Patients Involved – Informed Consent Feedback

Introduction

A patients involved case report of patient feedback improving an informed consent form. UCB employees consulted patients with epilepsy and rheumatoid arthritis to make the form simpler and easier to read and understand.

When does it happen? – Phase I

Description of the case

It was thought that potential patients were put off from entering a clinical trial because they could not understand the details surrounding the clinical trial. Therefore, the project aimed to make the informed consent form simpler and easier for the patients to understand.

In the first part of the project, patients were visited at home and asked to read existing consent forms. The staff observed their reactions and also discussed their opinions with them. The feedback from the patients was taken on to modify the informed consent form.

In the second part, a patient was invited to a workshop and

asked put forward the patient perspective on the modified informed consent form. The readability of the form was discussed as the intention was to make it easy for everyone to comprehend. There was also a survey which was filled out by patients on which they scored their preferences on the layout, text and colour of informed consent form.

Although readability studies are normally carried out at the beginning of the developmental process, in this instance, valuable and direct feedback was gained from different settings (i.e. not through the usual market research channel).

Type(s) of patient (advocates) involved

- Patients with personal disease experience.
- Expert patients / patient advocates with good expertise on disease, but little R&D experience.

Benefits of patient involvement

The experience demonstrated that patients valued being consulted on their preferences. The results of the survey were used to update the format of the informed consent sheet. There were some major changes to the existing documents, such as shorter paragraphs and changes to the design features. Sentences deemed to be very important by the patients were highlighted.

There was also a ‘Quick Guide’ produced which gave quick facts regarding the trial. This meant that patients did not have to read the entire informed consent sheet before finding out if they were eligible. They might get an advanced understanding of whether the trial could be right for them.

There are definite plans to involve more patients to gather feedback throughout the department. It is also thought that it

will be easier to match the correct patients to the trials.

Challenges and barriers

There were worries that the ethics committees might not approve the suggested format or text. The regulated environment meant that the amended versions of the informed consent sheet had to gain approvals from the ethics committees.

In the end, there were not any concerns from the ethics committees and approvals were obtained from many countries, with the comments being very minor.

There could have been potential challenges when trying to take on board all of the patient feedback and translating them into practical solutions. For example, the colour of the text might not have been suitable.

Learnings

The feedback from patients can be dependent on the type of patients involved. This means there can be a bias on the information gathered, based on personal experience and expertise. There also needs to be a trade-off between the wishes and suggestions of patients and what is realistically feasible.

The time involved in gathering feedback from the needs to be factored in to the process development stages. The cost also needs to be budgeted.

An open mind is needed to really gain the optimum out of the process. Going with a particular perception might prevent gathering a useful insight. For example, there was a lot of new and impressive technology on iPad but patients with tremor in hands are not able to use the touchscreen. This feedback was given very clearly by the patients themselves.

A3-Infomed-Consent_v1_EN

Attachments

- Patients Involved Case Report – Informed Consent Feedback

  Size: 408,889 bytes, Format: .pdf

  An infographic describing a patients involved case report of patient feedback improving an informed consent form.