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This Is What It Means To Be Engaged With Patients

by John Hodgson

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Don't describe a protocol of monitoring for nasty drug side-effects in a cancer trial as a "wait-and-see" approach: patients with the disease will think that your approach is to "wait and see if they die".

Don't insist on a trial design that requires 22 hospital visits to take blood samples or assess lesion progress. Yes, it's good to have data, but asking for 20 blood samples is too much for some patients. Cut down the blood samples and have patients take photographs of their own lesions.

Don't ask patients to fly across the country to the place where the trial-qualified staff are based: have visiting nurses – also trial-qualified – call in on the patients and do whatever is necessary.

Ask patients what they are really interested in as outcomes from a trial. The life-skills assessments that are routinely part of rheumatoid arthritis trials typically ask whether a particular treatment has helped a patient put on their socks and shoes, or cook a meal or undertake some task like walking across a room. But when you actually ask the patients what they want from an RA drug, they want to know if it will do something about fatigue: their fundamental problem is that they are so tired that they can't get out of bed – so putting on shoes

and socks is just irrelevant.

These were just a few of the insights that came from the session "It's all about the Patient – becoming more Patient-centric" at Informa's Partnerships in Clinical Trials meeting held in Hamburg. A panel of patient-engagers laid out some of the principles behind the new efforts by those who run and sponsor clinical studies to listen to the 'patient voice'.

It turns out that where it can be measured, patient-centricity can have some really positive effects of practical benefit to the pharma and clinical trial communities.

Replacing "wait-and-see" with the phrase "active monitoring" for a cancer trial approach increased recruitment almost overnight from 40% of target to 70% according to Sue Pavitt, a professor in applied health and translational research at the University of Leeds, UK.

Focusing rheumatoid arthritis trial assessments on fatigue, not dressing, gives patients the idea that the endpoint is relevant to them and aids recruitment, said Julie Hapeshi, a nurse-turned-trial-lead from the UK.

So far this new experiment of actively channelling patient input into clinical trial design is working out. Not only does it feel like it is the right thing to do, the results seem to be providing benefits not only for patients but for pharma, too.

In a lupus study run by AstraZeneca, patient consultation ahead of the trial not only reduced the number of hospital visits necessary for each patient by 25%, it also enabled investigators to get more out of the measurements they were taking on drug response and quality of life. So said Vincenzo Garzya, AZ's Patient-Centricity Excellence Director.

All of which excellent news really begs the question why this outbreak of common sense has only just happened in the in clinical trial community. Why haven't clinical trial organizations and pharmaceutical companies been listening to patients before? Why have companies only just begun to have Chief Patient Officers or Directors of Patient-Centricity Excellence? Why has it only just dawned on this industry that talking to its end-users might be good thing to do?

The answers that came back were revealing. Panel chair David Wright, Clinical Trial Patient Engagement Technologies Lead at Amgen Global Development Operations (yes, he has a very large business card) said: "I guess we kind of thought we were [engaging with patients]. The fact that weren't only became clear when we started having problems in recruiting patients, and when the outcomes of trials were poor."

Melissa Jean Mottolo, a Roche Patient Recruitment Strategist, said that it wasn't clear that regulators would give permission for this sort of contact. "We thought we weren't allowed to do

it. Everyone told us that there was no point in going to the FDA because they are going to say 'no'. In fact we went, and they said 'yes'."

She also added that the internet has meant that patients have found it easier to get information on their conditions. "Dr Google has been very useful," as David Wright put it

Lesley Robson, who is Clinical Operations Manager at Cancer Research UK's Centre for Drug Development, thought the explanation lay in a changed attitude among patients: "Patients are getting a voice. What used to happen was they got ill, came in for treatment and took whatever they got and never challenged it. Now they are more confident that they should have a say."

There may be other explanations, too. I have often heard it said at pharma conferences that the prescriber or the health insurer or the healthcare system is its customer, not the patient.

And when it comes to clinical trials, clinicians have served as gatekeepers to patients. "Gatekeeper" is a polite term: "nanny" or "minder" or "pimp" might serve sometimes.

Those basic truths about the commercial and clinical realities may have penetrated too far into the culture of the pharmaceutical industry and its suppliers/partners.

It's good to know that that may be changing, even if those waiting for the change have had to be – well – patient.

John Hodgson attended the Partnerships in Clinical Trials meeting 2015 in Hamburg Nov. 17-19. His blog posts can be read [here](#).