Promotional Material

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Informational Material

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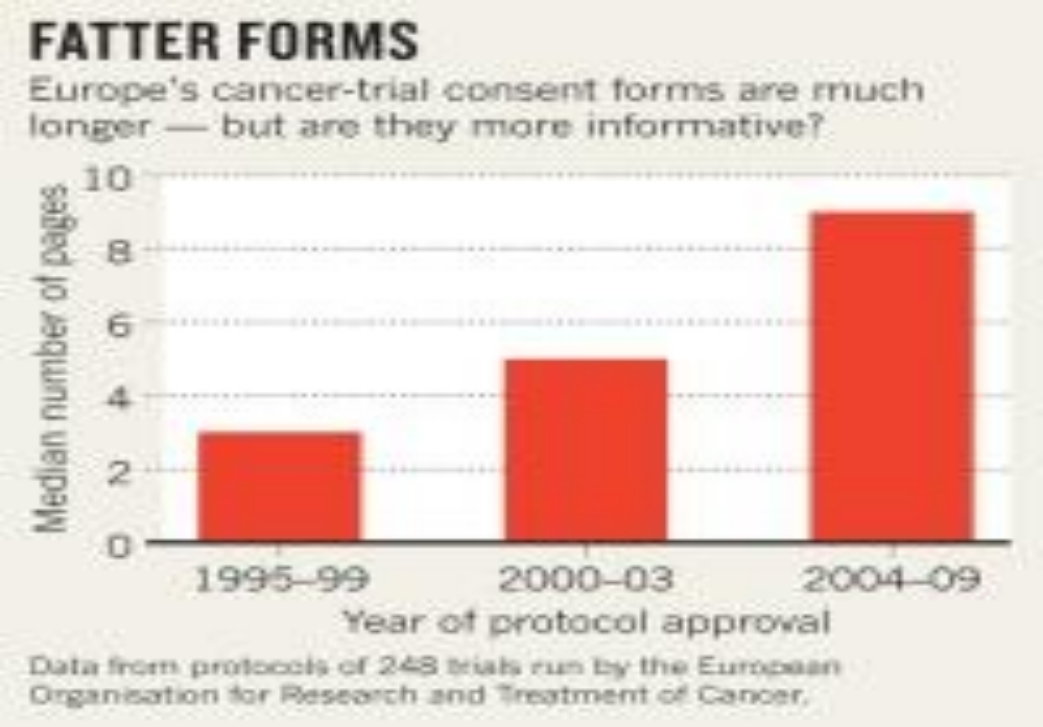
Some context…

NRES Guidance

- "Information…only one part of the process of seeking consent".
- "…consider how best the research might be presented…"
- "…discussion and questioning are the most effective means of providing information."
- "Studies with little or no intervention and less than minimal risk are likely to need a much shorter information sheet"
- "…you need not complete all sections."

Some more context…

- Survey of information sheets for cancer trials, by the European Organisation for Research & Treatment of Cancer



n = 248

D Cressey. *Nature* 2012; 482: 16.

Yet more context…

THE INDEPENDENT

Millions 'cannot read well enough for karaoke'

By Paul Bignell (17 December 2006)

Millions of adults have such poor reading skills that they struggle to keep up with karaoke lyrics, government research has found.

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- Sir Claus Moser report *(DfE,* 1999): 1 in 5 UK adults not "functionally literate"

What are trial sheets for?

- Trial sheets…
  - **Manifest function**: a decision-making tool.
  - **Latent function**: a prospectus and a contract.

- The sheet is… "*the outcome of a process of institutional scripting…"*
- Patients… *"do not recognise (the information) as operating primarily in their interest."*

Mary Dixon-Woods' research group, University of Leicester.

N Armstrong, et al. Sociology of Health & Illness 2012;
doi: 10.1111/j.1467-9566.2012.01469.x

Treweek et al. 2011 SR

- 45 trials.
- At least 16 were of altered information
- Trials mostly small
- …and heterogeneous
- Inconclusive pattern of results

Can we improve the information?

Revised format and wording by using…

- plain English;
- good practice in writing for patients;
- graphic design;
- user testing (small sample work).

AML16 trial: P Knapp, DK Raynor, J Silcock, B Parkinson. *BMC Medicine* 2011; 9: 89.

TGN1412 trial: P Knapp, et al. *J Med Ethics* 2009; 35: 573-8.

'Poor responders' trial: P Knapp, et al. *Trials* 2009; 10: 79.

NRIC AML-MDS TRIAL

PATIENT INFORMATION SHEET 2 & CONSENT FORM 2

1. **Study title**

AML-MDS Trial

2. **An invitation to participate in the AML-MDS trial**

You are being invited to take part in a clinical trial. Before you decide it is important for you to understand why the research is being done and what it will involve. Please take time to read the following information carefully and discuss it with others if you wish. Ask us if there is anything that is not clear or if you would like more information. Take time to decide whether or not you wish to take part.

Thank you for reading this information. If you decide to take part you will be given a copy of this information sheet and your signed consent form.

3. **What is the purpose of the AML-MDS trial?**

Acute Myeloid Leukaemia (AML) and Myelodysplasia (MDS) are malignant conditions of the bone marrow. They both result in failure of the bone marrow to manufacture enough blood cells (red cells, white cells and platelets), because the marrow contains too many leukaemia cells. The details of these conditions will have been explained to you by your Haematology Team. There are two approaches to treatment and these will be explained to you by your treatment team. The first comprises between 2 and 4 courses of intensive chemotherapy which are given 4-6 weeks apart usually as an inpatient. The aim of treatment is to kill off the leukaemia cells and allow the marrow to work normally which is called disease remission, and is expected to happen after the first or second treatment course. Because there is a risk of the disease coming back a further 2 or 3 courses of treatment are given. This approach has risks associated with it. This approach may or may not be considered suitable for you.

The second approach is to use drugs to control the leukaemia cells in the bone marrow rather than to try to get rid of them completely. This approach is less intensive and some of the treatments can be given by mouth and taken as a outpatient. The chances of the disease going into complete remission are lower, but much less time in hospital is required.

For some patients, particularly those who are less fit or have other medical conditions, this may be thought to be a better approach. Which treatment approach is adopted for you will be decided after you have had a discussion with your doctor.

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Newland Hill NHS
NHS Foundation Trust

AML-MDS Clinical Trial

National Research Institute For Cancer
Acute Myeloid Leukaemia and High Risk MDS Trial

We invite you to take part in a research study

- Before you decide whether to take part, it is important for you to understand why the research is being done and what it will involve.
- Please take time to read the following information carefully. Discuss it with friends and relatives if you wish. Take time to decide whether or not you wish to take part.
- You are free to decide whether or not to take part in this research study. If you choose not to take part, this will not affect the care you get from your own doctors.
- Ask us if there is anything that is not clear or if you would like more information.
- Thank you for reading this information. If you decide to take part you will be given a copy of this information sheet and your signed consent form.

Important things that you need to know

- We want to find out the best non-intensive treatment for Acute Myeloid Leukaemia (AML) and Myelodysplasia (MDS).
- We are testing three new medicines, which are Clofarabine, Mylotarg and Trisenox, and an existing medicine, which is Cytarabine.
- The medicines are given separately or together with other medicines, and this trial has four different groups or treatment options.
- Regardless of which treatment group you are in, you will receive four courses of treatment.
- Like all medicines used to treat leukaemia, the medicines used in this trial can have side effects.
- The trial fits into your normal treatment, so there are no extra hospital visits.
- You can stop taking part in the study at any time, without giving a reason.

Contents

How to contact us

If you have any questions about this study, please talk to your doctor at

Haematology Unit
Newland Hill NHS
Foundation Trust
Newland Hill Hospital
London NW16 7BJ
Tel: **01234 149 688**

AML16 trial sheet study

n=116

- **Participants finding & understanding all points:**

  Original 8 / 55; Revised 40 / 61

  (Chi^2= 31.5; p<.001; Odds ratio = 11.2)

P Knapp, et al. *BMC Medicine* 2011; 9: 89.

Testing revised information

n=116

- **Participants finding & understanding all points:**

  Original 8 / 55; Revised 40 / 61

  (Chi^2= 31.5; p<.001; Odds ratio = 11.2)

- **Reading time (mins):**

  Original 27.6 (sd 11.4); Revised 28.4 (sd 12.9)

  (F = 0.30; p=.86)

P Knapp, et al. *BMC Medicine* 2011; 9: 89.

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  Original sheet 8 /55; Revised sheet 40 /61

  (Chi^2= 31.5; p<.001; Odds ratio = 11.2)

- **Reading time (mins):**

  Original 27.6 (sd 11.4); Revised 28.4 (sd 12.9)

  (F= 0.30; p=.86)

- **Preferred sheet:**

  Original 15 /116; Revised 101 /116

  (Sign test p<.001)

P Knapp, et al. *BMC Medicine* 2011; 9: 89.

THE UNIVERSITY of York
The Department of Health Sciences

Thoughts and ideas

1. The effect of revised information on recruitment (START)
   - writing to people at home or recruiting in person
2. What effect on recruiting clinicians?
3. Information preferences (Antoniou, *J Med Ethics* 2011)
   - complexity; media; content
4. Informed decision making
   - options; value sensitive; structured guidance to decision-making
5. Targeting those least likely to take part.

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