Data release from publicly funded trials

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Publicly funded trials

~ 60 % of ‘interventional studies’ registered on ClinicalTrials.gov have ‘non-industry’ funders

Antiepileptic drug monotherapy for epilepsy: a network meta-analysis (Protocol)

Nolan SJ, Sudell M, Weston J, Tudur Smith C, Marson AG

60% of trials publicly funded
Access to IPD from publicly funded clinical trials
The International Stroke Trial database

Peter AG Sandercock\textsuperscript{1*}, Maciej Niewada\textsuperscript{2,3}, Anna Cz\l{}onkowska\textsuperscript{2,3} and for the International Stroke Trial Collaborative Group

Abstract

Background: We aimed to make individual patient data from the International Stroke Trial (IST), one of the largest randomised trials ever conducted in acute stroke, available for public use, to facilitate the planning of future trials and to permit additional secondary analyses.

Methods: For each randomised patient, we have extracted data on the variables assessed at randomisation, at the early outcome point (14-days after randomisation or prior discharge) and at 6-months and provide them as an analysable database.

Results: The IST dataset includes data on 19,435 patients with acute stroke, with 99\% complete follow-up. Over 26.4\% patients were aged over 80 years at study entry. Background stroke care was limited and none of the patients received thrombolytic therapy.

Conclusions: The IST dataset provides a source of primary data which could be used for planning further trials, for sample size calculations and for novel secondary analyses. Given the age distribution and nature of the background treatment given, the data may be of value in planning trials in older patients and in resource-poor settings.
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Welcome to freeBIRD

A new website which allows free access to a bank of injury and emergency research data.

Making clinical trial data sets available to investigators from the FREEBIRD project team can improve patient care, advance medical knowledge and provide better value for money from health research.

The FREEBIRD website aims to facilitate data sharing in the area of injury and emergency research in a timely and responsible manner. It has been launched by providing open access to anonymised data on over 30,000 injured patients (the CRASH-1 and CRASH-2 trials).

We hope that other trial investigators will also upload their datasets and that FREEBIRD becomes a valued resource for all those committed to improving injury and emergency care.

Open Access
Restricted access (vs open access)

• Less efficient for data users
  – Time to data 2-12 months in our experience

BUT

• Agreement in place to protect data use
  – Reduces risk of re-identification or inappropriate use
    – Potential to share richer data

• Dialogue with original researchers may be easier?
UK Clinical Research Collaboration network of 45 CTUs

23 (51%) CTUs responded to the survey
Phase 1: CTU survey

- 30% had made a request for IPD in the last 12 months
  - Meta-analysis, follow-up of trial participants, methodological research, feasibility of setting up registry
- 65% had received a request for IPD in the last 12 months
  - Most common reason was for meta-analysis
  - All requests had been fulfilled (some partially)
Phase 1: CTU survey

• 70% would transfer their clinical trial data to a central repository (with restrictions/conditions)

• Approval process preference
  ➢ Open access 0
  ➢ Learned intermediary 25%
  ➢ Internal Review process 75%

• Data Access preference
  ➢ Central repository 25%
  ➢ Direct transfer 25%
  ➢ Restricted interface 50%
Phase 1: CTU survey

• Most common concerns about data sharing:
Phase 2: Guidance

- CTU survey
- Literature review
- Review of data sharing policy documents

Draft Guidance

Expert panel

Consultation with CTU network

Final Guidance
Phase 2: Guidance

“This guidance has been endorsed by Cancer Research UK, MRC Methodology Research Programme Advisory Group, Wellcome Trust and the Executive Group of the UK CRC Registered CTUs Network. The National Institute for Health Research (NIHR) has confirmed it is supportive of the application of this guidance.”

Guidance: Good practice at CTU/sponsor level

- **Policy**
  - A data sharing policy should be developed by the CTU

- **Scope**
  - IPD and associated documentation should be made available for all prospective publicly funded clinical trials and as soon as possible e.g. 18 months after trial completion

- **Data request process**
  - Sponsor approval for data sharing should be sought
  - Only bona fide research groups should be eligible to access data
  - Data access requests should be made via application
  - Data access requests should be reviewed against specific criteria within 3 months
  - Details of all data requests and their outcomes publicly available

- **Data release process**
  - Data should be made available as soon as possible after approval of requests
  - Data should be made available on a secure server or via other secure data transfer method
  - Supporting documentation should be supplied with the dataset

- **Data use agreement**
  - A data use agreement should be utilised

- **Resources**
  - Funds requested from trial funders as part of initial trial grant applications
  - Reasonable costs may be recovered from data requesters if appropriate (not profit generating)
  - Host organisations to provide funds for ongoing support of a data sharing system
Guidance: Good practice at trial level

• **Prior to trial funding**
  – Identify data sharing stakeholders and highlight the data sharing policy
• **During trial set-up**
  – Identify roles and responsibilities for data sharing on delegation log
  – Include outline plans for data sharing in the protocol
  – Include detailed plans for data sharing in the trial data management plan
  – Include a data sharing statement in the consent form and information in the patient information leaflet.
  – Annotate the complete set of blank Case Report Forms (CRFs)
• **End of trial**
  – Prepare the anonymised dataset ready for sharing (level of anonymisation should be determined in conjunction with other considerations such as original patient consent and method of data transfer)
  – Dataset preparation should be done by individuals with an understanding of data management and basic statistics, with quality control provided by a further individual who is independent of the process
  – Prepare ‘data pack’ ready for sharing. This would typically include (i) electronic datasets (ii) supporting documentation (minimum requirement would be protocol with amendments, blank CRFs, dataset specifications including data variable amendments). Timing of data pack preparation may be reactive or proactive.
Phase 3 - Implementation

- Guidance to appear in open access journal and disseminated
- UKCRC Data Sharing Task and Finish Group established

**Remit**
To facilitate the implementation of data sharing good practice across the UKCRC registered CTU network, to provide advice and support to CTUs about data sharing, and to liaise with external organisations regarding data sharing.

**Aim**
To help every UKCRC registered CTU implement, or develop a plan for implementation of good practices for sharing data from clinical trials by the end of 2016.
Thank you

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