

Case Study

This is a case study of documentation created by Almac-Durham project team for a phase III cardiology trial run from 2001 through 2003. This was a very complicated double blind protocol for patients undergoing PCI. Patients were randomized, in a 1:1 fashion to receive one of the following treatments.

1. Drug A + GP IIb/IIIa inhibitor of choice
- OR
2. Drug B + GP IIb/IIIa inhibitor of choice

The study pharmacists were unblinded and study drug Drug A and Drug B were provided to the sites in an open label manner. There were two challenges in implementing this project: keeping the study blinded and getting the assigned treatment to the patient quickly.

Based on the hospital formulary and physician preference, sites can choose to use either Integrilin or ReoPro as their GP IIb/IIIa inhibitor of choice. Patients were randomized and received their first dose of study drug in the cath lab. The patient was on the table with the guide wire inserted when the site called to randomize. It was the sponsor's expectation that the study drug be mixed and delivered to the cath lab within 15 minutes of randomization. This was a rather tall order since it can take five minutes just to walk the infusion from the pharmacy to the cath lab in some institutions.

Prior to study start up the Almac project team did an informal survey of site pharmacists to get their initial impression on the feasibility of doing the project. The feedback we received from these sites was sent to the sponsor. To determine the quickest way to prepare the study drug we formed a focus group of investigational drug pharmacists that we had been working with for years from sites that would be enrolling in this trial. This group of pharmacists came to Almac-Durham and met with the sponsor to discuss the protocol and to come up with the most efficient way of packaging the drug kits and preparing the study drugs.

To help the sponsor reach their goal and using feedback from the focus group meeting, the Almac Pharmacist developed the following strategy for implementing the protocol.

1. **A detailed drug preparation card was designed.** This card calculated all of the bolus doses and infusion rates the sites needed to prepare and administer the study drugs. It even took into account eptifibatide dosing adjustments for patients with a creatinine of greater than 2mg/dl. The sites do not have to do any calculations to prepare the doses or determine the infusion rates.
2. **Infusion and bolus dose labels for the syringes and infusion bags were provided to the sites.** This eliminated the need for the sites to enter the order into the computer to generate labels for the study drugs. This was especially useful for the first doses.
3. **A list of items needed to make "prep kits" was provided to the sites.** The hospital pharmacy IV rooms prepared and stocked prep kits that contained all of the supplies necessary to make the infusions. This saved time on having to pick out the supplies when the order was received in the IV room.
4. **A list of frequently asked pharmacy questions was prepared.** The Almac Pharmacist was on call 24x7 to answer questions from the sites regarding the study drug for these trials. We logged these questions and periodically send out a list of most commonly asked questions to the sites.
5. **The Almac Pharmacist also designed a "Ready to Randomize" form for the sites to use.** The site pharmacist called the IVRS and performed the actual randomization. This form allowed for the study co-coordinator to complete their part of the form (top-half) and then hand it off to the pharmacist to make the randomization call and record study number and treatment assignment.
6. **It was critical to the success of this trial that the study drug was administered properly.** To track this, the Almac Project Team reviewed all of the drug accountability documents that the sites complete. The Almac Pharmacist tracked dosing errors and provided this information to the unblinded trial statistician.