand your role in the study. Be prepared and willing to explain your role to others.
- If there are e-training modules that you can complete, do so and print and file your certificate of completion for quality assurance purposes and for your portfolio of evidence for continued professional development (CPD). Remember to log onto the South African Pharmacy Council’s website and update your details.
- The pharmacy must be of a good standard for the clinical trial. Standard Operating Procedures (SOPs) must be written – you can make use of your contacts established at other sites for guidance. Adapt these SOPs so that they are tailor made for your Clinical Research Site. Make sure that all your SOPs are date and version controlled and that you have all copies filed, i.e. current and superseded versions.
- Ensure that all study documentation is in order. Deal with all minor matters first and then look at the broader context.
- Create a telephone/e-mail contact list of everyone involved in the study. Paste it onto the wall near your telephone and computer for ease of reference. Also, have a list of names to contact in an emergency, e.g. when there are electricity cuts or who you will need to contact on an after-hour/weekend basis. These should be on your mobile phone as well. This will ensure that you have access to relevant telephone numbers when you are not on site.
- Benchmark with other sites what equipment is required. Make use of trusted suppliers only. Ensure that your equipment meets required standards and complies with all the requirements of the international entity.
- Draw up an inventory log of all the equipment in the pharmacy, making note of serial numbers, date, time and place of purchase and servicing intervals. Paste this at eye level onto the wall for easy referral.
- Create manual temperature-monitoring sheets on which the temperature of the refrigerators and freezers can be noted. Pay attention to leaving enough space to record the date, time and temperature.
- Create a log sheet for the cleaning staff. Ensure that they have a working knowledge of how to correctly clean the surfaces, e.g. which detergents to use and how frequently they should clean. Clearly indicate weekends and public holidays on the cleaning log sheets. Display this log sheet on the door. Should you work with a biological safety cabinet, have a log sheet indicating who cleaned the cabinet before and after use. Paste this onto the front of the cabinet.
- Should your pharmacy have access control, a log sheet for all entries and exits should be pasted onto the door. This will be helpful when
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tracing people as well as dates, times and the amount of traffic entering/exiting the pharmacy.

• Determine how you are going to work with your participants’ files when the study commences. How are you going to number the participants? How are you going to retrieve their files for their next visit? Are you going to have a separate file for each participant or have files per visit? Make sure that you know how the database operates from which the participants are selected.

• Don’t be afraid to work with different colours. Colour coding is not only aesthetically pleasing, but also assists you to remember where things are located. If your budget allows, look for different coloured dividers, files, post-its, coloured pens and markers.

• Ensure that you always have a backup on hand for all documentation. At the end of a working day, make sure that you have backed up all of your files with the date as part of the file. For example, XYZ study (12.03.2018).doc. This will make life easier for you when mishaps occur, e.g. when you have erroneously saved a file under another name. You can then just go to the previous day’s back up and retrieve the data from there.

• Create bin cards for noting when you receive new stock and when and to whom you issue stock. This will form a guideline for when you need to replenish stock.

• Bear in mind that some investigational products have expiry dates. Ordering of these products should thus be continuous and you should ensure that stock levels are adequately maintained. These investigational products could also have specified storage conditions so ensure that the necessary documentation is available for you to prove that you adhered to these conditions.

• Always ensure that all documentation is completed by the end of the day. Most importantly, when dispensing investigational products, first complete the study product accountability forms because they will reflect the stock levels in your pharmacy at the time of use.

• Make sure that you write neatly and clearly – auditors and inspectors do not accept the excuse that you have bad handwriting! Complete all forms and labels in black ink. Should an error be made, correct it by drawing a single line through the error and then entering the correct information. Date and initial such changes.

• Work in a systematic manner, ensuring that your work space is clean, neat and tidy and presentable at all times. Being in a supervisory position, it is essential that you convey your standard of work and work ethic to those who work below you.

• Your Clinical Research Site will have regular visits from the international entity’s delegates, monitored by assigned monitors, inspected by the South African Pharmacy Council and could be inspected either announced or unannounced by the South African Health Products Regulatory Authority (SAHPRA) formerly known as Medicines Control Council (MCC). Be sure that at the end of each day your documentation reflects what you have performed during the day. Remember Murphy’s Law – anything can happen. Do your best and be accountable at all times.

• When the clinical study commences, you will soon obtain a holistic view of the whole clinical study.

Lastly, on a personal level, my advice to all future aspiring clinical trial study pharmacists is that you have to decide whether this is an environment in which you would like to work. For this, you must be detail-orientated, document-based, be able to work under tremendous pressure, have good interpersonal skills, be able to work in a team-driven environment, have loads of patience and be able to multitask.

Good luck!