NHS Tayside/University of Dundee: Joint Research Office:

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Boosting compliance rates at Universities: Where are we now?

• **Accusation:**

Sponsors, including Universities, the NHS, and Chief Investigators were behaving unethically in not reporting their clinical trial results.

A situation which harms patients, wastes taxpayers' money, and slows down the development of new treatments, vaccines and cures.

Lack of transparency
Not reporting results?!?! But we’ve been inspected.....

• Should we take this complaint seriously?

• 28/39 are published in journals
• 5/39 are not published despite completing >1 yr ago (so 13%, not 60%)
• 3/39 are under analysis but not yet published (mostly completed v recently)
• 2/39 either weren’t completed or might have been completed but not published
• 1/39 is still ongoing

• UoD only 49/211 results uploaded (23%)
• Transparimed accusation correct. We had not been uploading results.
• RECOGNITION THAT THIS IS AN ISSUE THAT NEEDED ATTENTION!
• We cannot behave or be perceived to behave unethically!
Recognise the environment we work in - Tayside
Actions

• Employed a dedicated person
  • Still not always 100%....
  • Still face problems
  • Still sometimes late

To the Public therefore, are we still not being transparent?
Patient and Public Involvement

• Patient and Public Involvement with researcher
  • Reviewing participant information sheets
  • Contributing to the design of research
  • Contributing to the conduct of the research

• Sponsor expectations
  • Had there been involvement?
  • Requesting evidence of involvement
Which studies?
Which Registers?

• All projects to be registered
• If not, why not?
• Cost of registration to be included in grant application where permissible

• NHS REC Committees now looking for this

• Eudract mandatory for CTIMPS
• ISRCTN for others
• No longer as Sponsor routinely approving registration on Clinicaltrials.gov
Possible areas for Sponsor involvement

• **How do we manage expectations?**
  • Not all PPI suggestions are possible to carry out

• **How do we help with an understanding of legal constraints?**
  • Insurance
  • Data Protection

• **How do we develop general knowledge of approvals processes?**
  • What is Sponsor, REC, R&D
Was there a need for greater understanding?

- No one responding to short survey had heard of eudract
- No one responding knew what the Sponsor was
- Everyone had heard of ‘ethics’ but not the role it plays
- No one had heard of Clinicaltrials.gov
- Everyone said Pharma companies are in charge of drug trials
- No one correctly knew the role of NHS R&D
Sponsor / PPI

We are making ourselves available

• ZOOM meetings with PPI groups
• Q&A sessions
• Training events (on hold currently due to COVID)

Helping the public understand how we govern trials
Explaining the role of other ‘approvers’
Encouraging involvement