MRC-NIHR Trials Methodology Research Partnership: Webinar recording

SUMMER SESSION

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

Presented by Fiona Lugg-Widger (Cardiff University)

24 August 2022

The slides are also available below.

For any queries, please contact uktmn@nottingham.ac.uk

https://www.youtube.com/watch?v=McaUmLpBWmk

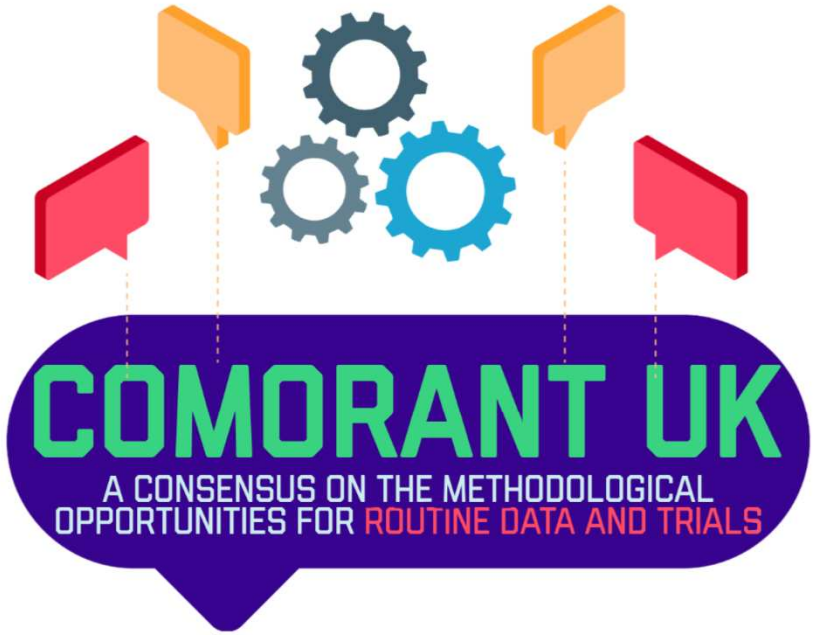
Supplementary links

COMORANT-UK website:
https://www.cardiff.ac.uk/centre-for-trials-research/research/studies-and-trials/view/comorant-uk

COMORANT-UK Study email: comorant-uk@cardiff.ac.uk

TMRP Health Informatics Working Group:

https://www.methodologyhubs.mrc.ac.uk/about/working-groups/health-informaticswg/

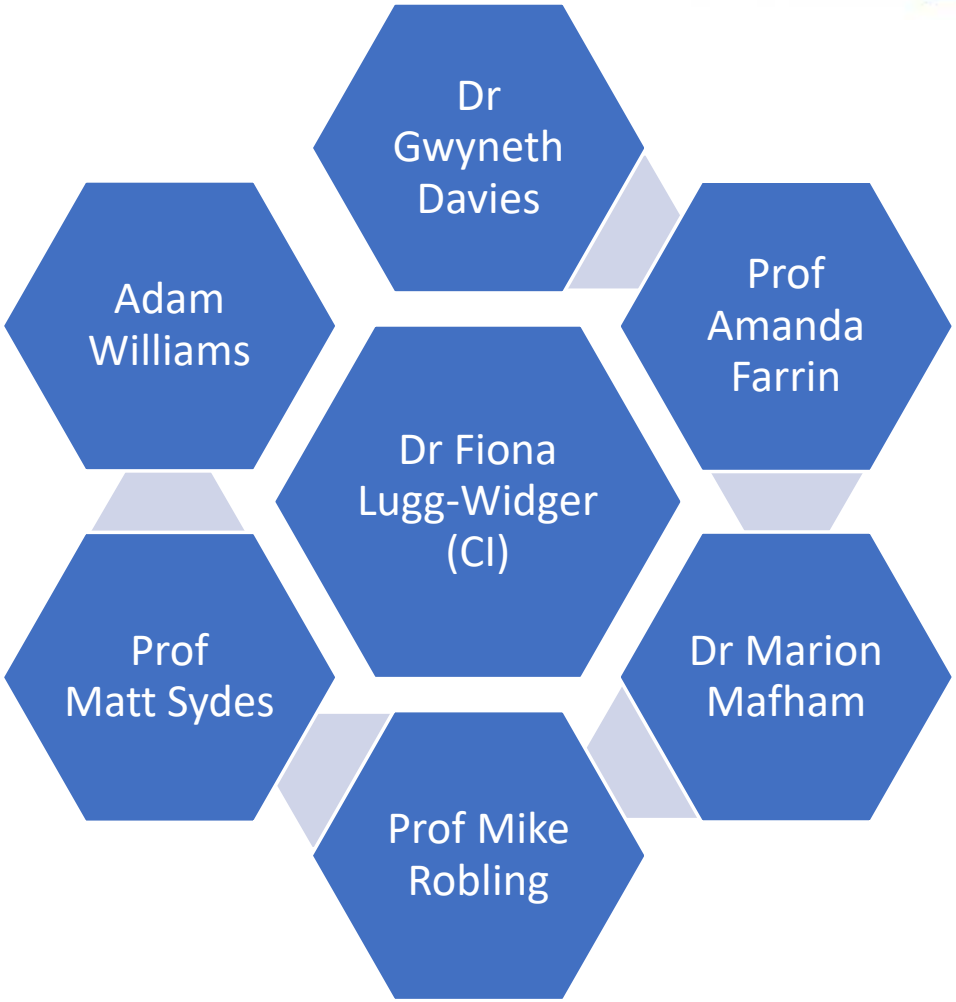


TMRP Summer Webinar

Wednesday 24th August

Dr Fiona Lugg-Widger, Research Fellow, Centre for Trials Research, Cardiff University

Study Team


Dr Gwyneth Davies
Adam Williams
Prof Amanda Farrin
Dr Fiona Lugg-Widger (CI)
Prof Matt Sydes
Dr Marion Mafham
Prof Mike Robling

Background to COMORANT-UK

Routinely collected data for randomized trials: promises, barriers, and implications

Kimberly A. Mc Cord, Rustam Al-Shahi Salman, Shaun Treweek, Heidi Gardner, Daniel Strech, William Whiteley, John P. A. Ioannidis & Lars G. Hemkens

Trials **19**, Article number: 29 (2018) | Cite this article

Int J Popul Data Sci. 2018; 3(3): 432.
Published online 2018 Sep 21. doi: 10.23889/ijpds.v3i3.432
PMCID: PMC8142952
PMID: 34095522

Challenges in accessing routinely collected data from multiple providers in the UK for primary studies: Managing the morass.

Fiona V Lugg-Widger,[1,*] Lianna Angel,[1] Rebecca Cannings-John,[1] Kerenza Hood,[1] Kathryn Hughes,[2] Gwenllian Moody,[1] and Michael Robling[1]

Accessing routinely collected health data to improve clinical trials: recent experience of access

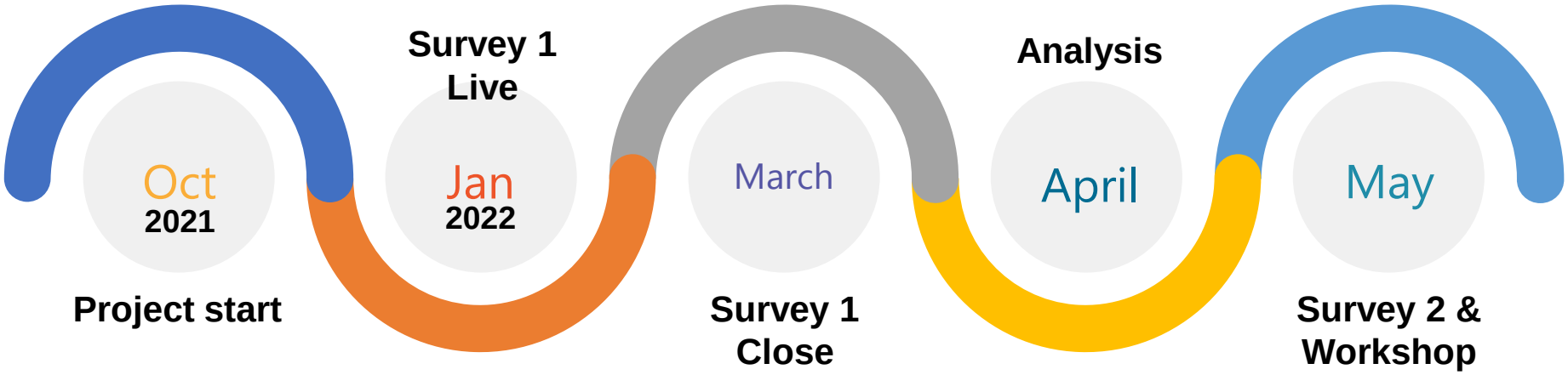
Archie Macnair, Sharon B. Love, Macey L. Murray, Duncan C. Gilbert, Mahesh K. B. Parmar, Tom Denwood, James Carpenter, Matthew R. Sydes, Ruth E. Langley & Fay H. Cafferty

Trials **22**, Article number: 340 (2021) | Cite this article

This funded work aimed to systematically identify the ongoing challenges related to the use of routinely collected data in trials, from the perspective of all relevant stakeholders in the UK

Overview of COMORANT-UK

Method: A 3-step Delphi method consisting of two rounds of anonymous web-based surveys and a virtual consensus meeting with key stakeholders



Key Stakeholders

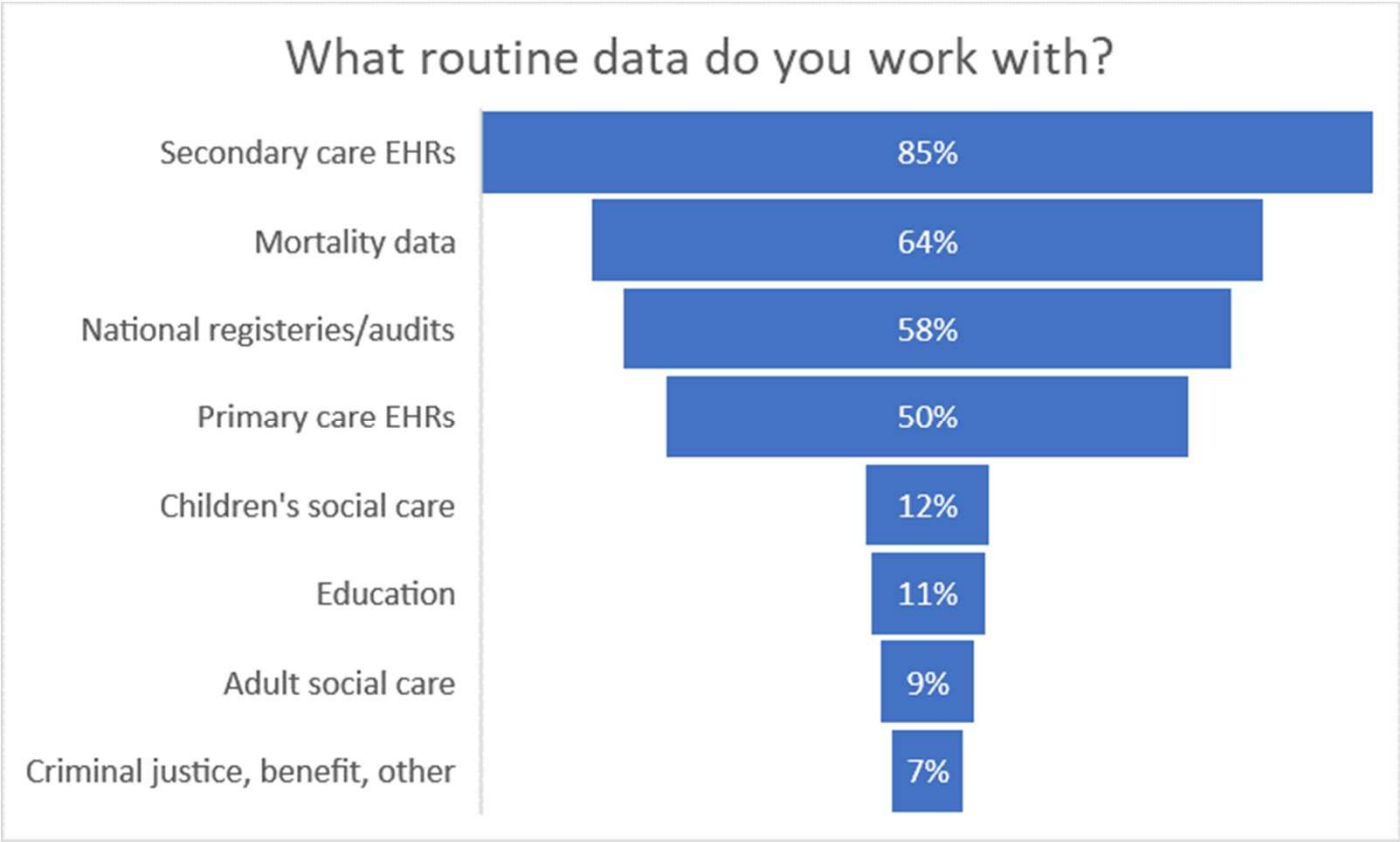
- Trialists/Data Scientists
- RCD infrastructures
- Funding bodies
- Data providers
- The public
- Support networks
- Regulating bodies

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.

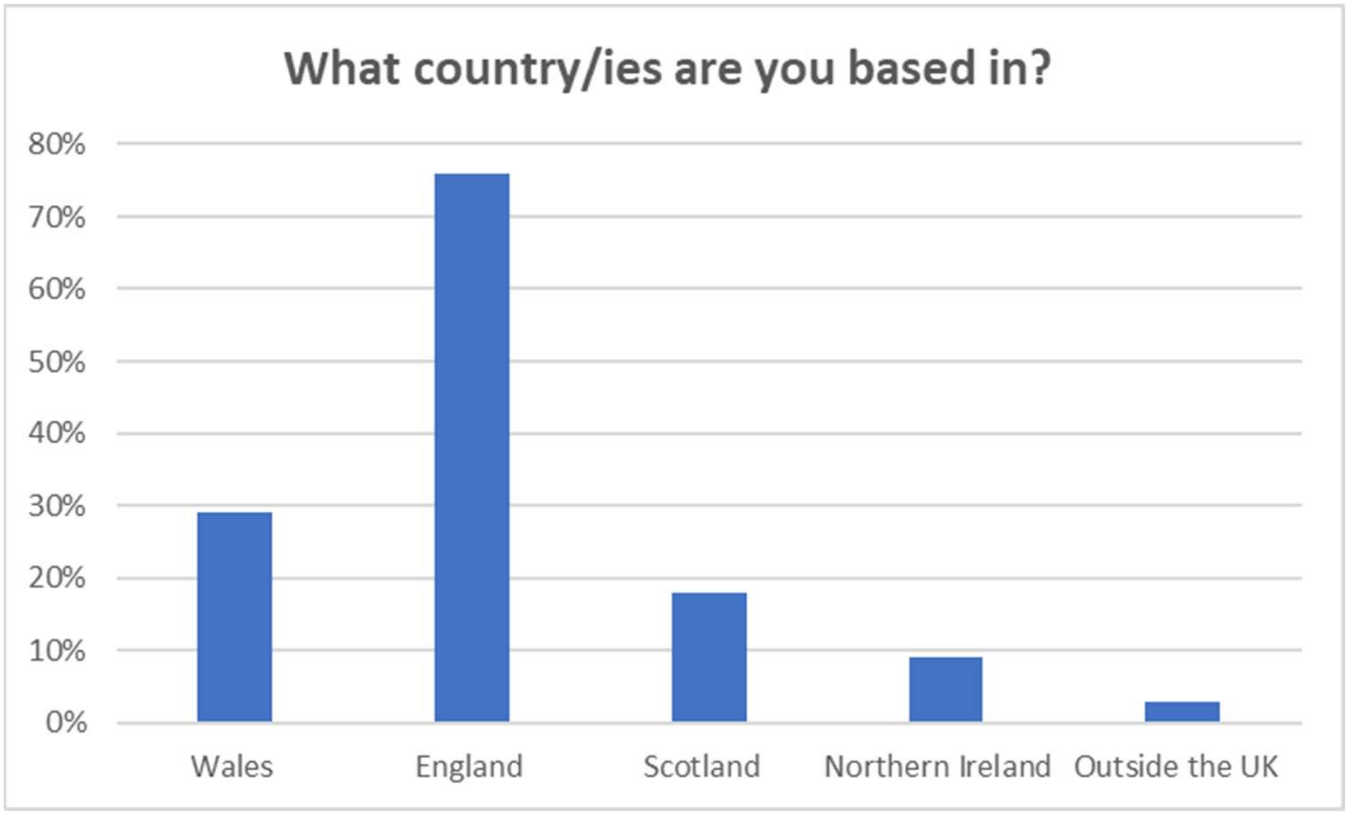
Survey 1: Identifying all remaining questions and challenges



n = 66

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

Survey 1: Identifying all remaining questions and challenges



Number of challenges / questions submitted:

260+

Survey 1: Identifying all remaining questions and challenges

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"

"It will not be feasible for routine data to replace trial-collected data for the assessment of trial outcomes unless the data can be obtained within a similar timeframe."

"We have experienced delays of over a year"

"Substantial delays in obtaining approvals to receive data"

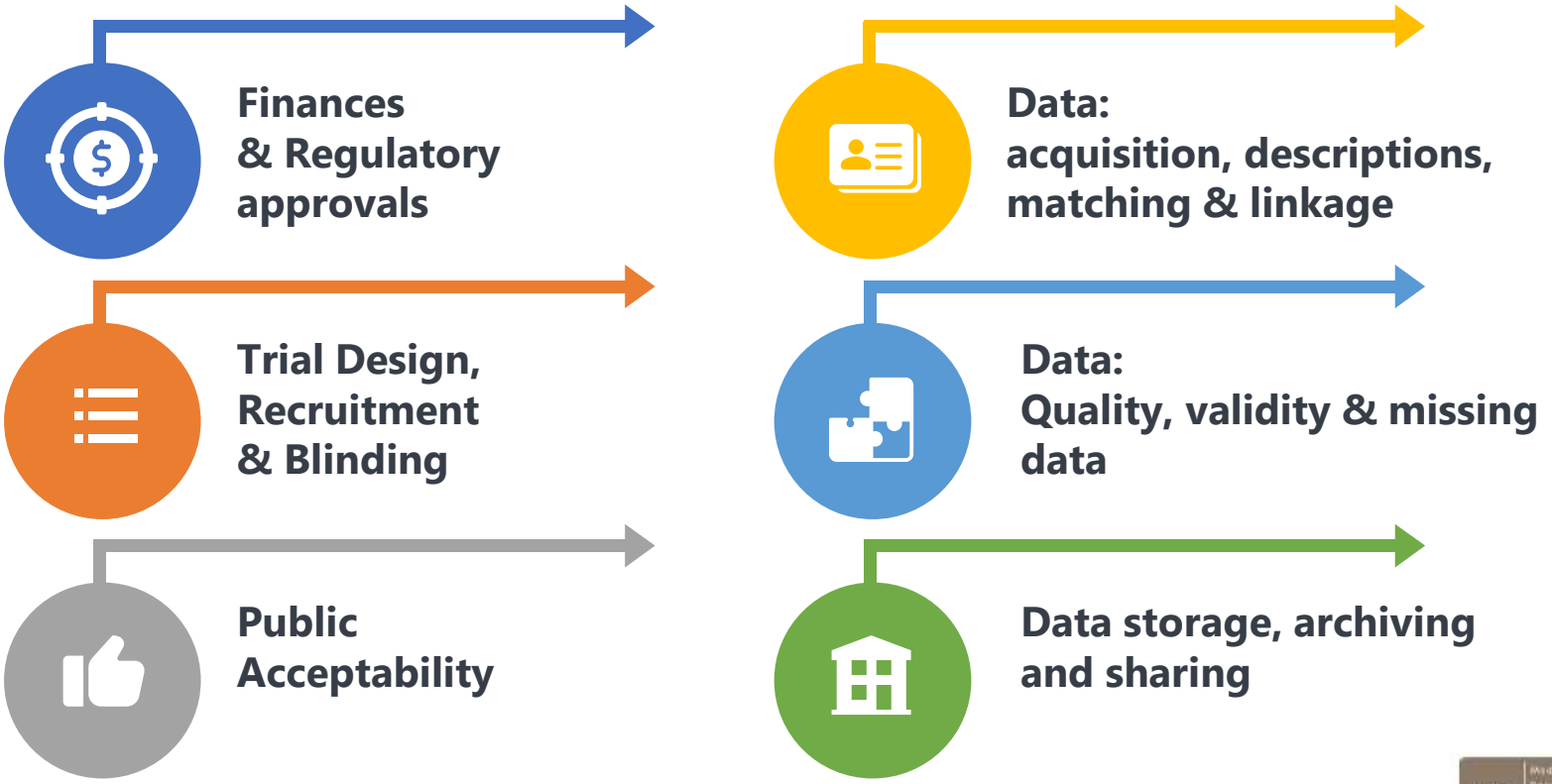
Survey 1: Identifying all remaining questions and challenges

Can standardised consent wording for trials linking to routine data become acceptable to data providers?	"One standardised consent wording that covers data linkage to any/most data providers. At the moment, NHS Digital wording is very specific, and it is very hard to find out what is acceptable without sending the PIL/consent form to them to check. If different wording is required from each data provider, then consent forms get large."
	"How should informed consent be worded for trials using routinely collected data?"
	"Complex applications for admin data to link to trial data, particularly with respect to the precise wording required for the consent form and patient information form"

Survey 1: Identifying all remaining questions and challenges

	Where do I store the data to be safe and acceptable by data providers and participants?
Where do I store the data to be safe and acceptable by data providers, regulators, funders and participants?	Where do I store the data at the end of the trial to be kept safe at low cost?
	Storing data on University Computers is a challenge - requires special data protected servers to be created, takes long to set up (involves IT and DP), difficult to know/understand technical details when initially applying for ethics approvals etc
	Alternative to above is accessing an NHS computer for data storage, which is not accessible for university staff unless we have an NHS account (via honorary contract) and access to an NHS computer.
	Data transfer and security issues at own organisation

Survey 1: Identifying all remaining questions and challenges



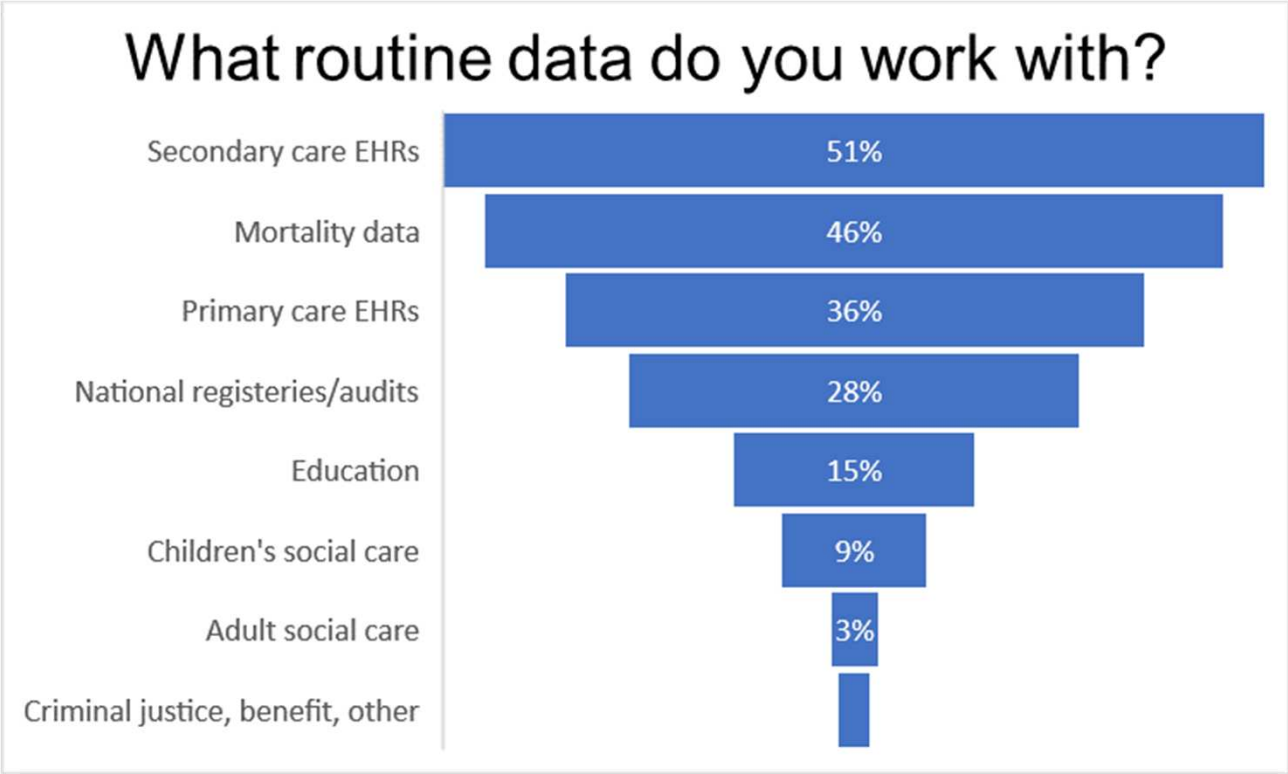
*Some responses not included when unclear or did not relate to routine data & trials

e.g. payments for trial participation

Survey 2: Selecting a top 10

"Please read the list and drag/drop up to **10 questions that you think it is most important for researchers to answer** based on your own experiences."

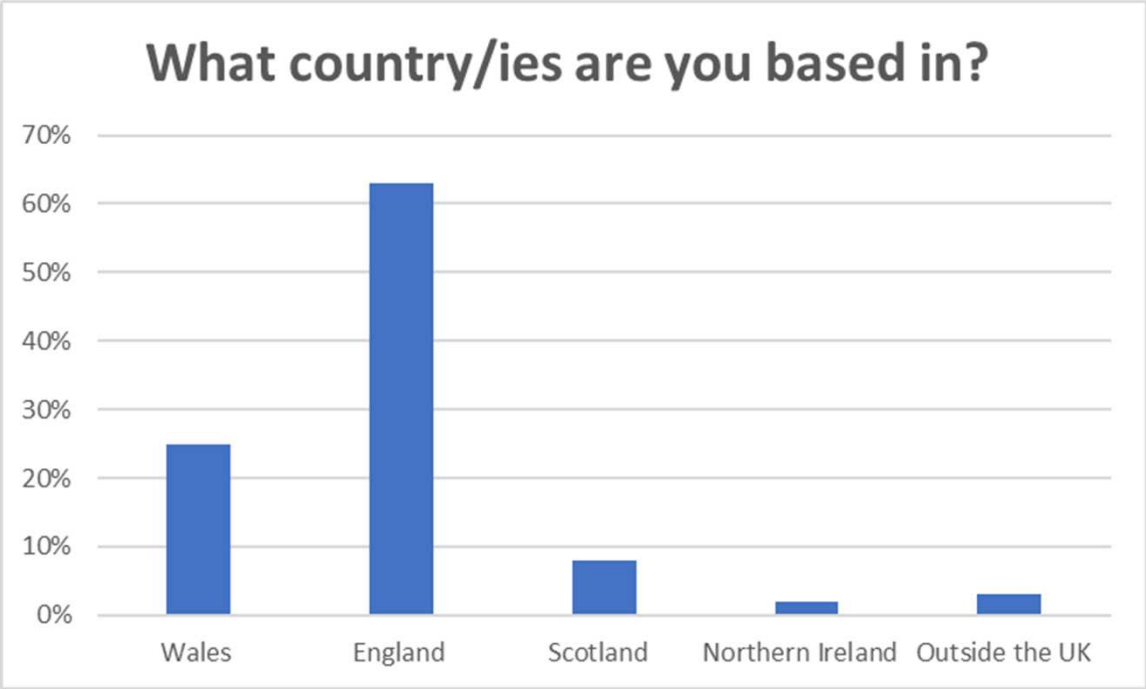
Survey 2: Selecting a top 10



n = 88

65% - Trialist
2% - Member of public
7% - Data Provider
2% - Funder
15% - Supports trials

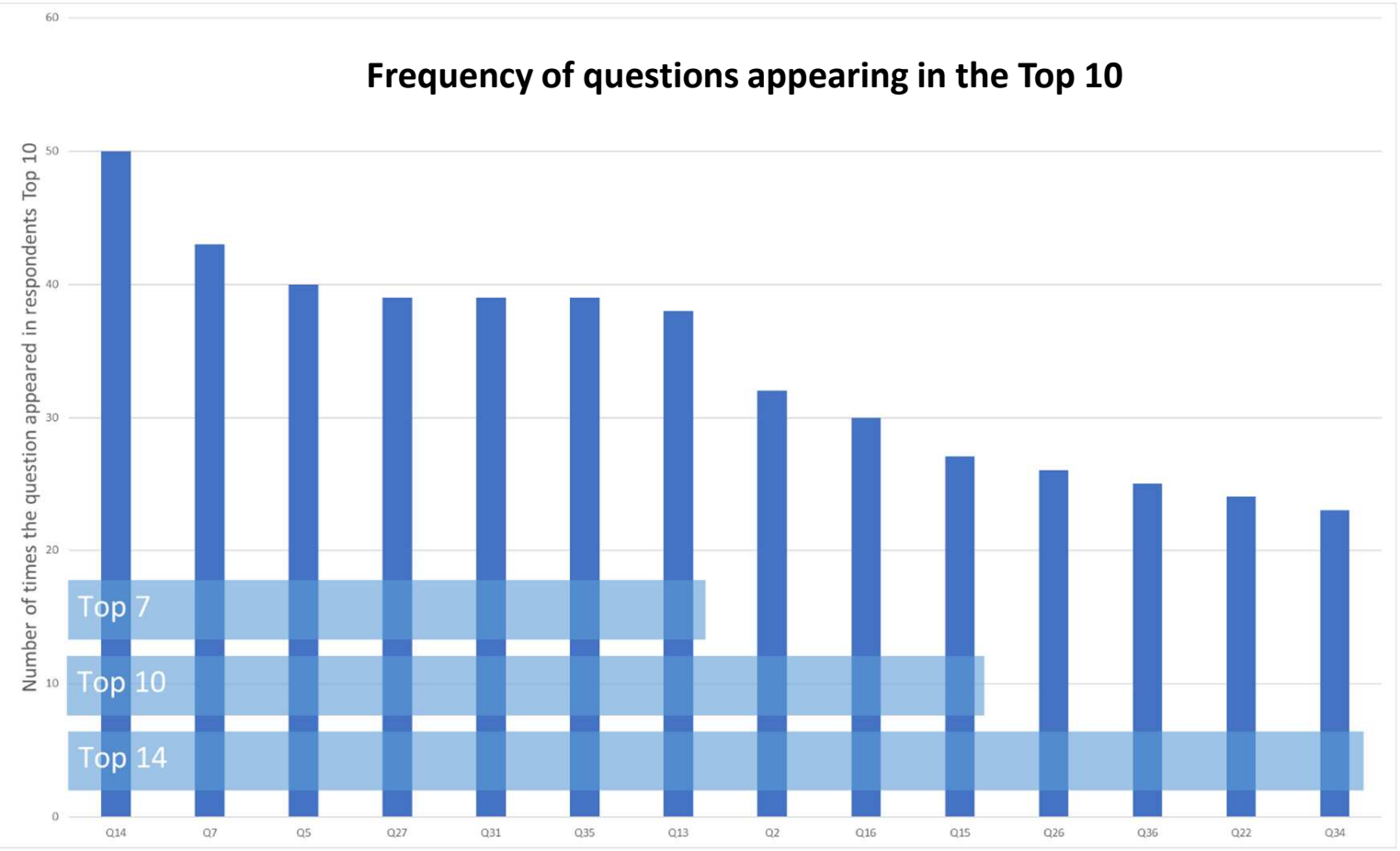
Survey 2: Selecting a top 10



Completed survey 1?

Yes: 30%
No: 45%
Unsure/Missing: 25%

Survey 2: Selecting a top 10



All 40 questions had been included in a respondent's top 10 at least 5 times

-

The highest ranked question was included 50 times

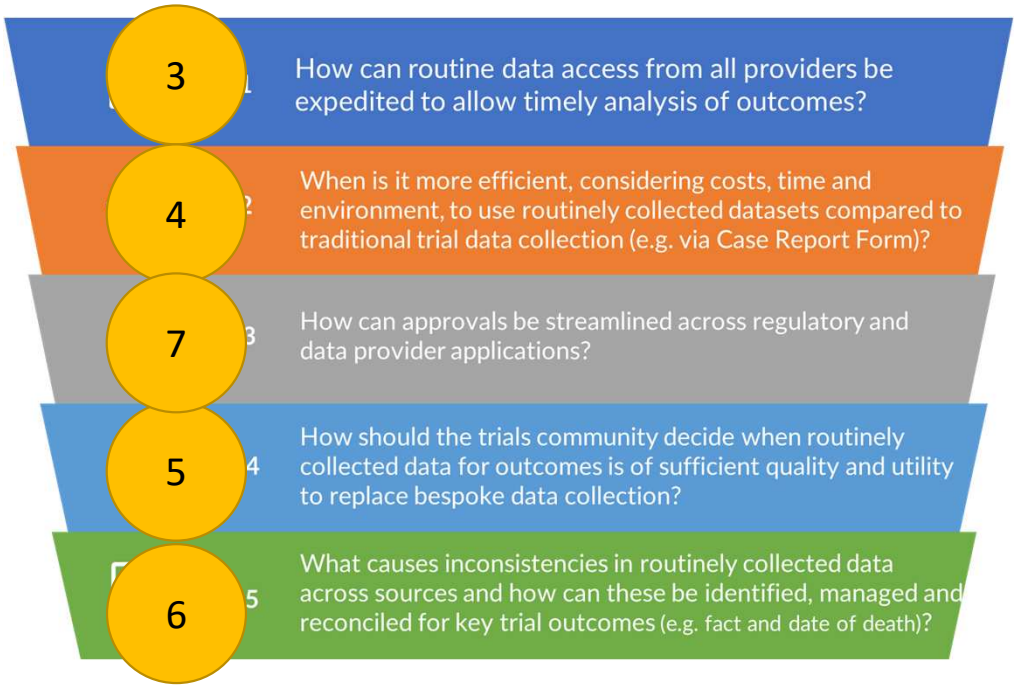
Survey 2: Selecting a top 10

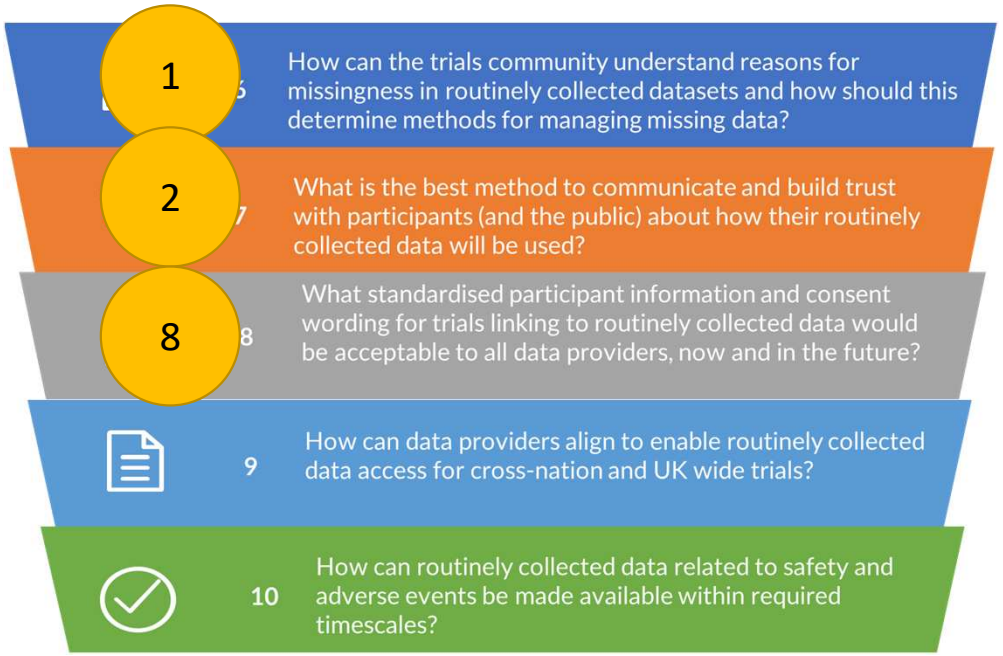
1. How can routine data access from all providers be expedited to allow timely analysis of outcomes?
2. When is it more efficient, considering costs, time and environment, to use routinely collected datasets compared to traditional trial data collection (e.g. via Case Report Form)?
3. How can approvals 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)?

Survey 2: Selecting a top 10

Survey 2: Selecting a top 10

Rankings by non-trialists





Survey 2: Selecting a top 10

★	11	How can we develop methods to enrich datasets through data linkage (e.g. linking educational datasets with primary care data)?
★	12	What are the best and most cost-effective methods for retaining routinely collected data at the end of the trial whilst aligning with regulatory and data provider requirements?
	13	How can the knowledge of how routinely collected data (including codes) are recorded be translated/communicated for use by those receiving and analysing the data?
	14	How should data providers engage with the staff recording the routinely collected data to improve data quality and optimise for trials research?

Survey 2: Selecting a top 10

Is a relaxation of standards in clinical trials data collection acceptable when using routine data? (Routine data is collected for very different reasons after all, often to do with budgets or general treatment pathway, and not focused on answering outcomes for clinical trial questions)

Which data sets exist that would be of use for clinical trials but are deemed inaccessible and why?

What is the impact on data sharing on trial retention periods once the legislated archival time has passed. This is not currently covered in any legislation

Consensus Meeting: Agreeing a final list

- Discuss survey 2 ranked questions
- Consider additional questions
- Agree top list to take forward
- Finalise wording of these

N= 13 Stakeholders

Consensus Meeting: Agreeing a final list

Is a relaxation of standards in clinical trials data collection acceptable when using routine data? (Routine data is collected for very different reasons after all, often to do with budgets or general treatment pathway, and not focused on answering outcomes for clinical trial questions)

22. Will regulators accept routinely collected data within a clinical trial? And if so, what do we need to evidence?

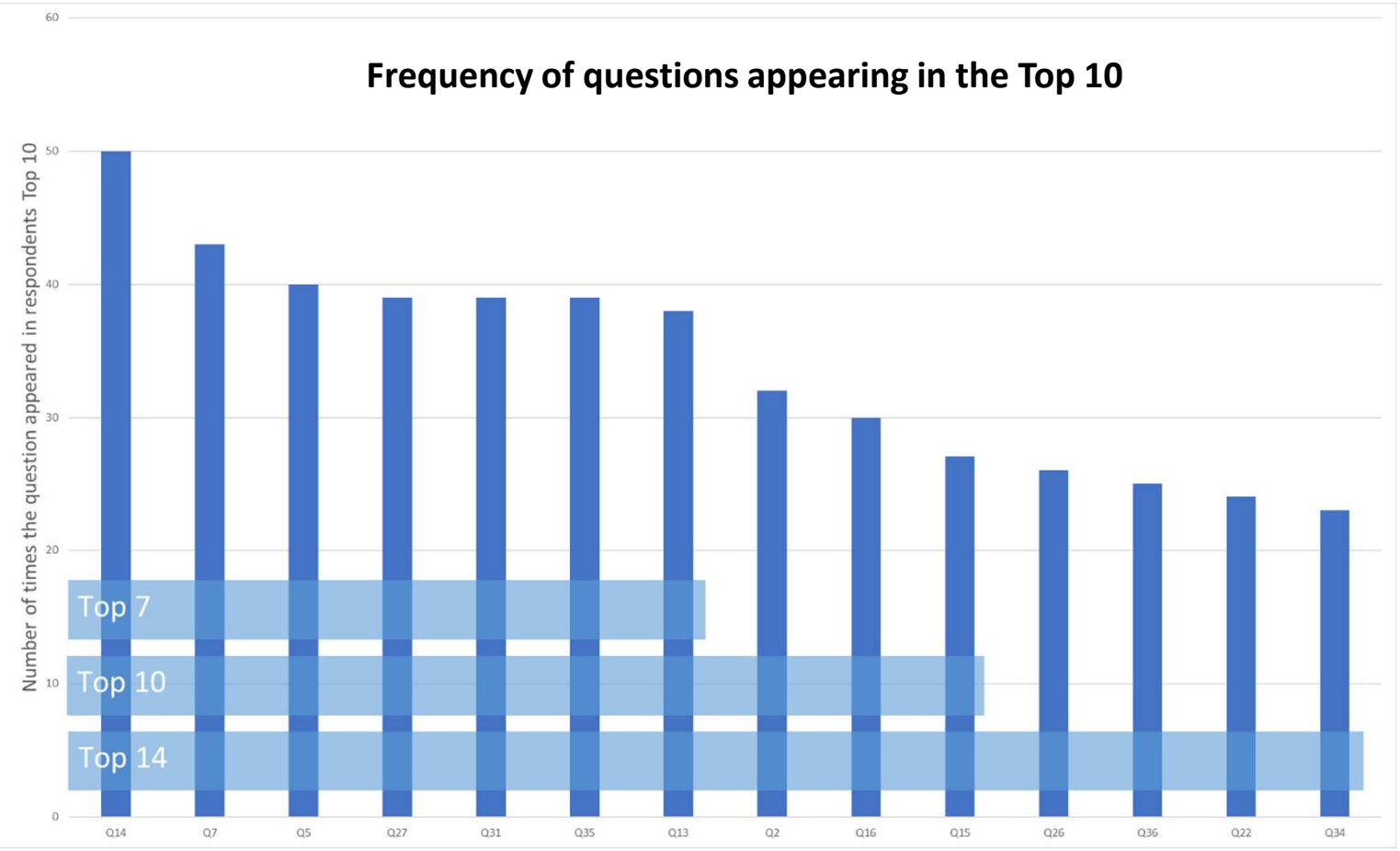
Which data sets exist that would be of use for clinical trials but are deemed inaccessible and why?

17. Where can trialists access information on what routinely collected data are available for specific clinical areas and howto access those data?

What is the impact on data sharing on trial retention periods once the legislated archival time has passed. This is not currently covered in any legislation

28. What is the most cost-effective method for onward data sharing of routinely collected data?

Consensus Meeting: Agreeing a final list



Agreed by consensus:

Top 7 (60%)
Top 10 (10%)
Top 12 (30%)
Top 14 (0%)

COMORANT UK

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?

Trial Design

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

Communication

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?

Trial Open

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 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 Data

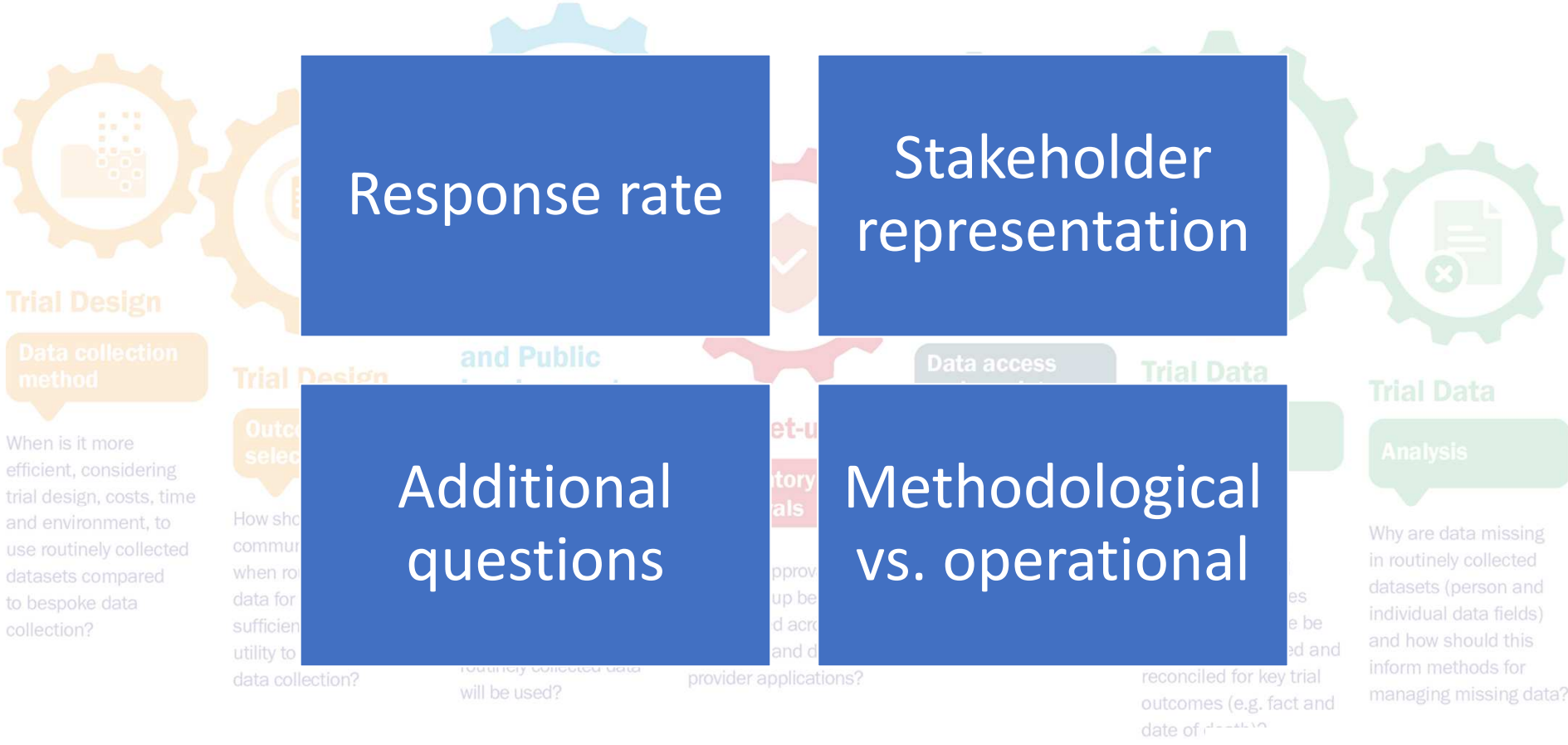
Analysis

Why are data missing in routinely collected datasets (person and individual data fields) and how should this inform methods for managing missing data?

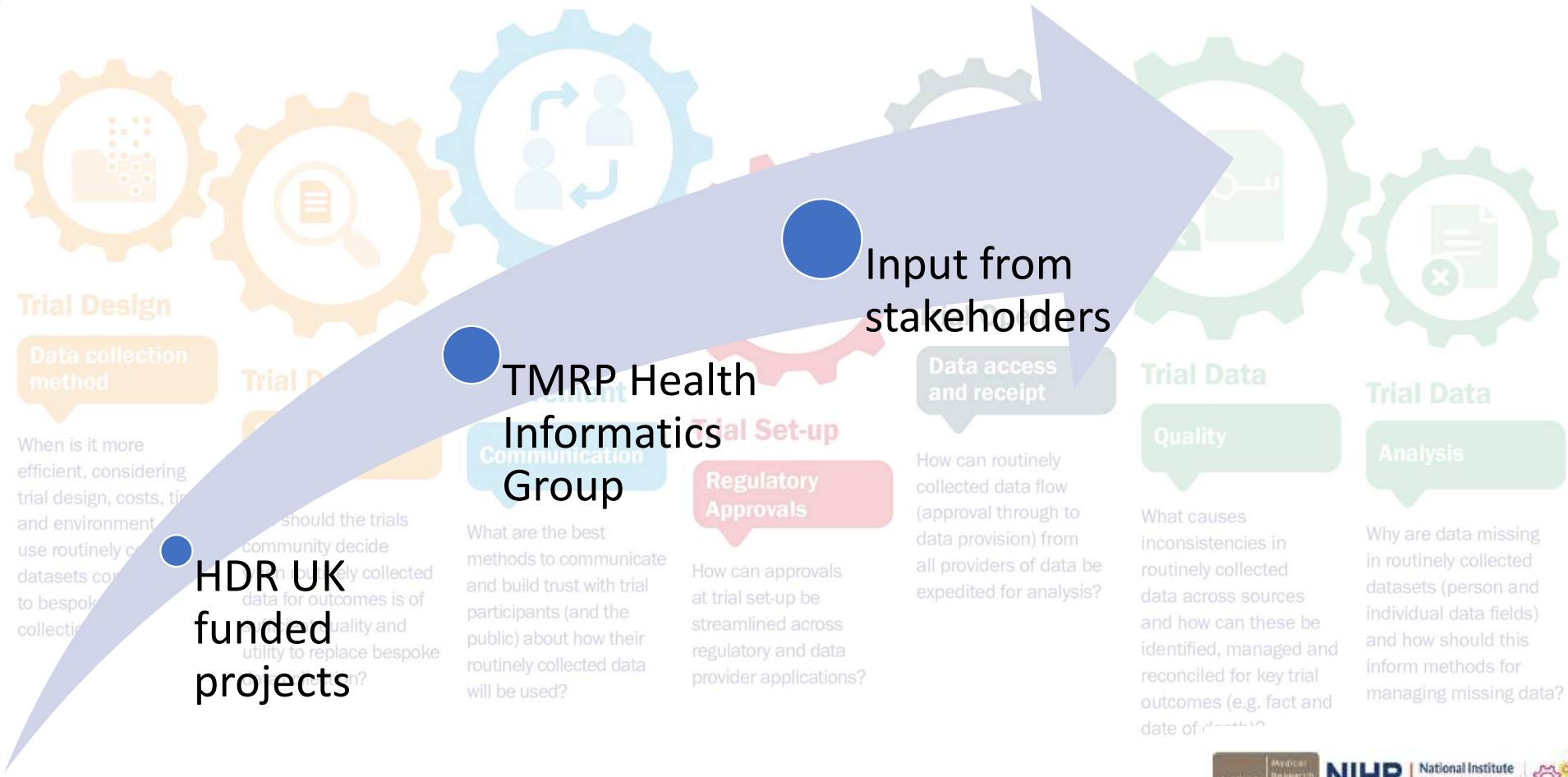
https://www.cardiff.ac.uk/centre-for-trials-research/research/studies-and-trials/view/comorant-uk

MRC | NIHR National Institute for Health Research | TMRP Trials Methodology Research Partnership

Strengths and Limitations



Taking these forward



HDR UK funded projects

TMRP Health Informatics Group

Input from stakeholders

Acknowledgements

Study Team: Dr Gwyneth Davies, Prof Amanda Farrin, Dr Marion Mafham, Prof Mike Robling, Prof Matt Sydes, Adam Williams & Dr Fiona Lugg-Widger (Chief Investigator)

Thanks to those who supported in the dissemination of surveys:

- HRB-TMRN
- TMRP Working Groups
- UKTMN
- UKCRC