



The Role of the Pharmacist in the Clinical Supply Chain

Wyndi Phillips at Almac describes how a pharmacist can offer valuable input in the clinical development process

About the Author



Wyndi Phillips received a PharmD from Campbell University School of Pharmacy in North Carolina and then completed a Pharmacy Practice Residency at Mercer University and Piedmont Hospital in Atlanta, Georgia. After completing the residency, she began her pharmacy career in 1998 at Duke University Medical Centre. She has also worked in small rural hospitals and community pharmacies. One of her most rewarding pharmacy experiences was managing anticoagulation clinics for a large healthcare organisation where she met with up to 50 patients a day to monitor their anticoagulation therapy, and worked closely with their physician to determine the best therapy for each patient. In 2003, Wyndi joined Clinical Trial Services, now known as Almac Clinical Services, working as a pharmacist at their Durham site.

Email: wyndi.phillips@almacgroup.com

How did you become involved in clinical trials?

I had an interest in learning more about clinical trials and pharmacist opportunities in pharmacy school, but decided to get direct clinical and patient care experience before exploring other options. I became more interested in clinical trials during my hospital experience, where I had some exposure to the trials being conducted at the site. I also worked directly with study sponsors to set up trials at the anticoagulation clinics. This interest led me to start looking for pharmacist career options working directly with clinical trials.

Can you describe a typical working day?

The great thing about the work day for an Almac Clinical Trials pharmacist is that it is never 'typical'. There are always new challenges arising at sites, with the sponsor or at the distribution depots. Responsibilities of the Clinical Trials pharmacist include working with the sponsor, CRO, depots, IVRS and other groups in study startup, to ensure the drug will be packaged correctly and available for the first site ready. Once the study begins, the Almac pharmacist oversees the drug inventory throughout the world and assists the study team with any drug related issues or concerns.

What are the main challenges faced by pharmacists working on clinical trials?

Pharmacists working on clinical trials face a number of challenges today, especially with the ever-changing global economy and technology. These challenges include dealing with the increasing complexity of clinical study designs, coupled with the increasing pressure to be the first to market, and keeping up with the continually changing regulations governing investigational products. There are an increasing number of formulations requiring special storage, handling and preparation. It is also very important to keep abreast of current technology supporting study drug forecasting, patient randomisation, study drug assignment and management, drug accountability and reconciliation, and data collection.



What is the advantage of having a pharmacist in your organisation?

Almac Clinical Services recognises that having pharmacist expertise in-house positions us to provide a more comprehensive and patient-focused service. Pharmacists have an understanding of how the drug will need to be prepared and dispensed at the site. This knowledge helps to determine the best way to package the drug for ease of use at the clinical site and to manage overall drug inventory. Pharmacists know the length of time it will take to prepare medications, and whether the protocol is reasonable from their perspective. Almac pharmacists can serve as an unblinded resource for site drug questions by providing dose advice and other drug-specific knowledge, as agreed on by Almac and the client. The pharmacist can also write dosing instructions, pharmacy calculation worksheets and other drug-related instructions. These materials can be included in study-specific pharmacy manuals and pocket cards, which can serve as very useful tools for the site pharmacist.

How do you see the role of the pharmacist progressing in the supply chain?

A pharmacist provides a knowledge base which gives a unique opportunity to provide valuable input at many points throughout the supply chain. Pharmacist input during the study design phase is important to ensure proper comparator sourcing, labelling, blinding, preparation and drug accountability and reconciliation. Pharmacists can also provide ongoing support to site personnel during study start up and maintenance of the trial.

What major studies have you been involved in, and how has your role assisted these?

One particular recent study demonstrated the value a pharmacist can add to clinical trial drug supply management. Two identical study programmes divided into a total of four Phase III, double-blind, randomised studies in 39 countries enrolling approximately 3,000 patients. The programmes were exploring different therapeutic options for the study drug. The drug supply was pooled across the four studies.

The study team included the sponsor teams for each study, CROs for each study (eight for the first study and three for the second study), two IVRS teams, nine drug distribution depots and the Almac Clinical Services clinical supply team. The Almac clinical supply team was responsible for the following:

- Clinical supplies management
- Site pharmacist training
- Development of training materials for sites and CROs
- Labelling, packaging and distribution of drug supply
- Depot management
- Sourcing of comparators and concomitant medications
- QP release
- Retest/expiry date management



The sourcing of comparators was a challenge because of drug shortages, labelling requirements and QP release issues. The plan was to source locally, but this was not possible in all 39 countries. We were able to source locally in 15 countries, and others were provided with drug sourced either from the US or UK. The countries also varied on the labelling requirements of comparators.

Inventory management for these studies proved to be challenging for several reasons. The determination of label groupings was difficult due to a dynamic country list, varied startup times, and the balance of drug supply with the number of depots. Bulk drug supply was challenging in these studies because of weight based dosing, varied duration of therapy and difficulty in determining actual usage at sites. There were multiple study drug and comparator lots used, and therefore multiple expiry and retest dates to manage. The IVRS was set up to only order study drug, not comparators, because the need to supply comparators was identified after the IVRS specifications were finalised. Sites ordered comparators via fax based on sponsor approval. To deal with the inventory challenges, the clinical supplies team monitored inventory levels globally. The Almac team also monitored expiry/retest dates and managed the retest date extensions throughout all 39 countries.

The study drug was supplied to the pharmacy as open label, bulk supply. The site pharmacist was responsible for blinding the weight based study drug against standard therapy. Study drug and standard therapy doses had to be adjusted continuously based on lab values provided to the pharmacist only. The lab results affected the frequency of infusions and the comparator choice. Issues for blinding included: volume of IV medication, timing of medication and dosing interval of medication. The site pharmacist had to ensure all of the above remained blinded throughout the 14-21 days of therapy for each patient. Patients were allowed to leave the hospital and receive the remaining therapy through home health. This provided another challenge, as the local home health agency had to follow the same procedures and maintain the blind.

The Almac pharmacist trained site pharmacists and monitors through interactive teleconferences with printed materials. Almac served as the unblinded contact for the sites if questions arose regarding how to maintain the blind. The clinical trials pharmacist wrote detailed dosing and preparation instructions and provided guidelines for dosing adjustments. At times, we also recommended the timing for the next lab values to ensure the drug dosage was adequate. An Almac pharmacist was available 24 hours a day to answer drug-related questions. This study would have been difficult to manage without an unblinded pharmacist available to assist the site pharmacist in determining the best way to manage the patients' therapy, while also maintaining the blind. It was beneficial to have a pharmacist on the clinical supply team because it was important to understand the how and why of the study drug and comparator needs would vary throughout the world, and therefore be in a better position to manage the inventory.

Contact:

E: clinicalservices@almacgroup.com

T: +1 (919) 479 8850

T: +44(0)28 3836 2436