Interview with Pauline Kitchiner

Transcription

My name is Pauline Kitchiner, and I work at GSK's Clinical Unit in Cambridge. Which is a purpose built clinical unit to conduct phase one or phase two studies. We have a strong focus on experimental medicine. I manage a team of people who are responsible for recruiting patients and healthy volunteers on to our clinical trials.

It started about a year ago, as most of the company would agree, that information sheets or informed consent forms are not patient friendly at all. They're lengthy, the words, the terminology that they use are not easily understood by the patient, so we wanted to change that. A year ago, got in contact with a "Focus on the patient" group with GSK to see how they could help. To see if they could set up a group of patients and healthy volunteers that could actually look at our patient information sheets and make suggestions as to where we could improve it. Make it simpler, make the language easier to understand. That's how we started initially.

I contacted Kay Warner …She's our contact for … part of GSK's „Focus on the patient" group. And we put a proposal together, which was approved by the clinical unit in Cambridge, to go ahead with this. She identified four patients, two who hadn't got the specific disease that we were looking into and two that did had the specific disease that we were looking into. Which was primarily Sjorgen's syndrome. We had to get this approved by the sponsor because obviously this was their clinical trial. That's very important is the sponsor won't approve this activity, then they're not going to listen to any

of the changes that the patients might suggest.

It was very quick to set up, very easy to set up. We got contracts with the patients, we engaged them by telephone on the first instance to make sure they understood the activity we were asking them to do, and that they were comfortable with it. From then, when the informed consent forms were in draft form, we then invited the patients in to actually go through protocol design with them, and again, the objectives of this activity.

WHAT IMPACT DID THE INVOLVEMENT OF PATIENT EXPERTS HAVE?

It had a very good impact. There was lots of changes made according to their suggestions. There were things that were spelled out a lot clearer. There was the way that it flowed was changed to read, and as well as the disease, how it was explained to them. That was also changed to make it more readable for them. One of the interesting things is that the protocol had a biopsy procedure in it, and one of the patients were adamant they would not take part in a study because of the biopsy procedure. She felt that was too unbearable, so in reality, that was a good feasibility check for us. We perhaps know that identifying these patients aren’t going to be as easy as perhaps we may have thought so.

WHAT ARE SOME OF THE CHALLENGES AND BARRIERS WHEN INVOLVING PATIENT EXPERTS?

We have to get the sponsor’s approval first and foremost. Because although we say we’re moving towards patient centric trials, there’s very slow movement, if any. I personally haven’t seen it, so that’s why the CUC wanted to start, the Clinical Unit at Cambridge wanted to start the involvement with patients to move towards patient centricity.

One of the barriers was that they only had a week turn around time to review which is extremely tight, so they were well prepared for that in advance. We'd actually gone through the protocol design before that stage. When they got the draft ICF, I really knew they had to work on it just within a week to return their comments, so that was a bit difficult. I think moving forward next time what we'd do is ask for more time first of all, and also have more time for a couple of round table reviews so we can actually get them all in, if distance allows, and then we can have that easier discussion, face-to-face discussion. That would be an advantage.

HOW HAS THE INVOLVEMENT OF PATIENT EXPERTS CHANGED THE WAY YOU WORK?

Well, moving forward in 2017, the Clinical Unit in Cambridge would like to have patients review all of the protocols, all of the clinical trials that are coming through during that year. Again, it's sponsor dependent, but that is our aim, and what we'd like to do. Then start to move towards their review of the protocols at concept stage, so we're really looking and identifying what patients are willing to do. Is the trial too burdensome for them? Would it affect our recruitments? And things like that.

Well recruitment is sometimes very difficult. People will all say patient recruitment is the hardest, so it's far better if you engage patients at a very early stage to get involved in your design of your actual protocol as well as the informed consent form, so that you've got a study that people want to take part in and that is patient centric. You won't be struggling to recruit for if you've got the right things written in, and the procedures are doable.