



Setting Up Mental Health Clinical Trials at an NHS site

The implementation of a stages model with measurable targets

Improving UK clinical research set-up times is a key government priority¹. Delays increase public expenditure, reduce health outcomes for patients and lower the competitiveness of the UK².

INTRODUCTION

Oxford Health NHS Clinical Research Facility recognise that their set up times are a key priority. The facility delivers priority disease clinical mental health research such as, dementia studies³. An analysis of set-up processes within NHS delivery teams is a novel concept. Therefore, the Oxford facility aims to meet this unmet need and evaluate how set-up processes can be simplified, streamlined and more efficient at an NHS site.

METHODS

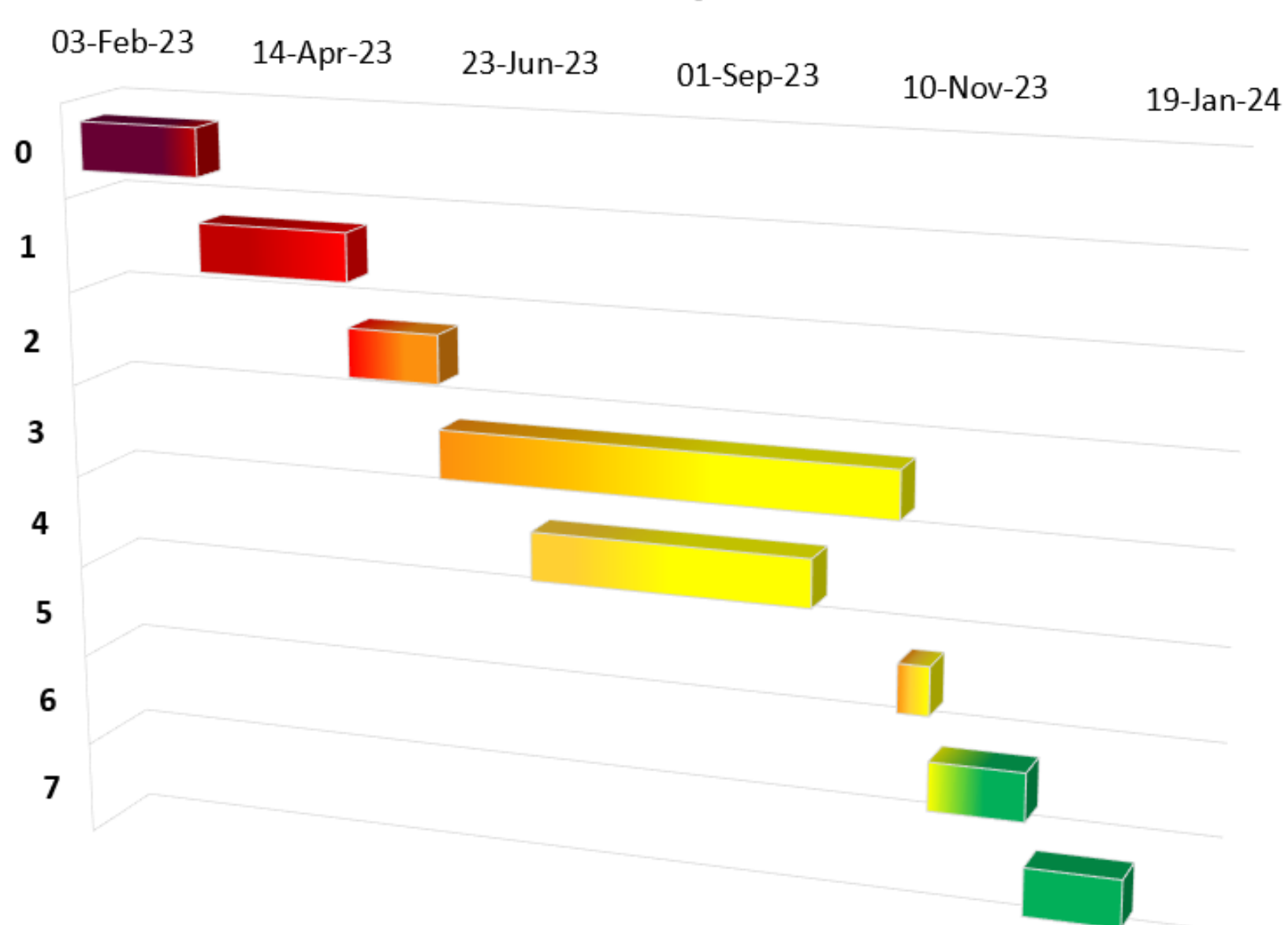
Key set-up timepoints were identified using pre-existing local milestones and site performance proxy metrics commonly used by commercial sponsors to select sites. Descriptions of set-up tasks have been described at each stage with task durations recorded. Other study characteristics include ethical application status, sponsor, phase, intervention, study risk, intensity, and complexity.

INITIAL FINDINGS

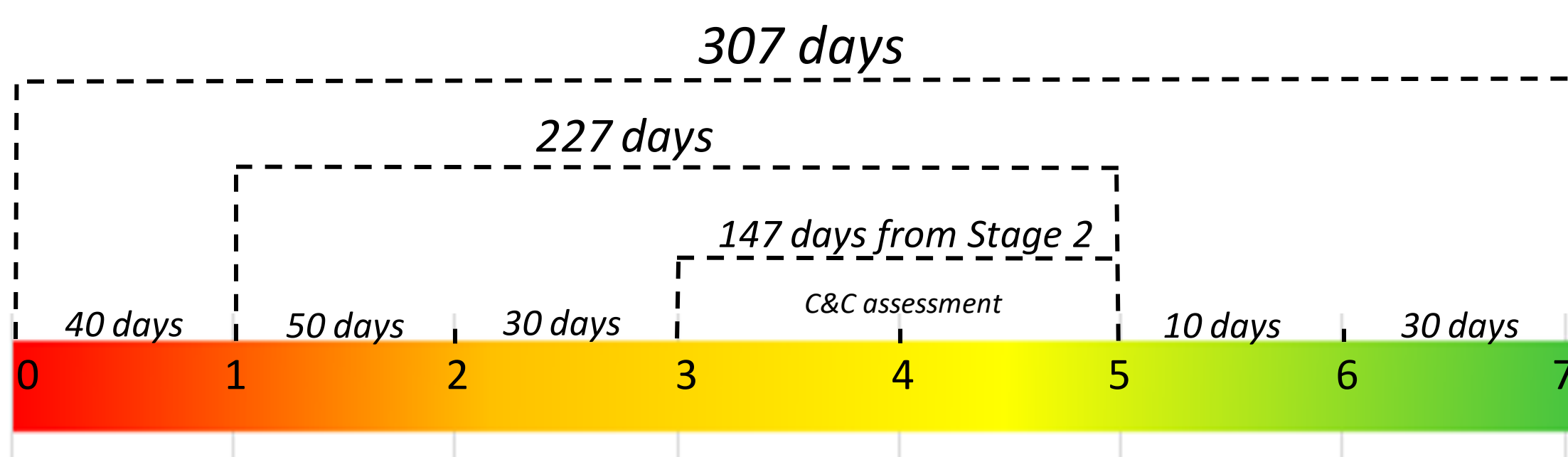
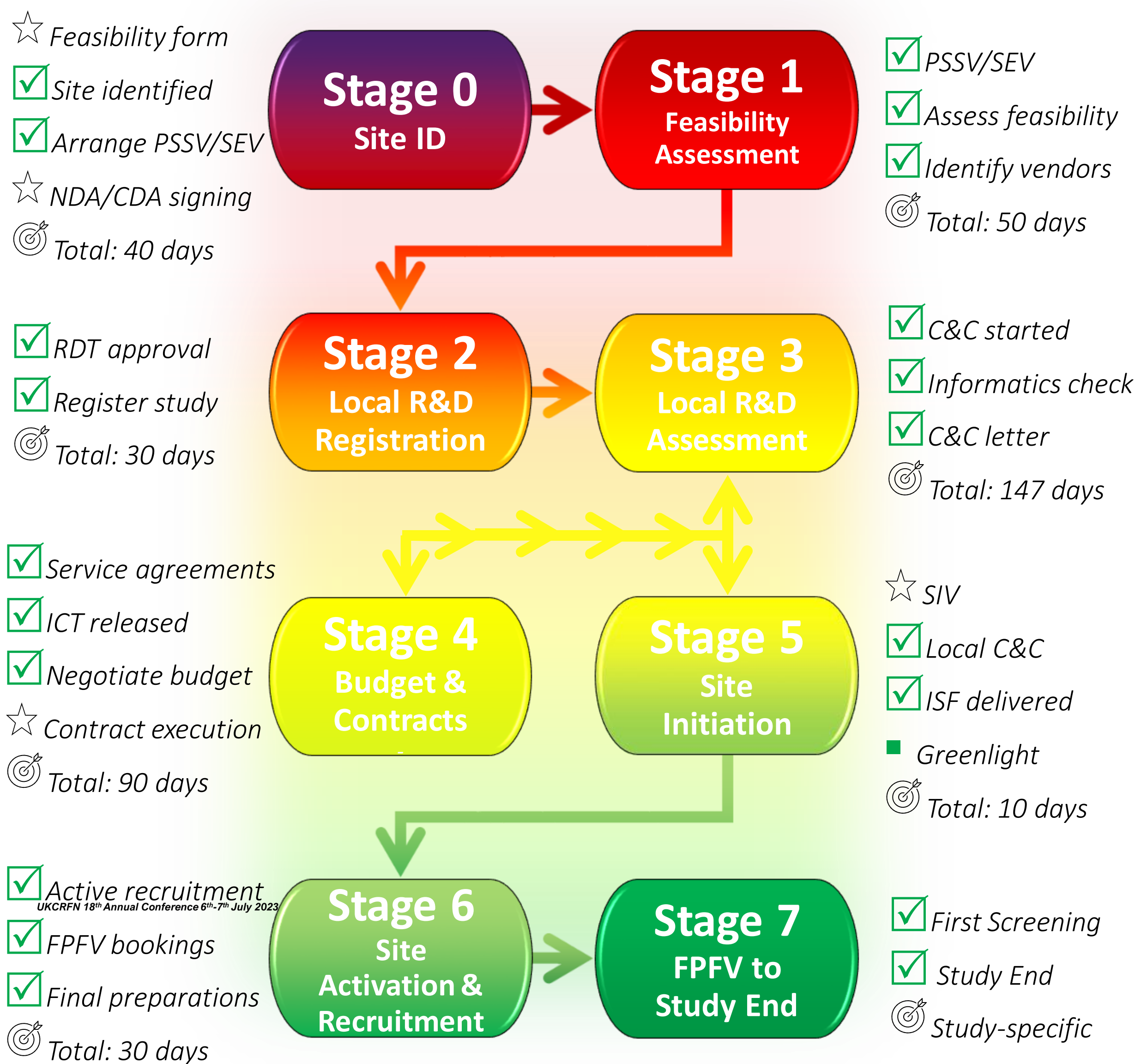
Table 1. Days (M) spent at local stages with Contract Research Organisation (CRO) proxy metrics.

Local Stages	Target	M	N	CRO Proxy Metrics	Target	M	N
0	40	41	9	Feasibility form return	13	6	1
1	50	55	10	CDA Signature	6	10	7
2	30	15	8	CDA to SEV/PSSV	66	57	5
3	147	105	1	Contract Execution	90	79	1
4	90	78	1	Contract Execution to SIV	13	4	1
5	10	9	1	PSSV/SEV to Green Light	227	197	1
6	30	55	1	C&C Letter to FPFV	30	65	1

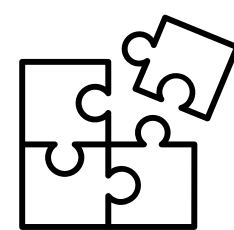
Ideal Set-Up Times



Stages & Targets Model



IMPLICATIONS



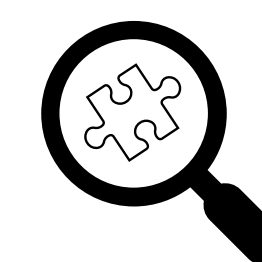
BIG PICTURE
of information

- Increased efficiency "drives innovation, which translates into improved care"¹.
- Empowers local sites to:
 - identify key trends.
 - predict timelines.
 - replicate processes.
 - be competitive.



SUMMARY
of facts

- Qualitative and quantitative reporting to local and national bodies.
- Mutual understanding with commercial partners.
- Track progress and project manage multiple studies.



EXPLORE
a topic

- Compare study set-up times and identify barriers.
- Explore potential solutions.
- Analyse the effect of:
 - key study characteristics.
 - task type and duration.

References

¹Department of Health & Social Care (2022) The Future of Clinical Research Delivery: 2022 to 2025 implementation plan. Available at: <https://www.gov.uk/government/publications/the-future-of-uk-clinical-research-delivery-2022-to-2025-implementation-plan/the-future-of-clinical-research-delivery-2022-to-2025-implementation-plan>.
²Kearney, A., McKay, A., Hickey, H., Balabanova, S., Marson, A.G., Gamble, C. and Williamson, P., 2014. Opening research sites in multicentre clinical trials within the UK: a detailed analysis of delays. *BMJ open*, 4(9), p.e005874.
³Oxford Health NHS (2021) Meet the NIHR Oxford cognitive health Clinical Research Facility. Available at: <https://oxfordhealthbrc.nihr.ac.uk/meet-the-nihr-oxford-cognitive-health-clinical-research-facility/>.

Acknowledgements

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