Patients Involved – Patient friendly informed consent

Introduction

A collaboration of the Patient Consumer Group [part of National Research Institute for Health Research (NIHR), Clinical Research Network] with the pharmaceutical company Eli Lilly.



Where in the process? – Strategic framework to launch

When does it happen? – Strategic framework to Launch

Description of the case

In the UK, the National Institute for Health Research (NIHR) was established in April 2006 to provide the framework through which the Department of Health could position, maintain and manage the research, research staff and research infrastructure of the NHS in England as a national research facility. The NIHR's mission is to maintain a health research system in which the NHS supports outstanding individuals working in world-class facilities, conducting leading-edge research focused on the needs of patients and the public.

For a clinical study involving children aged 7 to 14 years, via the Medicines for Children Research Network (part of the

NIHR), Lilly UK Clinical Operations sought feedback on a parental patient information leaflet (PIL) from a consumer representative group.

The input received from the consumer group resulted in a major revision of the document and consequently to a revision of the child and adolescent assent forms. Whilst connecting with the NIHR Clinical Research Networks has become common practice for the planning, set-up and enrolment of clinical trials, the involvement of consumer and patient advocacy groups is only just starting to happen.

Type(s) of patient (advocates) involved

- Patient's parents with personal disease experience. Parents experienced in reviewing patient information leaflets (PIL).

Benefits of patient involvement

Obtaining feedback from the consumer group on how they would like to see a PIL was very helpful for Lilly on our journey to move into a patient centric organisation. This collaboration led Lilly and CRO partner to recreate the documents with much more patient friendly wording, avoiding business, technical and medical terminology (e.g. sponsor, vendor, and subject) that might be difficult for someone outside of the field of clinical research to understand.

Besides the appreciation from the patient point of view, the benefit for Lilly was also the shortened review timeline from the Ethical Review Board (ERB) (just 20 days from ERB meeting to approval being issued) and the very few comments received on the documents.

ERBs are becoming increasingly interested in how patients are

being involved in the research process. A question exists in the ERB application form to capture this, and although patient involvement is currently not a requirement, it is something ERBs like to see.

Challenges and barriers

Making changes to patient information leaflets / consent forms (ICF) is not an easy task since we have an ICF creation process with mandatory templates and wording. To accommodate the suggestions from the consumer group, parts of the compound documents well as the local ICF template needed to be adjusted / modified, and changes internally approved, which took additional time and significant discussion with all functions involved.

Although the consumer group reviewer had a very short turnaround time of two weeks, the whole process with obtaining feedback, incorporation into our documents, internal discussion and approval of changes etc. took some additional time which resulted in a delayed ERB submission of approximately one month against the original planned date.

Learnings

Understand upfront how the review process works for the consumer / patient advocacy group in question –what is the expected turnaround time and do they meet according to a fixed schedule (e.g. ad hoc or monthly meetings)?

Upfront planning very early in the set-up process to allow sufficient time for the consumer group consultancy step thereby avoiding any delay to the ERB submission timeline. Early communication of the plan to the Lilly study team members who will be called upon for input to support the ICF development.

The ideal would be to create a standard process to include consumer representative/patient advocacy groups for the majority of Lilly clinical studies in the UK and have discussions with other EU affiliates to learn from this process and find synergies.

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Attachments

- Patients Involved: Patient expert on external Bioethics Advisory Panel
  Size: 898,102 bytes, Format: .pdf
  An infographic describing a case report on the inclusion of a patient expert on a pharmaceutical company’s external Bioethics Advisory Panel.