Open versus restricted access to full academic trial protocols: advantages and disadvantages

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Objective

• To examine the approaches to protection of intellectual property (IP) in two multi-centre trials currently being conducted in Canada.
What is/is not an “academic trial”? 

• **IS NOT:**
  – industry initiated

• **IS:**
  – initiated by the principal investigator

• **COULD BE:**
  – clinical
  – health technology assessment
  – compare treatments or treatment policies

• Funded or not

• Peer-reviewed or not
What is IP?

• Legal rights that result from intellectual activity in the industrial, scientific, literary and artistic fields.
• Outcome of creative work
• Trade marks and patents

• What is the IP in academic trials?
IP in academic trials

- Sample selection
- Recruitment/consent
- Baseline data
- Randomisation
- Intervention
- Outcome measurement
- Analysis
- Interpretation

The art of trial design
Standardised elements
IP associated with the package
Two examples

• **CHIPS (Control of Hypertension in Pregnancy Study, ISRCTN71416914)**
  - women with hypertension - randomised to tight or less tight control of hypertension.
  - primary outcome: composite of pregnancy loss/neonatal intensive care.
  - recruiting 1028 pregnant women in 14 countries.

• **FACT (Folic Acid Clinical Trial, ISRCTN23781770)**
  - pregnant women - randomised to receive either 4 mg folic acid or placebo daily.
  - primary outcome: development of pre-eclampsia.
  - recruiting 3656 pregnant women in 4 countries.
Approaches to protecting IP

- **CHIPS** – “open access”
  - publish protocol
  - [http://sunnybrook.ca/research/content/?page=sri_proj_cmicr_trial_chips_home](http://sunnybrook.ca/research/content/?page=sri_proj_cmicr_trial_chips_home)
  - Lancet

- **FACT** – “restricted access”
  - non-disclosure agreements (NDAs)
  - local investigators/institutions must sign NDA before full protocol is provided
Open access

• **Positive consequences**
  – possible/actual sites have easy access to full study design;
  – potential for open discussion between collaborators;
  – study investigators held to high standards of reporting.

• **Negative consequences**
  – details are available with potential for plagiarism.
Restricted access

• **Positive consequences**
  – details of study only available if legal agreement is signed.

• **Negative consequences**
  – may restrict academic openness and collegiality;
  – provide additional barriers to site recruitment;
  – investigators may select the results they wish to present (even if trial is registered).
Discussion

• Academic institutions
  – reputation and wealth depends on IP
  – need to protect their IP and that of investigators
  – risk management approach

• NDAs
  – the legal way to “protect” IP
  – may suggest lack of trust in co-investigators

• IP in academic trials is difficult to pinpoint
Discussion

• Selective reporting of outcomes from RCTs
  – half of registered trials not published
  – inadequate description in registries
  – description of outcomes
    • vague description
    • unreported substantive changes between registration/publication
    • outcomes not reported
    • significant outcomes more likely to be reported than non-significant
Discussion

• **Open access** to trial protocols will not prevent bias in reporting
• **But** investigators will be held to higher standards of reporting
• **NDAs** are becoming more common in Canada
  – could be unstoppable trend
  – delaying recruitment of sites
  – potential for bias in reporting
Conflict of interest/bias

- **Laura Magee** – PI for CHIPS
- **Sue Ross** – Steering/working committee member for CHIPS
- **Stephen Wood** – Calgary site investigator for FACT
References


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