Enrolling in clinical trials

Introduction

Before a participant can enrol in a clinical trial, they must be recruited, screened, and give their informed consent. The process of enrolling in clinical trials is carefully regulated in order to protect the participants and maintain the clinical trial's internal validity. The following article covers aspects of how patients are informed about clinical trials, the screening process, and the structure and requirements of informed consent.

Advertising and recruiting for clinical trials

How participants are informed about a clinical trial

The methods used to advertise clinical trials are controlled by legislation. In addition to advertising, trial organisers will seek potential participants via information provided to sources such as patient organisations, patient registries, hospitals, and pharmacies. Participants can also find information about clinical trials from clinical trial registries. Patients can get information from their doctors.

In recent years, traditional print-based advertising methods, such as posters in doctors' offices, have expanded into the use of digital tools. These new tools range from dedicated clinical trial recruitment websites (for instance, the EU Clinical Trials Register (EUCTR)) to social media sites.

Information used in recruiting patients for clinical trials

Regardless of the route used to reach out to potential trial participants, an Ethics Committee should give a favourable opinion according to the appropriate guidelines.

The means used to recruit patients through advertisements can be diverse; however, the advertisements should always:

- Include the contact details for the organisation running the clinical trial
- State the disease studied and purpose of the trial
- Outline the inclusion/exclusion criteria based on which participants may or may not take part in the trial
- Give brief details of the benefits (for example, regular health exams)
- Mention the time needed for the completion of the trial
- Mention patients' groups for support to patients in recruitment (where available).

On the other hand, advertisements must not:

- Promise a good outcome or a cure for the disease
- Be coercive, especially when a trial is trying to recruit vulnerable patients, such as those with learning difficulties
- State that the medicine being tested is safe or that it works.

Screening process and enrolling in clinical trials

Prior to formal enrolment in a clinical trial, patients who are interested in participating will go through a screening process. Inclusion and exclusion criteria such as age, gender, the type and stage of a disease, and previous treatment

history will help to establish the patient's eligibility – whether or not they can enter the clinical trial. Those who meet the initial requirements are then invited to further screening at a screening appointment.

Once the screening process determines that the patient meets the inclusion criteria, the patient has a consultation where more information about the trial is provide and an Informed Consent Form is signed. The informed consent process is one of the things that contributes significantly to the protection of patients during their participation in a clinical trial.

Informed consent

During the informed consent process, the sponsor representative goes through all elements of the clinical trial process with the potential participant. At this time, participants learn the purpose and potential benefits and risks of a study before deciding whether or not they which to participate.

The structure of informed consent

The informed consent discussion, the written informed consent form, and any other written information provided to patients should include explanations according to the Guideline for Good Clinical Practice (GCP).[1]

According to EMA guidelines, the information provided to the prospective participant should explain:

- That the trial involves research;
- The purpose of the trial;
- The trial treatment(s) and the probability for random assignment to each treatment;
- The trial procedures to be followed, including all invasive procedures;
- The participant's responsibilities;

- Any aspects of the trial that are experimental;
- The reasonably foreseeable risks or inconveniences to the participant and, if applicable, to an embryo, foetus, or nursing infant;
- The reasonably expected benefits. If there is no intended clinical benefit to the participant, they should be made aware of this;
- The alternative procedure(s) or course(s) of treatment that may be available to the patient, and their important potential benefits and risks;
- The compensation or treatment available to the patient in the event of trial-related injury;
- The anticipated prorated remuneration, if any, to the patient for participating in the trial;
- The anticipated expenses, if any, to the patient for participating in the trial.

Additionally, prospective participants must be made aware:

- That their participation in the trial is voluntary and that they may refuse to participate or decide to withdraw from the trial at any time without penalty or loss of benefits to which they are otherwise entitled;
- That the monitor(s), the auditor(s), the research ethics committees, and the authorities will be granted direct access to the participant's original medical records for verification of clinical trial procedures and/or data, without violating the confidentiality of the participant, to the extent permitted by the applicable laws and regulations and that, by signing a written informed consent form, the participant or the participant's legally acceptable representative is authorising such access;
- That records identifying the participant will be kept confidential and, to the extent permitted by the applicable laws or regulations, will not be made publicly available. If the results of the trial are

published, the participant’s identity will remain confidential;
- The participant or the participant’s legal representative will be informed when information that may affect to the participant’s willingness to continue participation in the trial becomes available;
- Contact details from which to obtain further information regarding the participant’s rights, and who to contact in the event of a trial-related injury;
- Foreseeable circumstances or reasons for which the participant’s participation in the trial may be terminated;
- The expected duration of their participation in the trial and the approximate number of participants involved.

For more information on informed consent, see the fact sheets attached below.

Patient Involvement

Patient organisations and representatives can be involved in the informed consent process, particularly in giving input during the development of the informed consent form to ensure that it:

- Is written entirely in understandable and non-technical or scientific language
- Does not contain persuasive language
- Explains that participation in the study is entirely voluntary
- Provides fair perspectives on the possible disadvantages and risks of participation
- Outlines any direct benefits for the individual and any other beneficial outcomes of the study, including furthering our understanding of the topic.

More generally, patient organisations can participate in

clinical trials by:

- Having patients and members of the public actively involved in the different stages of research, and working together with researchers and health professionals (doctors, nurses)
- Contributing ideas for clinical research design, management, and support
- Fostering collaboration between clinical researchers and members of the public
- Getting involved in the research process rather than being a passive participant
- Making sure that clinical research is relevant, useful, and beneficial to patients
- Assisting participants and the study team with the informed consent process.

[glossary_exclude]References

1. European Medicines Agency (2002). *Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95)*. London: EMEA. Retrieved 12.08.2015 from http://www.ema.europa.eu/docs/en_GB/document_library/Scientific_guideline/2009/09/WC500002874.pdf[/glossary_exclude]

[glossary_exclude]Attachments

- Fact Sheet: Informed Consent
  Size: 104,438 bytes, Format: .docx
  This fact sheet covers the basics of Informed Consent, including the minimum aspects of a trial that the sponsor representative should explain to prospective trial participants.

- Fact Sheet: Informed Consent Regulations

  Size: 104,871 bytes, Format: .docx

  This fact sheet covers the regulations and safeguards that are in place in order to ensure the rights, safety, and well-being of participants in clinical trials.

- Fact Sheet: Informed consent – Vulnerable populations

  Size: 103,983 bytes, Format: .docx

  This fact sheet covers the additional considerations that must be taken into account when obtaining informed consent from patients who belong to vulnerable populations.

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