Priority setting the opportunities for routinely collected data and trials: COMORANT-UK

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To systematically identify ongoing challenges for use of routinely collected data in trials, from the perspective of all relevant stakeholders in the UK.
Methods

3-step Delphi method with two rounds of anonymous web-based surveys and a virtual consensus meeting with key stakeholders.
Stakeholders

- Trialists/Data Scientists
- RCD infrastructures
- Funding bodies
- Data providers
- The public
- Support networks
- Regulating bodies
Survey 1: Identifying all remaining questions and challenges

Please consider all aspects of the study lifecycle when considering what are the remaining unanswered questions and challenges.

Please list all of the challenges and research questions that you can think of.
What routine data do you work with?

- Secondary care EHRs: 85%
- Mortality data: 64%
- National registers/audits: 58%
- Primary care EHRs: 50%
- Children’s social care: 12%
- Education: 11%
- Adult social care: 9%
- Criminal justice, benefit, other: 7%

- n = 66
  - 77% - Trialist
  - 9% - Member of public
  - 6% - Data Provider
  - 5% - Funder
  - 2% - Supports trials

Challenges / questions submitted: 260+
How can routine data access from all providers be expedited to allow timely analysis of outcomes?

“Data access times do not suit the requirements of clinical trials.”

“How can access to routine data be expedited?”

“It can take a long time to get routine data, delaying trial analysis”

“not ... feasible ... to replace trial-collected data for the assessment of trial outcomes unless ... obtained within a similar timeframe.”

“We have experienced delays of over a year”

“Substantial delays in obtaining approvals to receive data”
Survey 2: Selecting a top 10

- N=88 respondents
- All 40 questions included in a respondent’s top 10 at least 5 times
- Highest ranked question was included 50 times
Consensus Meeting

1. Discuss survey 2 ranked questions
2. Consider additional questions
3. Agree top list to take forward
4. Finalise wording of these

N= 13 Stakeholders
Agreed Top Seven

**Trial Design**
- **Data collection method**: When is it more efficient, considering trial design, costs, time and environment, to use routinely collected datasets compared to bespoke data collection?

**Outcome selection**: How should the trials community decide when routinely collected data for outcomes is of sufficient quality and utility to replace bespoke data collection?

**Patient and Public Involvement**: What are the best methods to communicate and build trust with trial participants (and the public) about how their routinely collected data will be used?

**Trial Set-up**
- **Regulatory Approvals**: How can approvals at trial set-up be streamlined across regulatory and data provider applications?
- **Data access and receipt**: How can routinely collected data flow (approval through to data provision) from all providers of data be expedited for analysis?

**Trial Open**
- **Data quality**: What causes inconsistencies in routinely collected data across sources and how can these be identified, managed and reconciled for key trial outcomes (e.g. fact and date of death)?
- **Trial analysis**: Why are data missing in routinely collected datasets (person and individual data fields) and how should this inform methods for managing missing data?

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https://www.cardiff.ac.uk/centre-for-trials-research/research/studies-and-trials/view/comorant-uk
**HDRUK North:** How should the trials community decide when routinely collected data for outcomes is of sufficient quality and utility to replace bespoke data collection?

- Sep meeting: Develop agreement on guidance
- Next steps: Consensus work and piloting

**Cardiff:** What are the best methods to communicate and build trust with trial participants and the public about how their routinely collected data will be used?

- Online course via HDR UK Futures
- Next steps: Survey CTUs and discussions with trial teams

Next steps: PRIMORANT (HDRUK)
Launched: 13th November

Routine Data in Clinical Trials: Building Public Trust

Module 1: Course introduction

Module 2: Drivers of public trust

Module 3: Involving & engaging – and inclusivity

Module 4: Communicating about routine data

Module 5: Funding and measuring impact

https://www.hdruk.ac.uk/careers-in-health-data-science/futures/
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