e-Science and ethical/regulatory issues

a comparison with randomised clinical trials

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What is a randomised clinical trial?

- Has information technology at its core
- Establishes an evidence base for a choice in health care
- Equivalent treatments are compared between balanced patient populations (random decision to treat must be ethical)
- Ideally, treatment is double-blind
- Detailed personal information collected on participants
What is a randomised clinical trial (cont...)?

- Periodically reviewed (decision to randomise/adverse events)
- Typically 5 years to complete recruitment of c. 2,000 patients
- Subject to endpoint, data collection can take up to 5 further years to complete
- Results analysed and published
- Further follow-up can continue for many years if appropriate/funded
Why are clinical trials routine?

- Well established groove with over 155 public sector cancer trials currently recruiting in the UK
- Collects prospective, informed consent
- Peer review by funding medical research organisation prior to ethical approval means little question of the importance of the proposal
- 26 large offices (running cancer studies) dedicated to supporting clinical trials
- Familiar consortia: clinician as Principal Investigator, Senior Statistician probably already known to MREC
- Trials coordination is a well defined skill
Trial Design and Execution

- From initial concept to recruitment of first patient can take up 3 years
- Prospective informed consent greatly simplifies the ethical approval process
- Does not use cutting edge IT and rarely establishes new systems
- Informed consent specifies which non-NHS staff see data and describes their duty of care
e-DiaMonD and Ethics Issues

- Legal case for implicit consent overridden at MREC
- Presentation difficulties, resolved by having a clinician to front negotiation
- Administrative difficulties in finding people in the Trusts to get project staff onto honorary NHS contracts (≡ duty of care)
- Still having to plan for PIAG submission
How can future e-Science projects ‘ride the groove’

- Plan for prospective collection of informed consent
- Take care over consent form and you can allow for changes in research purposes
- Try to keep the proposed work focussed and concise to streamline ethical approval
- Understand clinical trials and try express your project on the same terms if possible
- Consider including a large CTO within your consortium: ensure they contribute to planning and approval
- Consultancy services are also available