Title: Priority setting the remaining opportunities for the use of routinely collected data in trials: COMORANT-UK

Applicants:

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Background and Summary of Original Objectives

Researchers are increasingly seeking to use routinely collected data to support data collection in clinical trials. This approach has potential to transform the way clinical trials are conducted in the future. The availability of routine data for research, whether healthcare or administrative, has increased and infrastructure funding has enabled much of this. However, challenges remain at all stages of a trial life cycle.

The COMORANT-UK study aimed to systematically identify, with key stakeholders across the UK, the ongoing challenges related to trials that seek to use routinely collected data.

What was achieved

This 3-step Delphi method consisted of two rounds of anonymous web-based surveys (steps 1 and 2), and a virtual consensus meeting (step 3). Stakeholders included trialists, health relevant data infrastructures (i.e. HDR UK), funders of trials, regulators (HRA, MHRA), data providers and the public. Stakeholders provided research questions/uncertainties that they believed are of particular importance (step 1), and then selected their top 10 in the second survey (step 2). The ranked questions were taken forward to the consensus meeting (step 3) for discussion with representatives of the stakeholder groups.

A total of 66 respondents yielded over 260 questions or challenges for the use of routinely collected data in trials. These were thematically grouped and merged into a list of 40 unique questions, 88 stakeholders then selected their top ten from the list in the second survey. The top 14 questions were brought to the virtual consensus meeting in which stakeholders agreed a list of seven priority questions.

The seven questions are:

1. How can routinely collected data flow (approval through to data provision) from all providers of data be expedited for analysis?
2. When is it more efficient, considering trial design, costs, time and environment, to use routinely collected datasets compared to bespoke data collection?
3. How can approvals at trial set-up be streamlined across regulatory and data provider applications?
4. How should the trials community decide when routinely collected data for outcomes is of sufficient quality and utility to replace bespoke data collection?
5. 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)?
6. Why are data missing in routinely collected datasets (person and individual data fields) and how should this inform methods for managing missing data?
7. 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?

These questions address both evidence gaps (requiring further methodological research) and implementation gaps (requiring training and/or service re-organisation).

Outputs / Examples of Impact

An infographic has been developed which summarises the top seven prioritised questions. This is available on the study page [https://www.cardiff.ac.uk/centre-for-trials-research/research/studies-and-trials/view/comorant-uk], the TMRP page and has been distributed to stakeholder networks.

An abstract has been submitted to ICTMC 2022 conference and accepted conference abstracts should be publicly available.

The full manuscript is currently being drafted with the intention to submit to Trials in July 2022: “Priority setting the remaining opportunities for the use of routinely collected data in trials: COMORANT-UK”

Next steps

HDR UK has recently funded two projects to study team members from the COMORANT-UK study that will begin to address the prioritised questions.

The PRIMORANT study was funded on the basis that it would select two of the top questions emerging from the COMORANT-UK study. It will address the following two questions through a combination of best practice guidelines and a training curriculum hosted by HDR UK Futures:
#4 - How should the trials community decide when routinely collected data for outcomes is of sufficient quality and utility to replace bespoke data collection?
#7 - 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?

The DUCkS study will provide an in-depth look at data utility using data from the STAMPEDE trial contributing to the growing evidence base required to answer *question #5 - 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)?*

The HDR UK submission for continued funding, which is currently under review, takes these questions forward in the next funding period with the intention to address through the trials workstream and development of training resources.

Finally, through the TMRP Health Informatics Working Group, other questions are already starting to be addressed that have been included in the top ranked questions for example developing standardised participant information and consent wording for trials linking to routinely collected data – ranked in the top 10 of COMORANT-UK.

These will all lead to further, collaborative projects and funding bids from across the community.