Supporting the trial design process

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.

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

Figure 2 – an example of an advice message

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