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

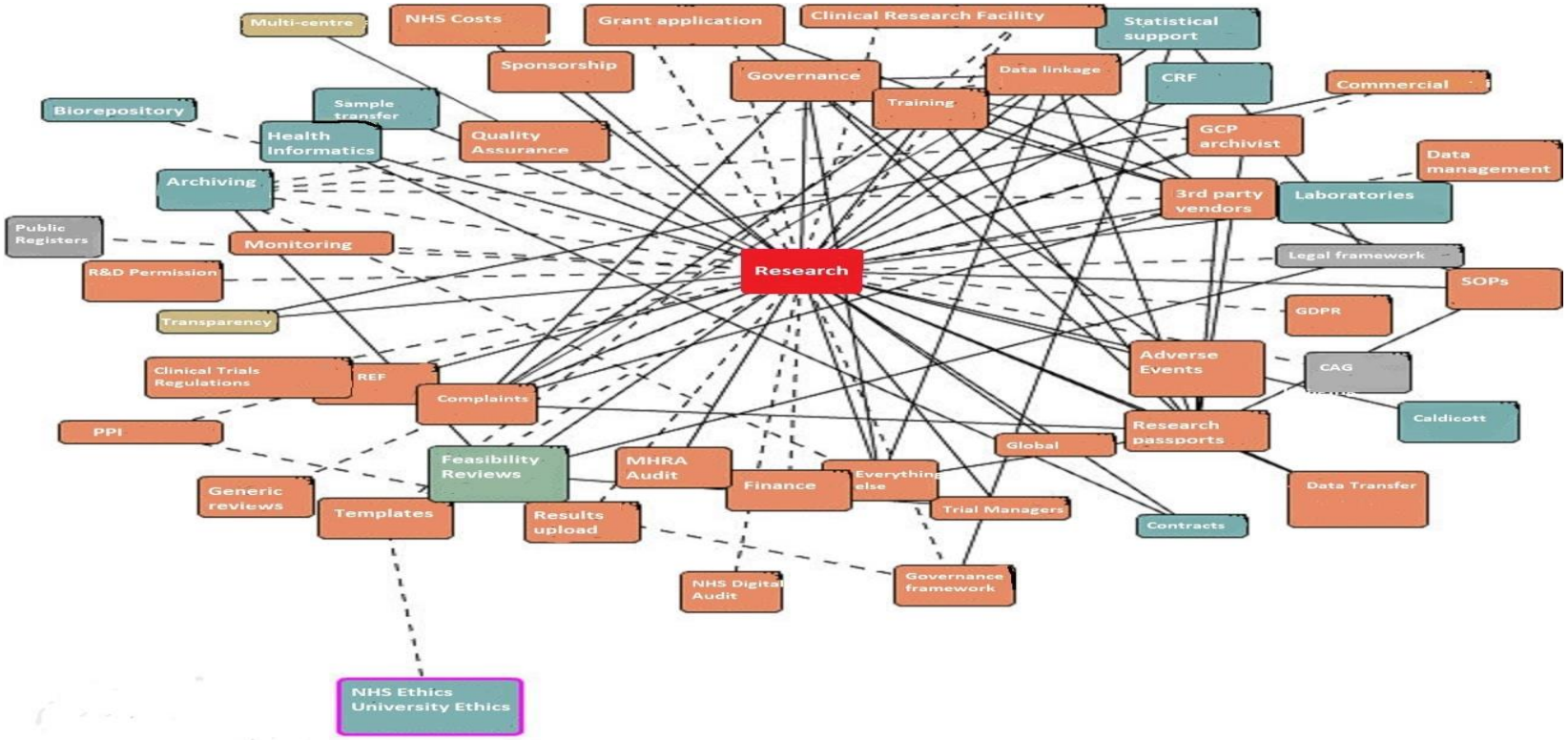
Not reporting results?!?!
But we've been inspected.....

- 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

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- **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

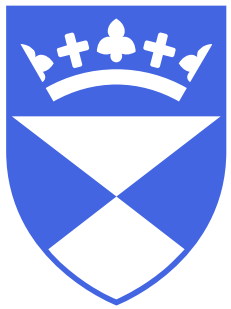
We are making ourselves available

- 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



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