Clinical Trials in the era of Big Data: changing the paradigm

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Big Data and Clinical Trials

Unlocking the potential of NHS Patient Data in Research

Observational & Interventional
CPRD
{Clinical Practice} {Research} {Datalink}

1. Clinical Practice

2. Data-Link

Linkage
3. Research

Did the investigator assign exposures?

- Yes: Experimental study
  - Random allocation to groups?
    - Yes: Randomised Controlled Trial
    - No: Non-randomised designs
- No: Observational study
  - Testing a hypothesis?
    - Yes: Analytical study
      - Sampling based on Exposure: Cohort study
      - Outcome: Case-control study
      -Neither: Cross-sectional study
    - No: Descriptive study
New paradigm
Pragmatic trials

- **RETRO-PRO**: the effectiveness of simvastatin compared to atorvastatin—a feasibility study (ISRCTN33113202)

- **eLUNG**: the effectiveness of antibiotics compared to no antibiotics for exacerbations of chronic obstructive pulmonary disease: a feasibility study (ISRCTN72035428)

  Dregan et al, 2014; Gulliford et al, 2014
New paradigm

Data | Regulation | Multiple Stakeholders
Regulation

Medicines and Healthcare Products Regulatory Agency

more dimensions to data

Biologics Standards & Controls

Medicines Devices CT Regulator
Stakeholders

- Funders
- Academia
- Industry
- Regulatory
- Healthcare
- Patients
Feasibility and Patient Recruitment

• 1/3 of all protocol amendments relate to protocol description and patient eligibility criteria.¹

• 50% of today’s clinical trials fail to achieve target recruitment rate.²

¹ Getz et al, Tufts CSSD, PR IR Sep-Oct 2011.
Protocol Design / Optimisation

• Trial design usually based on discussions with expert clinicians.¹

• 60% of all CT protocols are amended during the trial.²

• Completed protocols incur an average of 2.3 amendments = an average of 6.9 changes to the protocol.²

• 1/3 of protocol amendments are avoidable.³

• One protocol amendment incurs on average a cost of $0.5m.⁴

• 43% of protocol amendments occur before first patients are enrolled.²

¹ Proeve, CBI ClinTech, 03/2014.
Clinical Trial Delays

• Median total cycle time to identify and resolve a protocol problem is 61 days.\(^1\)
• Percentage of trials completing enrollment on time: 18% in Europe, 7% in the US.\(^2\)
• Almost 50% of all trial delays caused by patient recruitment problems.\(^3\)
• Each day a drug is delayed from market, sponsors lose up to $8m.\(^4\)

\(^1\) Getz et al, Tufts CSSD, PR IR Sep-Oct 2011.
\(^3\) Study Participant Recruitment & Retention in Clinical Trials: Emerging strategies in Europe, the US and Asia, Business Insights, June 2007.
\(^4\) Beasley, “Recruiting” 2008
New paradigm

Trials Suite
Clinical Practice Research Datalink


