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The Most Powerful Name in Corporate News

A Clinical Research Center addressing Protocols and Clinical Trials for New Compounds working through the FDA Approval Process

Beth Corbin – *Founder*
Albuquerque Clinical Trials, Inc.

CEOCFO: ***Ms. Corbin, what is the concept behind Albuquerque Clinical Trials?***
Ms. Corbin: We contract with pharmaceutical companies to carry out their protocols on new compounds working their way through the FDA approval process.

CEOCFO: ***What do you understand on a very fundamental level about the process that results in a superior job?***
Ms. Corbin: Everybody here is very much committed to the idea of excellence. The data that we collect is so important to the approval of new drugs and patient safety. Therefore, we have implemented many policies and procedures that insure we follow good clinical practice and agency guidelines. We have often been recognized for our high quality work. Of course, the true attestation to that is that the pharmaceutical companies we work for come back to us again to do new trials as they come up.

CEOCFO: ***Would you give us one or two examples? What might you do that is going to get to that quality that maybe others are not?***
Ms. Corbin: Part of it is our training program. We maintain high expectations for our clinical research coordinators and for the physicians who work in our clinical trials. We expect them to obtain advanced certification in research. All coordinators are expected to pass the ACRP certification exams. We have a rigorous training program for new employees joining our company as well as regular continuing education for all employees. We have a robust quality assurance program in place as well.

CEOCFO: ***Are there particular types of trials that you do, whether it is certain stages or certain diseases or compounds?***
Ms. Corbin: Certainly! There are four levels of testing recognized by the FDA (Phases I-IV). Phase I, which are often times in healthy volunteers and small numbers of patients through Phase IV which are post marketing studies. At the present time we are not doing Phase I trials, although we just bought a much larger facility planning to expand our capabilities to include Phase I in the near future. The trials that we normally do here are Phase II and III. Those are pre-FDA approval trials

CEOCFO: ***Why will you be incorporating Phase I now? Why is now the time?***
Ms. Corbin: This is a good time for us because we've perfected our systems and are happy with our working model. We're also in a strong financial position that will allow us to expand. We don't want to get too much bigger than we already are but we've always had an interest in doing early Phase I trials. Up until now we haven't had a facility large enough to accommodate the overnight stays often required in Phase I studies. In the new building we'll have private sleeping rooms where a patient can stay overnight and be observed. There will be an activity lounge with TV, games, food preparation and computer area. The unit would have its own nursing station with dedicated IV infusion and patient monitoring areas.

CEOCFO: ***How do you stay on top of technology, regulations and the way the market or the way the interest in the medical community is going?***
Ms. Corbin: We view this as critical and really do have to stay on top of what's going on. We generally have twenty five to thirty ongoing studies here at any given time. Right now, we have more trials than we have ever had, with additional trials slated for the 1st and 2nd Quarters of next year. We are in constant contact with our sponsors, our professional organizations and our vendors. We work in one of the most heavily regulated industries and everyone is looking over our shoulder. We have monitors here almost daily reviewing our data and they are great sources of information on trends in

the industry. I have a very sharp administrative team who are always researching new ways to insure good trial conduct and data collection.

CEOCFO: ***Would you tell us about the participants? Is it getting harder? How do you find the right people?***
Ms. Corbin: It really depends on the trial. We've been very fortunate. We have been in business since 1987, so we have a huge data base of patients who like to do clinical trials. We do trials on just about everything, except pediatrics, cancer and in-patient hospital trials. The fact that we have the capability to do studies on a wide variety of indications increases our accessibility. A patient might call us inquiring about an osteoarthritis study and, after talking, end up more interested in a migraine trail we're conducting. Patient's study interests are entered into our database which we reference when recruiting for new studies. We have newsletters that go out to patients, telling them what new trials are coming up and what the qualifications are. We do a lot of patient recruitment through social media and through advertising. We also get a fair number of patient to patient referrals. Patients who have a good experience tell their friends.

CEOCFO: ***Does it make a difference if someone has done a trial before? Does it skew the trial in any way if many of the participants have previously been part of a trial?***
Ms. Corbin: Yes, and that is a concern of pharmaceutical companies. Often times there are exclusion criteria that states patients "Cannot have participated in any other trial with this compound." That is because sponsors want to have as much variation or diversity as possible. It is not good to just use the same patients over and over again. Therefore, we are always seeking new patients. However, patients get a lot participating in a trial and they want to repeat the experience. We put a lot of emphasis on patient education; educating the patient not only the about the protocol, but about their disease as well. Subjects get state of the art medical care and everything is paid for by the sponsor. Each patient gets a lot of personal attention. They see the same study team at every visit, so there is good continuity that is often lacking in a general healthcare setting. Usually, once they finish a trial they want to do another one, because they've gotten so much out of participating. We just have to be careful they are enrolled in similar studies appropriately.

"Our mission is twofold: The health of our patients today and the health of our community tomorrow"
- Beth Corbin

CEOCFO: ***Are there particular studies that you would like to do if you are given a choice?***
Ms. Corbin: My personal interest is in rheumatology. Therefore, my team does a lot of lupus, rheumatoid arthritis and psoriatic arthritis. Almost fifty to sixty percent of the trials that we do are with biologics. This field of research is very exciting! In the next decade I think we are going to see a tremendous number of biologic medications coming out that will be of great benefit. As a company, we haven't had much opportunity to do dermatology trials and would like to be more involved in that area.

CEOCFO: ***How do you decide which trials are right for group?***
Ms. Corbin: When a trial feasibility comes in, we look over the protocol carefully. We have been doing this for so long we can usually spot studies that aren't appropriate for us. There are always surprises, but usually in reading the protocol and talking to the pharmaceutical sponsor we can detect problem areas ahead of time. We do not accept studies we don't feel we can perform well on. It does help to work for companies we've worked with before, because they know us, they know our work style and we know what they want. So we look at protocols and we think, "Okay, we can do this, we have the patients and the resources for it." We also look at the study vendor list which maybe extensive. Vendors provide the sponsors and sites with everything from the study medication to electronic data capture systems. Another aspect we consider is the benefit to our patients and what the benefit is to society as a whole.

CEOCFO: ***How do you mitigate some of the challenges when you are working with a small organization and they are too close/too protective of their idea?***
Ms. Corbin: It is difficult, because we have worked with some boutique pharmaceutical companies where they have one or two compounds in their pipeline and they are sure that their protocols are well written and that their processes faultless. As you have surmised, that is not always the case. We do try to be as diplomatic as possible, but if we can't work things out we will go up the chain, if we have to, to try to work out difficulties. It's a very tricky thing to do. My clinical trials administrator is the one this generally falls to. He is so skilled at negotiating with people he manages to get his point across without offending people!

CEOCFO: ***What has changed in your approach over time? What have you learned along the way?***
Ms. Corbin: It is a whole different industry than it was when I first became involved. When I founded this business in 1987, our contacts worked directly with the pharmaceutical company. All our communication was directly with the in house

teams, the auditors and monitors who came out to review our data worked for the pharmaceutical companies. Now a large percentage of our business is completely managed by Contract Research Organizations (CRO's) and you have less actual contact with the pharmaceutical sponsor. The number of vendors providing trial support has increased dramatically. We're found the more people you add to the mix the more the potential for miscommunication. That has become somewhat of a challenge for us. We've had to learn to communicate and solve problems working through a thick layer of middle men.

CEOCFO: ***You mentioned you often work with previous clients? How do you gain new clients? How do you standout when someone is looking?***
Ms. Corbin: We have our website of course, but we actually do not have to do much client recruitment anymore. We have worked with so many companies and have an established work record so typically more protocols come from sponsors that come back to work with us. Reputation and performance and quality metrics are the best way to distinguish ourselves. We are really in a fortunate position - that we can turn down trials rather than having to recruit them.

CEOCFO: ***What should we expect if we speak a year from now? What might be different for you?***
Ms. Corbin: We are planning to add additional research staff to expand our capacity to do an increased number of trials and we are going to add that Phase I unit, which is something new for us that we are very excited about!

Interview conducted by: Lynn Fosse, Senior Editor, CEOCFO Magazine

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