Using routine data for recruitment and follow-up in large-scale clinical studies

Dr Michael Lay
CTSU, OXFORD
Who?

- HPS (Randomised 20,000)
- SEARCH (Randomised 12,000)
- ASCEND (Randomised over 10,000)
- THRIVE (Randomised 25,000, 8,000 in the UK)
- BIOBANK (Recruited 500,000)
UK BIOBANK

- Prospective trial.
- Aim to recruit 500,000 across ~20 sites.
- Inclusion criteria: age 40-70
- Sent ~9M invites to people within the catchment area of an assessment centre.

→ Automation Essential
UKB Process

- Acquire data
- Clean data, allocate to assessment centre.
- Invite to fill centre.
- Other stuff...
UKB Recruitment

Cumulative recruitment over time, showing data from April 2007 to June 2010 for various locations.
THrive

- Study in patients with heart related problems.
- Randomised 25,000 (8,000 in UK).
- Many assessment centres.
- Recruitment via local datasets.

- Dealt with over 170 individual data cleaning exercises. No two trusts the same.
ASCEND

- Study in diabetics.
- Postal – no assessment centres.
- Recruitment via multiple routes.

→ Lack of central access makes this study very hard.
Long Term Follow-Up?

- It could be worse...
Long Term Follow Up

- Death Registries
- Cancer Registries
- HES Data
- Other data sources

→ Importance of unique identifiers
Current THRIVE Follow-Up Processes

- Via the patient (not always reliable)
- Via the local site/nurse (can be problematic...)
- Some registries
- Not as practical for UKB or ASCEND.
Conclusion

- Existing registries can be very useful in Long Term Follow-Up and recruitment
  - Cheaper
  - Easier
  - Less intrusive
  - More comprehensive
And we’re done...

- Questions?