



Clinical Research

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Greetings Mr. McLaughlin:

My name is Jesse Bregman and I am one of the Study Start Up Associates at ICON Clinical Research. I'm writing you this letter today to let you know about the exceptional experience I had working with Claudia Ramirez at Dr. Amina Haggag's site for the B1971016 study, specifically as it relates to the regulatory document collection process.

As you may know Study Start Up is one of the most challenging and often times stressful parts of Clinical Research. Between ensuring each Investigator is GCP trained, as well as collecting the appropriately filled out regulatory documents as required, and coming to terms on language regarding Informed Consents, there are many times sites get delayed significantly due to complications at any one of the various stages. Additionally having experience working for a CRO, we do realize many sites are working simultaneously on many other studies as well, leading to a lack of response. I'm pleased to say that with Claudia I experienced none of these. Without question, this was one of the smoothest and most efficient start up experiences I've ever had with a site.

Claudia was always very timely with her responses, and always ensured that I received the items I needed quickly. To give you an idea on the specific swiftness she provided, the initial start up pack was sent on 26Mar2013, and I received the final outstanding regulatory document from Claudia on 08Apr13. If there hadn't been some issues surrounding the contract/budget Dr. Haggag's site would've been approved for the B1971016 study the day the drug system went live on 26Apr13. Even so, Dr. Haggag was officially approved shortly thereafter (as one of the very first sites to be initiated) on 10May13 and since that time has been able to enroll 97 patients for this study. It's widely known that the quicker and more efficiently study start up goes, the easier the rest of the study goes. As a direct result of Claudia's cooperation regarding ICON and Pfizer's start up process, Dr. Haggag's has been able to be one of the highest enrolling sites for this study (overall 6<sup>th</sup> out of 32 sites).

I again want to the time to say how much of a pleasure it has been to work with Claudia for this study. I look very forward to working with Claudia again, should I be lucky enough to be put on a study where Dr. Haggag is selected again.

Sincerely,

Jesse Bregman

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