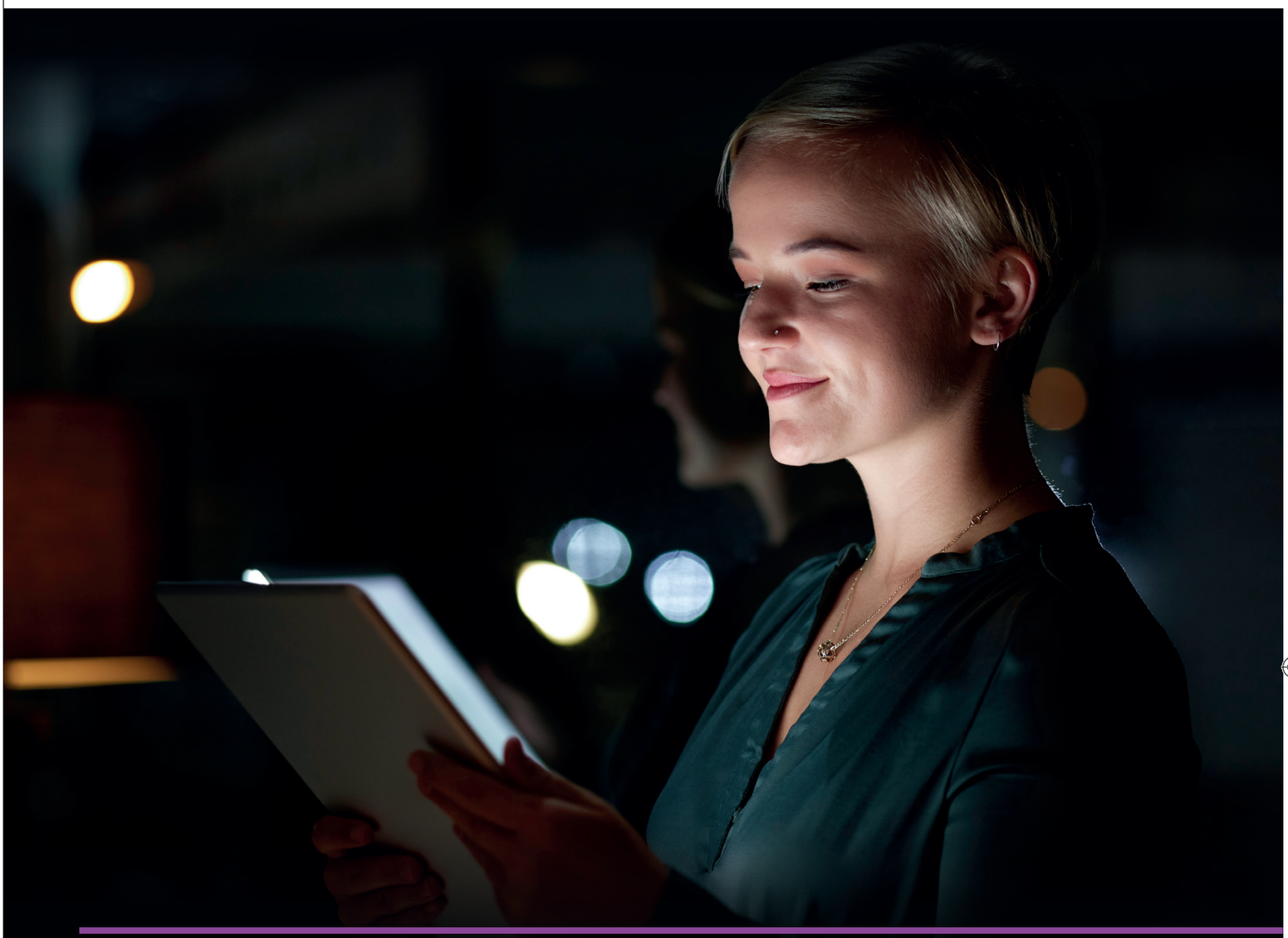

Enhancing Communication in Clinical Trials: The TMRN-TMRP Communication Wheel

Frances Shiely, Ratna Sohanpal, Andrew Willis, Talia Isaacs, Julia Wade, Vincent Russell, Shaun Treweek, Annabelle South, on behalf of the Communication Working Subgroup of the MRC-NIHR-TMRP

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Abstract

The Trial Conduct Working Group of the Trials Methodology Research Partnership established a working subgroup in 2020 to advance the research agenda on best practices for communicating with stakeholders across the clinical trial lifecycle. Through an iterative process, the subgroup developed the TMRN-TMRP Communication Wheel, a visual aid identifying key groups of stakeholders and when to engage with each during trial development, conduct, and dissemination of results. The TMRN-TMRP Communication Wheel aims to promote systematic communication plans that effectively engage diverse stakeholders at different trial stages according to their distinct needs. An evaluation process will refine the wheel following its launch.

Introduction

Clinical trials are essential in advancing medical knowledge, testing new treatments, and ultimately improving patient care. Communication within the clinical trials landscape is a complex web that involves various stakeholders, including patients, healthcare professionals, researchers, funders, and policymakers. The Health Research Board Trials Methodology Research Network (HRB TMRN) in Ireland and the MRC-NIHR Trials Methodology Research Partnership (TMRP) in the UK has developed a tool called the "TMRN-TMRP Communication Wheel" to guide the development of more effective communication strategies within clinical trials. Communication is the lifeblood of clinical trials. It transcends all phases of the trial, from the initial planning stages to the dissemination of results. Effective communication ensures that everyone involved in the trial is on the same page, from the researchers designing the study to the patients participating in it. It also plays a vital role in securing funding, engaging stakeholders, ensuring the ethical conduct of trials and promoting the translation of results into policy and practice. In recognition of the paramount importance of effective communication, the TMRP Trial Conduct Working Group identified it as one of the top priorities within their research agenda. A working subgroup (SWG) was established to delve deeper into this issue, with the aim of determining the best methods and timings for communication with all relevant stakeholders throughout the clinical trial lifecycle.

The Birth of the TMRN-TMRP Communication Wheel

The journey towards creating the Trials Communication Wheel began with a series of quarterly meetings of the Communication SWG. During these meetings, members discussed research priorities and identified key communication stakeholders within clinical trials. In December 2020, an initial diagram was drafted, incorporating the ideas and discussions that had taken place within the Communication SWG using the NIHR Involve Research Cycle guidance. Over time, this initial draft was refined through subsequent meetings, with each iteration enhancing its comprehensiveness and precision. As the TMRN-TMRP Communication Wheel took shape, a graphic designer was brought in to translate the ideas into a visually compelling and informative resource.

Defining Key Stakeholders and Communication Phases

Through eight iterations, the TMRN-TMRP Communication Wheel evolved into its final working version. Central to its design is the identification and classification of key stakeholders into seven distinct groups:

- **Patients and the Public:** Recognising the importance of patient-centredness in clinical research, this group represents the individuals who would potentially benefit from the trial outcomes directly.
- **Trial Participants:** This category includes individuals who are approached or are actively participating in the trial, as potential or enrolled participants.
- **Health and Social Care Professionals:** The insights and cooperation of healthcare providers are crucial in ensuring the smooth conduct of clinical trials.
- **Funding Bodies:** Securing funding is an essential step in bringing a clinical trial to life. Engaging with funders effectively is paramount.
- **Industry:** Industry partners, pharmaceutical or biotech companies, play a pivotal role in drug development trials.
- **Scientific Community:** Engaging with fellow researchers and experts is essential for peer review, knowledge exchange, and collaboration.
- **Policymakers:** Ensuring that the findings of a clinical trial inform healthcare policies and practices requires effective communication with policymakers.

Each trial team will need to identify more specific stakeholders within each of these groups that are relevant for their trial. Stakeholder mapping can be a useful process to help trial teams think through who their key stakeholders are, and how best to communicate with them.

The TMRN-TMRP Communication Wheel defines three phases within the clinical trial lifecycle: development, conduct and results. Within each phase, it specifies which stakeholders should be consulted. This clear and visual representation enables trialists to tailor their communication strategies based on the specific phase and stakeholder involved (Figure 1).

Accessibility and Feedback

One critical aspect of the TMRN-TMRP Communication Wheel's development was ensuring its accessibility. The colours and contrast combinations adhere to the Web Content Accessibility Guideline standards, making it user-friendly for individuals with varying visual abilities. Furthermore, the wheel was subjected to peer review and feedback, including presentation to the MRCCTU (Medical Research Council Clinical Trials Unit) PPI (Patient and Public Involvement) group at University College London, where their input was incorporated to ensure comprehensiveness and usability. Table 1 also provides a matrix to assist trial teams in the planning process.

Promoting Effective Communication in Clinical Trial

The TMRN-TMRP Communication Wheel is a dynamic tool that is expected to have an impact on the way clinical trials are conducted. By providing a structured framework for developing and refining communication plans in trials, this resource promotes more in-depth consideration of the complexities of communication within clinical trials and the resources that might be required to achieve this.

One of the key takeaways from the TMRN-TMRP Communication Wheel is the need for diverse strategies and resources to communicate effectively with a diverse group of stakeholders, each with unique communication needs. Tailoring communication approaches to both the specific stakeholder and trial phase will be crucial for success. The wheel can also be used to ask what resources/training exist to support trialists to communicate effectively with these stakeholders and identify what additional resources/training are needed.

An iterative evaluation process is planned for the TMRN-TMRP Communication Wheel, beginning in January 2024. This process will ensure that the tool continues to develop and evolve to remain relevant and effective in enhancing communication within clinical trials. As new insights and best practices emerge, they can be incorporated into future iterations, further refining and strengthening communication in the clinical trials landscape.

Conclusion

In conclusion, it is hoped that the TMRN-TMRP Communication Wheel will prompt a significant leap forward in the quest to enhance communication in clinical trials. By addressing the who, what, where, when, and how of communication, this resource empowers researchers, trialists, and stakeholders to navigate the intricate web of clinical trial communication with greater precision and effectiveness. It enables trialists to be systematic in their approach to communication, and it therefore has implications for ensuring inclusion of key stakeholders at each phase. It can be used to identify what resources/training exist to support trialists to communicate effectively with these stakeholders and identify what additional resources/training are needed. Ultimately, improved communication holds the potential to not only advance trial methods but also to bring us closer to better healthcare outcomes for all.

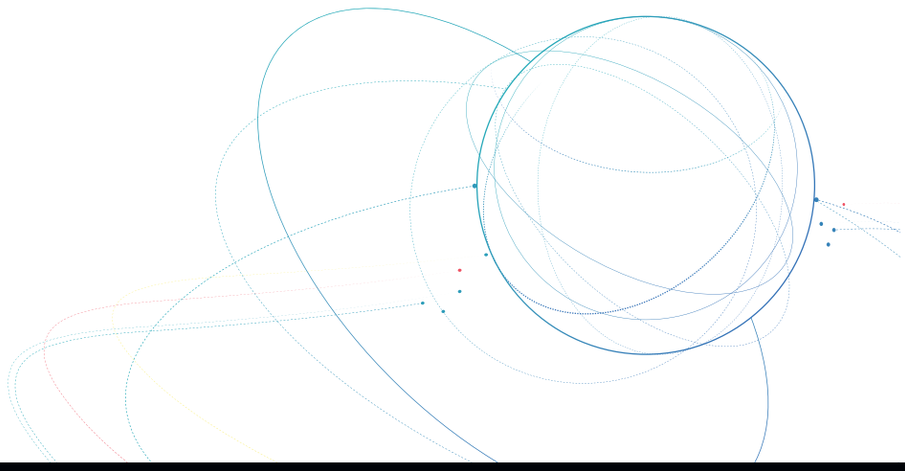


Figure 1 The TMRN-TMRP Communication Wheel

COMMUNICATION:
STAKEHOLDERS* TO CONSIDER FOR YOUR RESEARCH

LIST OF STAKEHOLDER GROUPS	
1	Patients and the Public
2	Trial Participants
3	Health and Social Care Professionals
4	Funding Bodies
5	Industry
6	Scientific Community
7	Policymakers

** List of stakeholders may depend on type of trial and trial topic.*

A stakeholder group may be appropriate to different stages of a trial. Communication about trial may vary depending on the progression of trial.

Table 1 The HRB TMRN Communication Wheel Matrix*

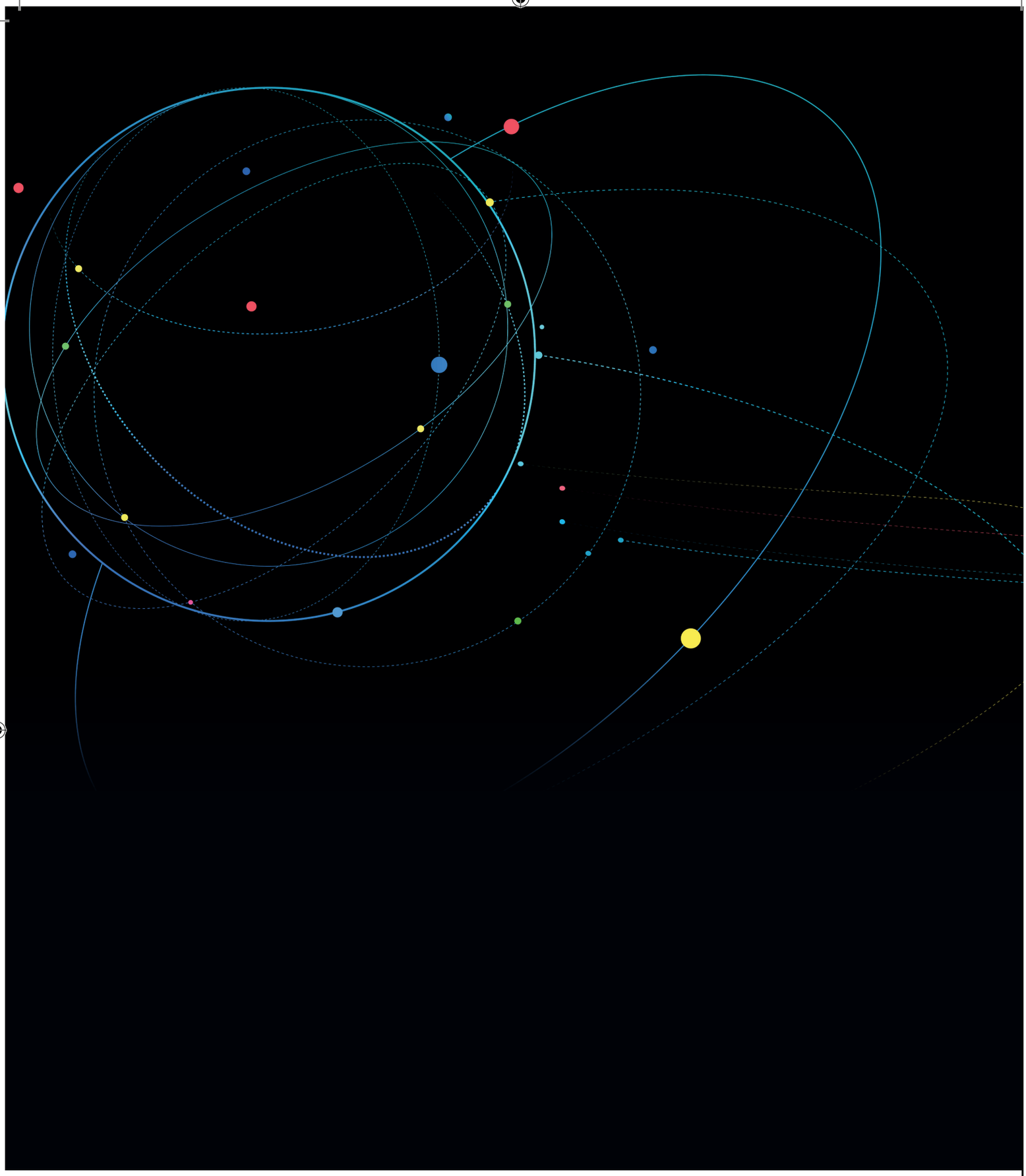
	Review of existing evidence & priority setting	Initial trial design & securing funding	Final trial design	Trial set-up	Trial delivery	Follow-up	Analysis	Dissemination and implementation
Patients and the public								
Trial participants								
Health and social care professionals								
Funding bodies								
Industry								
Scientific Community								
Policy makers								

*The colours in the matrix align with the trial development, trial conduct and trial results phases.

Appendix 1 Members of the MRC-TMRP-Communication Working Subgroup

Alistair Nichol	University College Dublin, Ireland.
Amanda Roberts	Patient and Public Partner.
Andrew Willis	HRB Trials methodology Research Network, HRB Clinical Research Facility, University College Cork, Ireland.
Annabelle South	University College London, UK.
Bridget Young	University of Liverpool, UK.
Cherish Boxall	Southampton Clinical Trials Unit, UK.
Chris Rogers	Bristol Trials Centre, University of Bristol, UK.
Declan Devane	HRB Trials Methodology Research Network , University of Galway, Ireland.
Ellen Murphy	HRB Clinical Research Facility, University College Cork, Ireland.
Emma Lidington	Cancer Prevention Trials Unit (CPTU), Kings College London, UK.
Emma Thomas-Jones	Centre for Trials Research, Cardiff University, UK.
Frances Sherratt	University of Liverpool, UK.
Frances Shiely	HRB Trials Methodology Research Network, HRB Clinical Research Facility, University College Cork, Ireland.
Garry Meakin	Nottingham Clinical Trials Unit, UK.
Gosala Gopalakrishnan	Hannah Swayze Department of Primary Care CTU, University of Oxford, UK.
Heidi Green	Couch Health, UK.
Iracema Leroi	Trinity College Dublin, Ireland.
Jamie Murdoch	Department of Population Health Sciences, King's College London, UK.
Julia Wade	University of Bristol, UK.
Katie Biggs	University of Sheffield, UK.
Katie Gillies	University of Aberdeen, UK.
Kerry Hood	Cardiff University, UK.
Leanne Gardner	King's College London, UK.
Leila Rooshenas	University of Bristol, UK.
Marie-Anne Durand	Aix-Marseille Université, Dartmouth University, USA.
Nancy Fernandes da Silva	Keele University, UK.
Nelly Owino	Oxford Vaccine Group, University of Oxford, UK.
Nicola Harman	University of Liverpool, UK.
Nicola Mills	University of Bristol, UK.
Nuru Noor	Medical Research Council Clinical Trials Unit, University College London, UK.
Pat Hoddinott	University of Stirling, UK.
Pouya Alaghband	York Teaching Hospital NHS Foundation Trust, UK.
Ratna Sohanpal	Queen Mary University of London, UK.
Rebecca Lewis	The Institute of Cancer Research, UK.
Robyn Woodward-Kron	University of Melbourne, Australia.
Rustam Al-Shahi Salman	University of Edinburgh & NHS Lothian, UK.
Saba Faisal	University of Bristol, UK.
Sandra Galvin	HRB-Trials Methodology Research Network, University of Galway, Ireland.
Sarah Lawton	Keele University, UK.
Shaun Treweek	University of Aberdeen, UK.
Talia Isaacs	UCL Institute of Education, University College London, UK.

Notes



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