



MRC-NIHR Trials Methodology Research Partnership: Webinar recording

How can trial teams build public trust for the use of routine data in trials?

Presented, on behalf of Health Data Research UK, by:

Rob Trubey and Fiona Lugg-Widger (Cardiff University)

24 October 2023

The slides are available below.

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

<https://youtu.be/P5mzUv7708M>

PRIMORANT: How can trial teams build public trust for the use of routine data in trials?

Rob Trubey, Fiona Lugg-Widger, Mike Robling, HDR UK



PRIMORANT: Background

- Many benefits to trialists and the public of using routine data in clinical trials
- But public trust can be fragile
- In our previous work on public involvement for RD, we found that:
 - Members of the public were very keen to be involved in conversations about how their routine data is used for research
 - Data providers saw public consultation as essential to successful data applications
 - Researchers were sceptical about value of PPI&E / unsure how to do it well



Working with the Public

Explores with researchers' public perspectives when researchers use administrative data

PRIMORANT: Background

CARDIFF UNIVERSITY Centre for Trials Research
PRIFYSGOL CAERDYDD Canolfan Ymchwil Treialon

COMORANT UK

COMORANT-UK: The prioritised seven questions to address

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.

This 3-step Delphi method consisted of two rounds of anonymous web-based surveys, and a virtual consensus meeting.

Stakeholders included trialists, health relevant data infrastructures (i.e. HDR UK), funders of trials, regulators (HRA, MHRA), data providers and the public.

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

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 providers) 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?

Collaborators
OXFORD, UCL, UNIVERSITY OF LEEDS, JISC Digital Hub, NIHR, MRC, NIHR National Institute for Health Research, TMRP

Funders
MRC, NIHR National Institute for Health Research, TMRP

For more information please see our study page: www.cardiff.ac.uk/centre-for-trials-research/research/studies-and-trials/view/comorant-uk

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?

Training development

- Training for clinical trialists: **Building public trust in routine data trials**
- Funded by and partnership with **HDR UK and training team**
- Developed through stakeholder consultation work:
 - **CTU survey**
 - **Workshop with public partners**
 - **Recorded conversations with PPIE leads, clinical trialists and topic experts**





Module 1: Course introduction



Module 2: Drivers of public trust



Module 3: Involving & engaging – and inclusivity

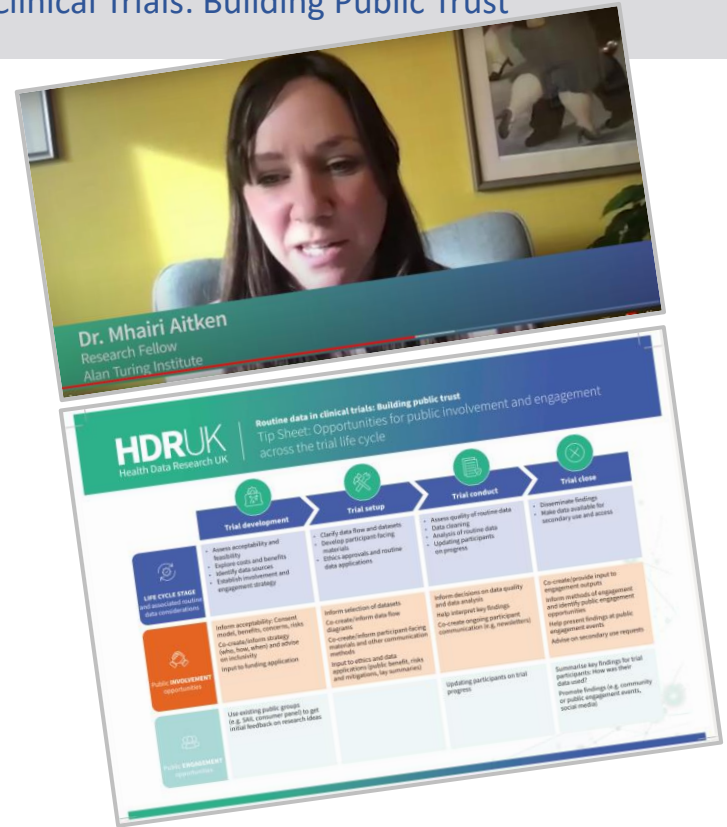


Module 4: Communicating about routine data



Module 5: Funding and measuring impact

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

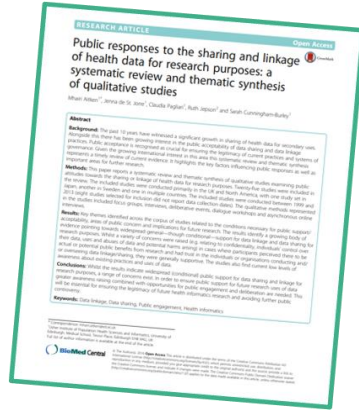


M2: Drivers of public trust

- What are they **key concerns** that the public have about the use of their routine data in trials?
- What are the **implications for trialists** aiming to build public trust?
- Why does **context** matter?



M2: Drivers of public trust

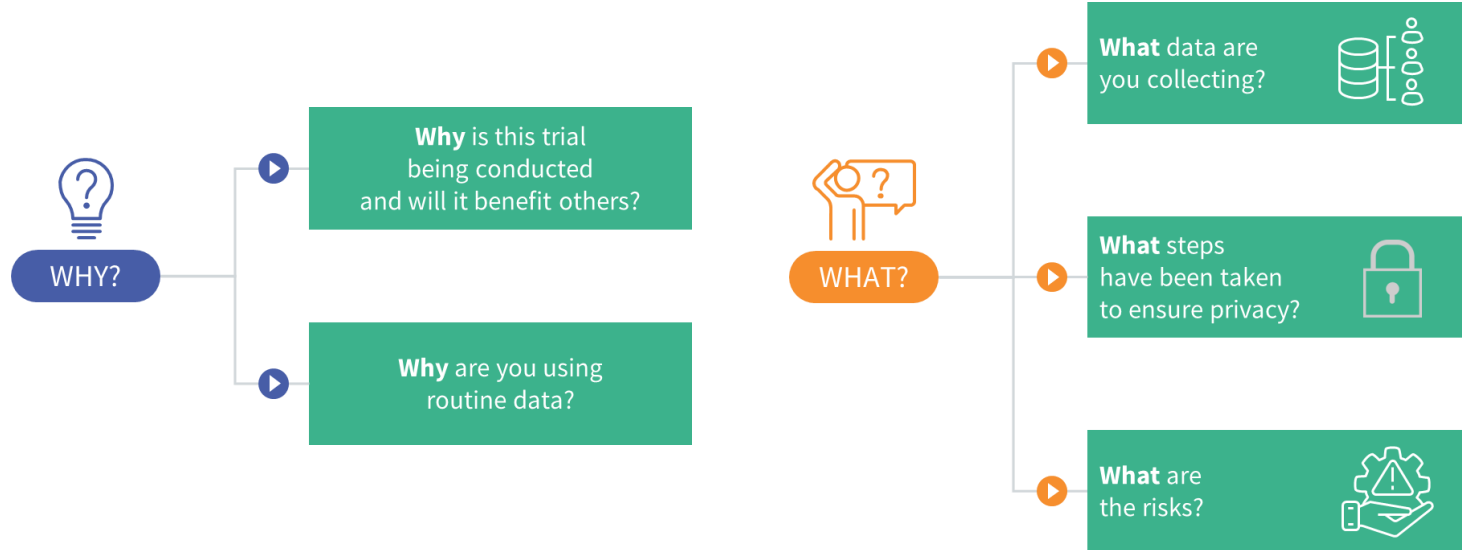


PUBLIC GOOD



DATA SECURITY

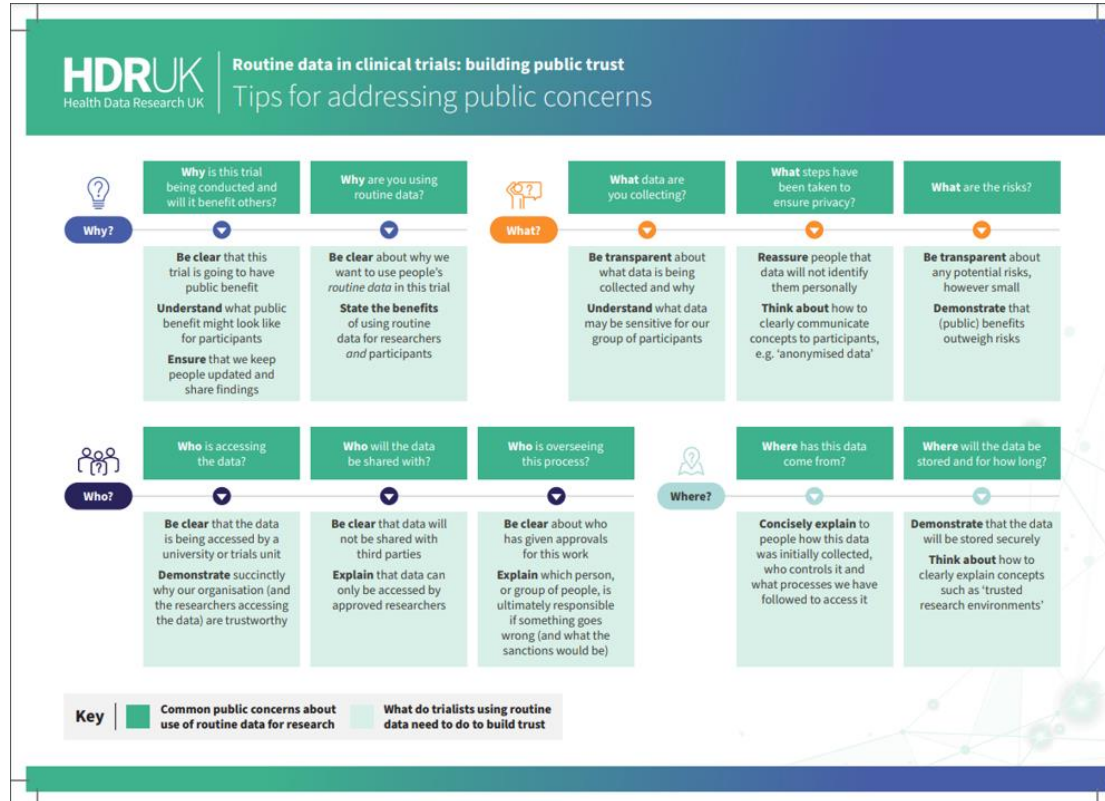
M2: Drivers of public trust



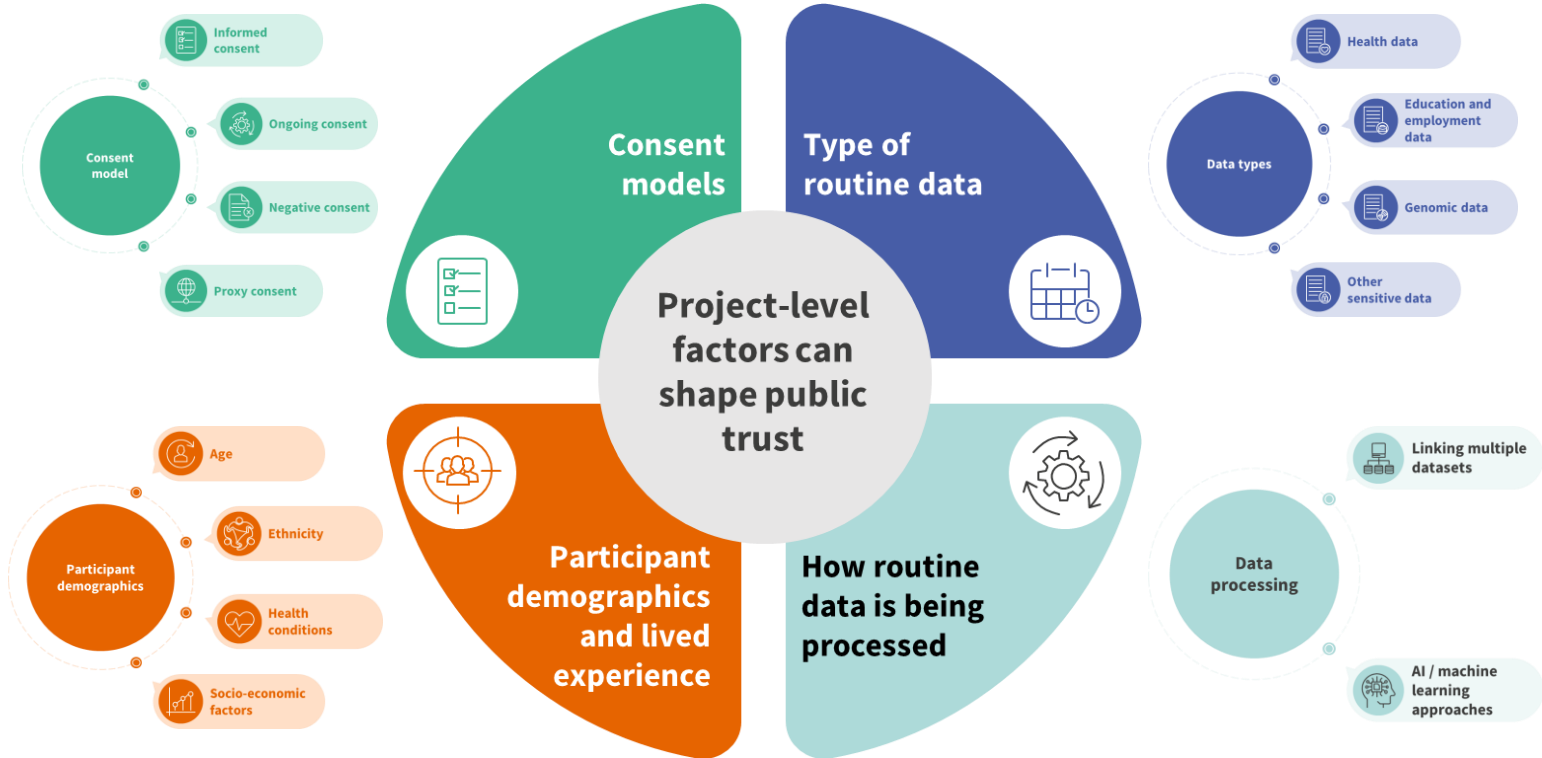
M2: Drivers of public trust



M2: Drivers of public trust



M2: Drivers of public trust - context

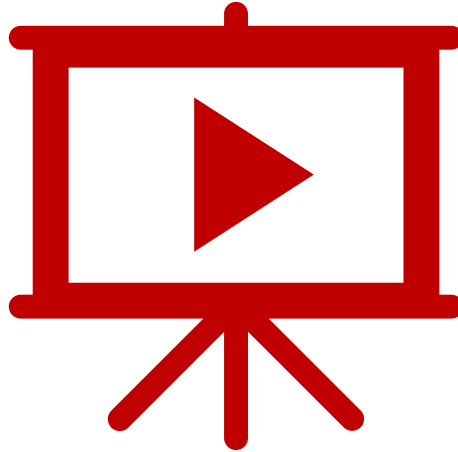


M3: PPI&E for building trust

- **How** should trialists involve and engage with the public in routine data trials?
- **When** should trialists seek to involve and engage the public in routine data trials?
- **Who** should we involve and engage with in routine data trials?



M3: PPI&E for building trust

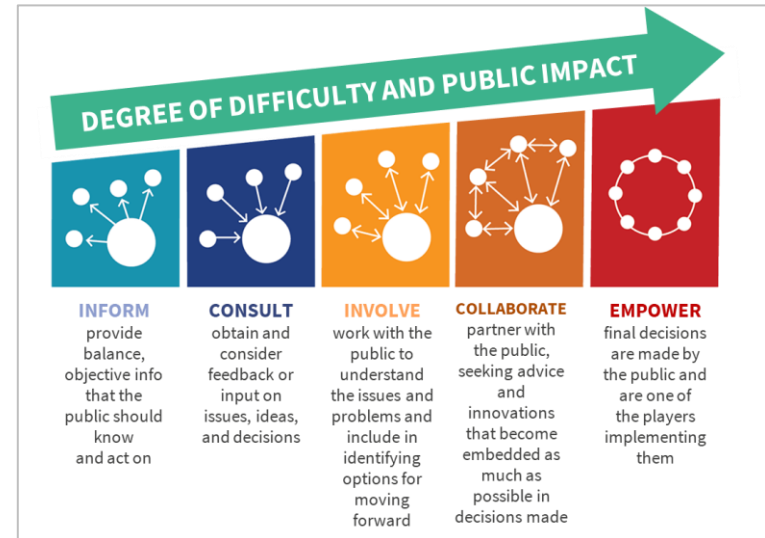


M3: PPI&E for building trust - how?

- Drawing on existing guidance and frameworks
 - NIHR UK Standards for Public Involvement
 - Consensus statement on PI&E in data-intensive research
 - PEDRI best practice standards
- Making sure it's meaningful
- Different ways to involve people in conversations about routine data
- Working to make it engaging

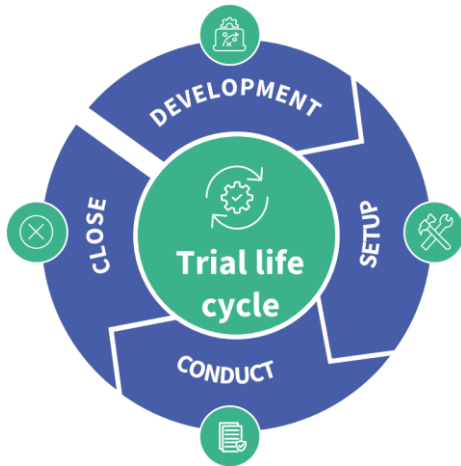










PEDRI: Public Involvement and Engagement Best Practice Draft Standards for the use of data for Research and Statistics



M3: PPI&E for building trust - when?

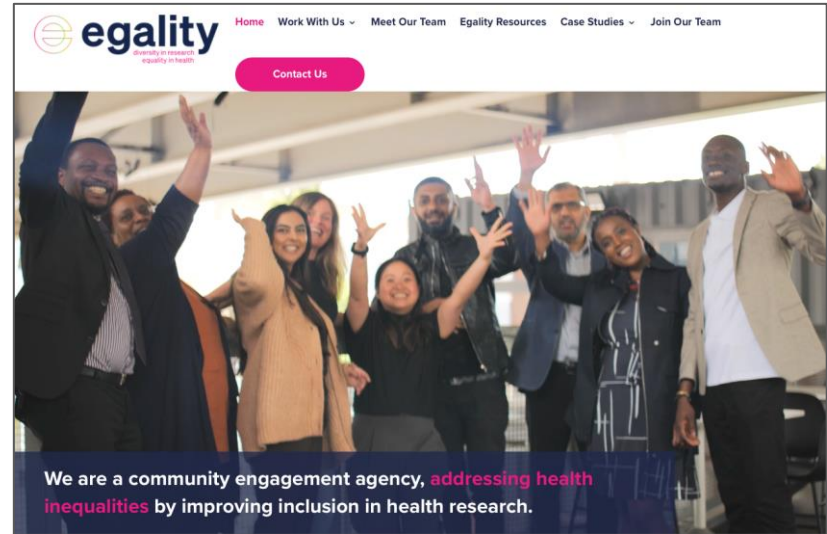
- As early as possible (including pre-funding)
- Throughout the trial lifecycle



 Routine data in clinical trials: Building public trust Tip Sheet: Opportunities for public involvement and engagement across the trial life cycle				
	 Trial development	 Trial setup	 Trial conduct	 Trial close
 LIFE CYCLE STAGE and associated routine data considerations	<ul style="list-style-type: none"> • Assess acceptability and feasibility • Explore costs and benefits • Identify data sources • Establish involvement and engagement strategy 	<ul style="list-style-type: none"> • Clarify data flow and datasets • Develop participant-facing materials • Ethics approvals and routine data applications 	<ul style="list-style-type: none"> • Assess quality of routine data • Data cleaning • Analysis of routine data • Updating participants on progress 	<ul style="list-style-type: none"> • Disseminate findings • Make data available for secondary use and access
 Public INVOLVEMENT opportunities	Inform acceptability: Consent model, benefits, concerns, risks Co-create/inform strategy (who, how, when) and advise on inclusivity Input to funding application	Inform selection of datasets Co-create/inform data flow diagrams Co-create/inform participant-facing materials and other communication methods Input to ethics and data applications (public benefit, risks and mitigations, lay summaries)	Inform decisions on data quality and data analysis Help interpret key findings Co-create ongoing participant communication (e.g. newsletters)	Co-create/provide input to engagement outputs Inform methods of engagement and identify public engagement opportunities Help present findings at public engagement events Advise on secondary use requests
 Public ENGAGEMENT opportunities	Use existing public groups (e.g. SAIL consumer panel) to get initial feedback on research ideas		Updating participants on trial progress	Summarise key findings for trial participants: How was their data used? Promote findings (e.g. community or public engagement events, social media)

M3: PPI&E for building trust - who?

- Led by your aims
- Focusing on people with lived experience
 - Carers, family members
 - Patient representative groups
 - Charities
- Including 'seldom heard voices'
 - A diversity of perspectives
 - Working with community groups & community engagement specialists

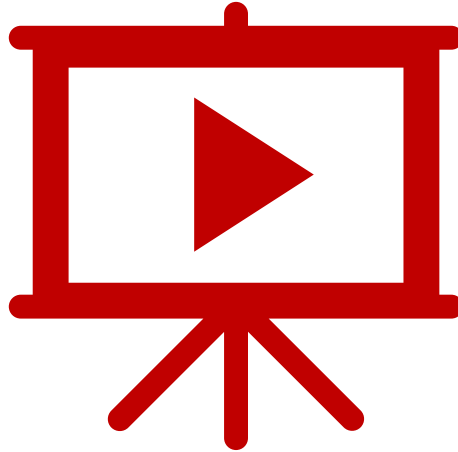


M4: Communication

- How can we communicate clearly about routine data in **participant-facing materials**?
- How can we use videos, infographics and other **creative communication** options to help build trust?
- How do we ensure that our communication is **accessible**?



M4: Communication – ppt-facing materials



M4: Communication - ppt-facing materials

- The challenge of striking the balance – transparency vs information overload
- Layering information
 - Leaflets
 - Online approaches
 - Spotighting key information
- Avoiding jargon
 - Understanding Patient Data
 - Working with public partners
- Using graphics, icons and diagrams

Project information

Item 1

Item 2

Item 3

Item 4

SUMMARY OF KEY POINTS

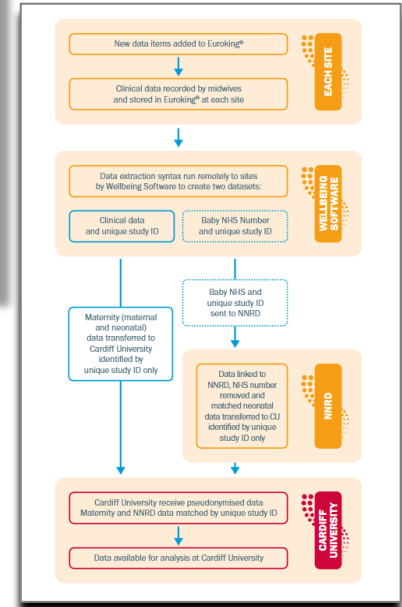
Item 1

Item 2

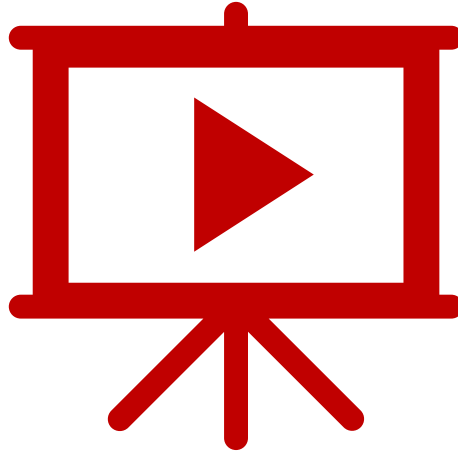
Patient Data

Finding the best set of words to use

Summary of findings



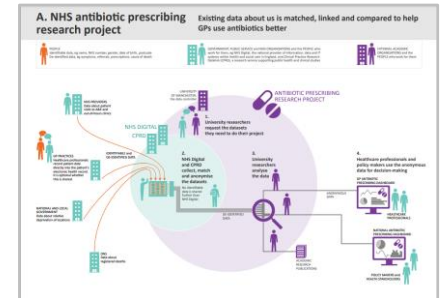
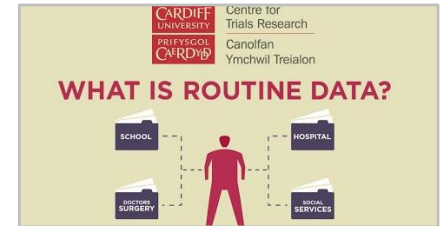
M4: Communication – creative approaches



M4: Communication - creative approaches

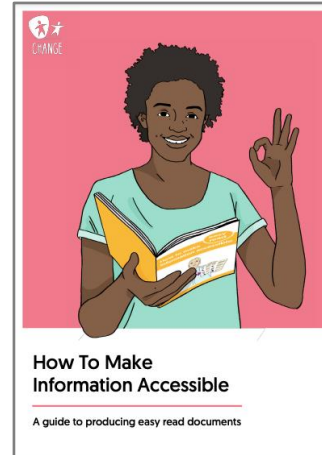
- Videos and infographics
 - Talking head or animated videos
 - Infographics and data flows
 - Importance of consistency and version control
- Trial / CTU websites
 - Add legitimacy
 - Host a range of useful information
- Involving specialists

The screenshot shows the website for the Centre for Trials Research. The navigation bar includes links for Home, Centre for Trials Research, About Us, and Routine data. The main heading is 'Centre for Trials Research'. Below this, there are links for 'About us', 'Research', 'Public and patient involvement', 'Collaborate with us', 'People', and 'News'. A sidebar on the left lists various services: 'About us', 'Data requests', 'Equality and diversity', 'Information systems and database development', 'PhDs seeking funding', 'Quality assurance and regulatory affairs', and 'Qualitative Research Group'. The main content area is titled 'Routine data' and features a large red play button icon over a folder graphic. Below the icon, text states: 'We work with major data providers Across the UK (such as Department of Health, Department for Education and NHS Digital) to develop and optimise ways to appropriately access and'.



M4: Communication - accessibility

- Language considerations
 - **Readability tools**
 - **Translation where needed**
 - **Working with public contributors**
- Accessible formats and design
 - **Summary versions**
 - **Easy Read versions**
 - **Other accessibility considerations for different populations**
- Working with specialists
 - <https://thinklusive.org/>



M5: Costs + evaluation

- Trust-building activities can be resource intensive
 - Staff time
 - Costs involved in working with specialists
 - Need to budget and justify costs
- Evaluation is important
 - Direct and proxy measures of public trust
 - Various tools for evaluating PPI&E
 - Not just from research perspective

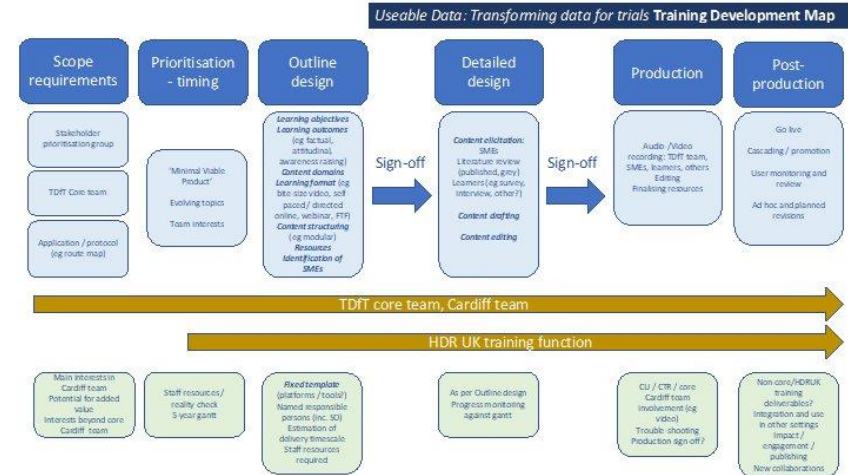




Official Launch: 13th November Routine Data in Clinical Trials: Building Public Trust

- HDR-UK funded Transforming Data for Trials workstream
- Cardiff leading on training and resources, with HDR UK training team
- Developing training modules across a range of routine data topics
- Subject Matter Experts key – get in touch!

• top-cat@cardiff.ac.uk



PRIMORANT TEAM *TD4T TEAM

CTR, Cardiff University: Dr Fiona Lugg-Widger*, Prof Mike Robling*, Dr Julia Townson, Dr Rob Trubey*;

HDR UK North: Prof. Amanda Farrin, Prof Paula Williamson, Prof Munir Pirmohamed, Prof Andy Clegg;

MRC CTU at UCL + BHF Data Science Centre: Prof Matthew Sydes*;

MRC CTU at UCL + NHS Digital: Dr Macey Murray*;

University of Oxford CTSU: Dr Marion Mafham*;

HDR UK Training Team: Sarah Cadman; Rosie Wakeham; Sam Wise

on behalf of the Trials Methodology Research Partnership (TMRP) Health Informatics Working Group / Routine Data Topic Group

Questions for the group

- What resources do you use to support your lay members?
- Do you have examples of involvement and engagement you'd like to share?