Patients Involved – Informed consent form: Writer's guide

Introduction

Partners from Ethic Committees (National Commission of Ethic Committees – CNCP), patient associations, and investigating centres worked in a writer's guide of five recommendations and six rules for Informed Consent Forms.

When does it happen? – Phase II-III

Description of the case

Good Clinical Practice requires the provision of clear and understandable written information. On this basis, Sanofi-France decided in 2005 to launch a qualitative assessment of the existing Written Subject Information (WSI) / Informed Consent Form (ICF) which highlighted five major defects:

- Confusion between the situation of research and the situation of care.
- Poorly organised document.
- The Ethics Committee as the primary recipient of the document.
- Little consideration given to patient.
- No connection between the written and the verbal

information given to patients.

Sanofi-France decided then to totally review its way of writing WSI / ICF for its clinical trials. In September 2006, on the basis of this report, Sanofi-France published a guide of recommendations on good clinical practices for writing WSI / ICF – Based on this guide, a practical and concrete template has been quickly developed for the use of Clinical Research Unit Team Members from Sanofi-France. This template proposes an innovative approach inform, substance and quality of writing.

Type(s) of patient (advocates) involved

- Expert patient / patient advocate with good expertise on disease and good R&D experience.
- Patients participating to clinical trials

Benefits of patient involvement

1. Innovative Form:

- Format of the document = A5 booklet connected to an ICF in triplicate A4 format on one page and connected to a patient card – NB: signatures only on the ICF.
- Use of cardboard inserts (particularly in case of multiple WSI or ICF for a same study) to distinguish between sections.
- Presence of a table of content with colour codes.
- Presence of a colour marker corresponding to the table of contents.
- Use of glossary covering terms that cannot be simplified.
- Use of diagrams and of a calendar (at the backend of the document) covering the steps and examinations of the study.

2. Innovative in Substance:

- Distinction between care and research.
- Choice of pertinent information that the patient needs to know to make the decision in an informed manner.
- Identifying the patient being capable, independent and rational.
- Placing the patient at the heart of the information system and as the primary recipient of the document.
- An homogeneous information system, avoiding redundancies and organising information with the patient in mind.

3. Innovative in Quality of Writing:

- Writing for people having reached no more than 'end of 1st year of high school'.
- Using short and simple sentences (only one idea per sentence; 15 to 20 words on average).
- Using common sentence structure (subject-verb-object).
- Using locutions to organise the sentence (logical connectors).
- Using no ambiguous sentences.
- Avoiding negative and passive turns of phrase.

Challenges and barriers

No specific challenges and barriers for conducting this project outside necessary alignment between the different partners at the beginning of the project, as well as finding the appropriate medical writing expertise. This template has been used for all studies of Sanofi-France since September 2007.

The Ethics Committees, investigating centres, patients associations and the National Commission of Ethics Committees very quickly adhered to the model and gave Sanofi-France their formal approval.

This template changed since the start of its implementation. Remarks from Ethics Committees, investigators and auditors, as well as Sanofi internal discussion and objectives of simplification are improving it constantly.

Learnings

The writing of WSI / ICF of Sanofi-France studies is now being done by the service provider company that has accompanied the company since the start of this adventure.

Sanofi-France has developed templates for specific cases: pharmacogenomics, pharmacokinetics, children, caregiver, patients unable to express their consent, etc.

Sanofi-France was also able to verify the 'universality' of the system by developing it on studies in Tunisia, Morocco and French-speaking Africa (Note: for Morocco and Tunisia, coexistence of a French version and an Arabic version).

Sanofi has made a document explaining to the patient the process and the rules of information and consent in clinical studies; this film is broadcasted on an institutional site external to Sanofi-France and on the Sanofi website:

http://moss-intranet.sanofi-aventis.com/ClinShare2/clinshare/Pages/EditoPatientICFvideo.aspx

A3-informed-consent-form-writers-guide-V1.0

Attachments

- Patients Involved Case Report – Informed consent form: Writer's guide
  Size: 925,393 bytes, Format: .pdf
  An infographic describing a patients involved case report on patient associations work with partners from

Ethic Committees (National Commission of Ethic Committees – CNCP) and investigating centres worked in a writer's guide of five recommendations and six rules for Informed Consent Forms.