

Supporting the trial design process



DESIGN-A-TRIAL
decision support for
clinical trial design

The complexity of clinical trials from both a medical and statistical perspective makes trial design and protocol authoring difficult and time-consuming. Clinicians and other health workers involved in authoring trials often have limited experience in research and limited access to statisticians.

Design-a-Trial is a decision support system to assist in the design of clinical trials.

Users enter details about their planned trial, and Design-a-Trial provides guidance on trial design and on statistical, medical and ethical issues, and generates both a draft trial protocol, compliant with clinical research guidelines such as Good Clinical Practice, and the ethics application form.

Design-a-Trial provides:

- guidance to the user in designing scientifically sound clinical trials
- statistical support and sample size calculations
- guidance and expert advice on trial design, statistical, medical and ethical issues
- a trial outline showing the schedule in graphical form
- the first draft of the protocol document and ethics application form
- a register of investigators and key personnel as required for the protocol and ethics forms



With Design-a-Trial it takes just a few hours to generate a structured protocol and an outline ethics application form.

The screenshot shows a software window titled 'CLHAR1 WEL - Design-a-Trial - Cover Sheet'. The interface includes a menu bar (File, Tools, View, Help) and a toolbar. A 'Browser' pane on the left lists various trial components like 'Cover Sheet', 'Trial Disorder Overview', 'Trial Interventions Overview', 'BOOST TREATMENT', 'Substitution Ethics Overview', 'Randomisation Overview', 'Measures Overview', 'Wash Procedures Overview', 'Allocation Overview', 'Trial Blinding Overview', 'Follow-up Overview', 'Data Analysis Overview', and 'Ethics Overview'. The main area is titled 'Cover Sheet' and contains a form with the following fields:

1. Trial identification number: [041-5390]
A trial ID has been generated for you. You can change this if you wish.
2. Full name of trial: [A Randomised Controlled Trial of CHARTWEL (a Continuous Hyperfractionated Accelerated Radiotherapy schedule) versus Conventional Radiotherapy in post-operative head & neck cancer patients.]
3. Short name of trial: []
4. Primary objective of the trial: [The aim of the study is to compare CHARTWEL given over a 18-day period with conventional radical radiotherapy given daily over a 6-week period. Preventing recurrence of the disease is the primary outcome measure.]
5. Secondary objectives of the trial: [Toxicity from the treatments, both early and late, disease-free, overall survival and quality of life will also be assessed.]
6. Expected number of trial centres: []
7. Expected duration of trial: [] []
From after recruitment to end of follow-up e.g. 3 years
8. Principal investigator name: []
Click on the address book to add a new person or to use someone already stored.

Figure 1 – an example of a data entry form in Design-a-Trial

Guidance in design



DESIGN-A-TRIAL decision support for clinical trial design

Design-a-Trial utilises medical knowledge (including indications, methods of measuring indications and drug information), statistical knowledge and ethical knowledge.

Design-a-Trial can use medical knowledge to highlight potential problems in the proposed trial, recommend patient exclusion criteria based on drug treatments and inform the user of drug contra-indications, interactions and side effects.

Statistical knowledge is used to assist the user in choosing tests for statistical analyses and to generate recommended sample sizes for each arm of the trial.

Ethical knowledge is used to prompt the user on ethical issues that should be considered in clinical research involving human participants.

Design-a-Trial supports the trial design process, while allowing investigators to design trials in ways they find comfortable.

As details of a trial are entered, Design-a-Trial generates a draft protocol that can be viewed in html or text format. In the html format, by clicking on links displayed, the user can view the page where data was first entered. In the text format the protocol can be amended in a word processing environment.

Design-a-Trial also links to *InferMed's* electronic data collection system MACRO to automatically generate the electronic case report forms for the trial.

Design-a-Trial enhances your expertise by:

- encouraging rigorous design that leads to effective trials with valid results
- helping your trials gain approval (clinically and ethically) first time round
- providing expertise to support both new and experienced trial designers



Advice View

? Please note the following advice

The intervention you are placing involves administration of amoxicillin, which changes the natural history of the trial disorder URTI, so you must either select a symptomatic therapy or consider a parallel group study in preference to a crossover study.

You may either accept or ignore the advice. If you choose to ignore it some justification for doing so should be entered in the box below.

If you choose to ignore this advice, please enter some justification for doing so.

Figure 2 – an example of an advice message



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