UKCRC Registered Clinical Trials Units

UKCRC Registered CTU Network –

A survey to review how Registered Clinical Trials Units (CTUs) manage the delivery of funded trials

UK Clinical Research Collaboration

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A survey to review how Clinical Trials Units (CTUs) manage the delivery of funded trials

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For a full list of CTUs that provided data for this report, please see Appendix 2.

Contents

1. Introduction

The UKCRC Trial Management Group developed a survey to quantify how registered CTUs are managing their portfolio of funded trials in terms of preparation, time periods within the funding for set-up and delivery, and the ultimate delivery in their trials meeting award timelines. No specific costings were asked in the questionnaire as it was known when this had been asked in the past that units are generally unwilling to disclose such information.[1]

The survey was sent out to all Trial Management contacts for the 50 UKCRC fully registered CTUs. The survey was open for responses between March and May 2025. 31 responses were received, giving a response rate of 62%. Responses were received from CTUs across the UK (Northern Ireland, Scotland, England and Wales).

2. Responding CTU Descriptors

Responses came from units of varying sizes, with the units being asked for the number of funded trials on their current portfolio where they were the lead CTU. The median portfolio size of a unit that responded was a unit with between 16 and 29 funded trials on their portfolio. Full details in Figure 1.

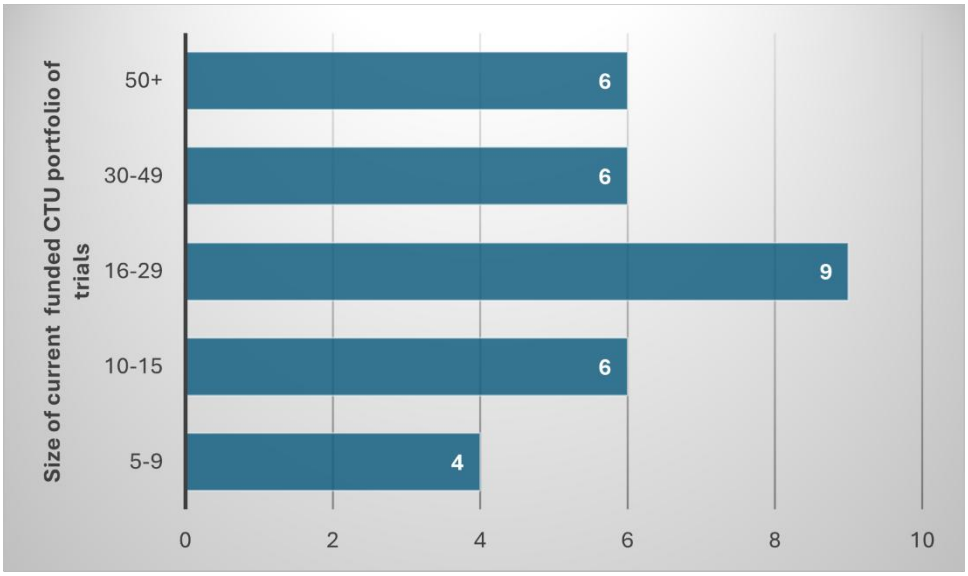

Figure 1- Size of CTU portfolio

Few units added more than 9 trials to their portfolio in the last 12 months, by far the most units had added up to nine trials to their portfolio in the last 12 months (87%). Full details in Figure 2. Only those with already large portfolios (at least 30 active trials) were the ones that added ten or more trials to their portfolio in the last year. Only one unit stated that these were all regulated trials (either CTIMPs or devices).

[1] Hind, D., Reeves, B.C., Bathers, S. *et al.* Comparative costs and activity from a sample of UK clinical trials units. *Trials* **18**, 203 (2017).

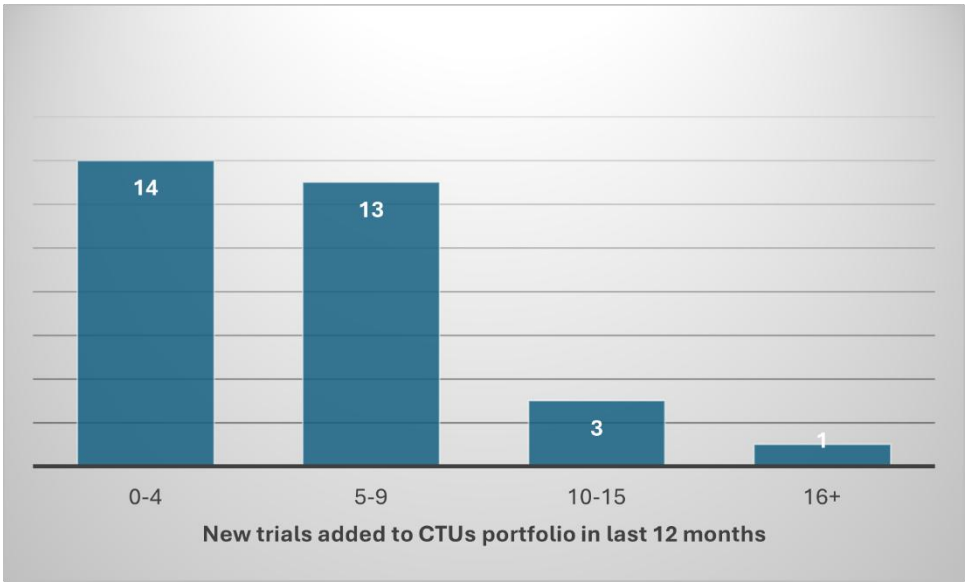

Figure 2 – Number of new trials (of any type) added to a CTUs portfolio in the last 12 months

Figure 3 – shows the breakdown by each CTU.

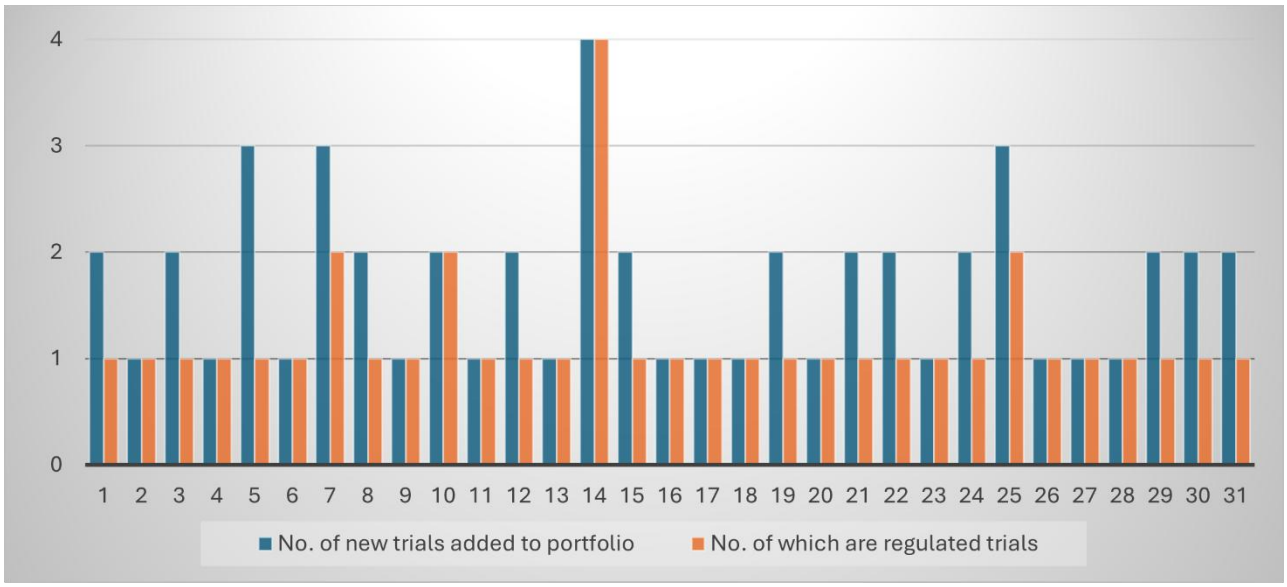

Figure 3 – Category of number of trials added to portfolio, and the breakdown of the type of trials within the last 12 months

The responses were transposed into categories – Category 1 represented – 0-4 trials, category 2 represented 5-9 trials, category 3 represented 10-15 trials and category 4 – over 16 trials.

(Note CTU identifier – relates only to the order of CTU responses – it is not a UKCRC CTU identifier)

Only one unit who indicated that they had added 16 or more trials in their portfolio stating that between 5-9 of their new projects had international sites, every other unit selected that they had between 0-4 new trials with international sites.

CTUs were asked to report the main funder of their trials – that is who funds the most trials in number rather than by income value – 84% reported that the NIHR was the main funder. Figure 4 shows the full breakdown.

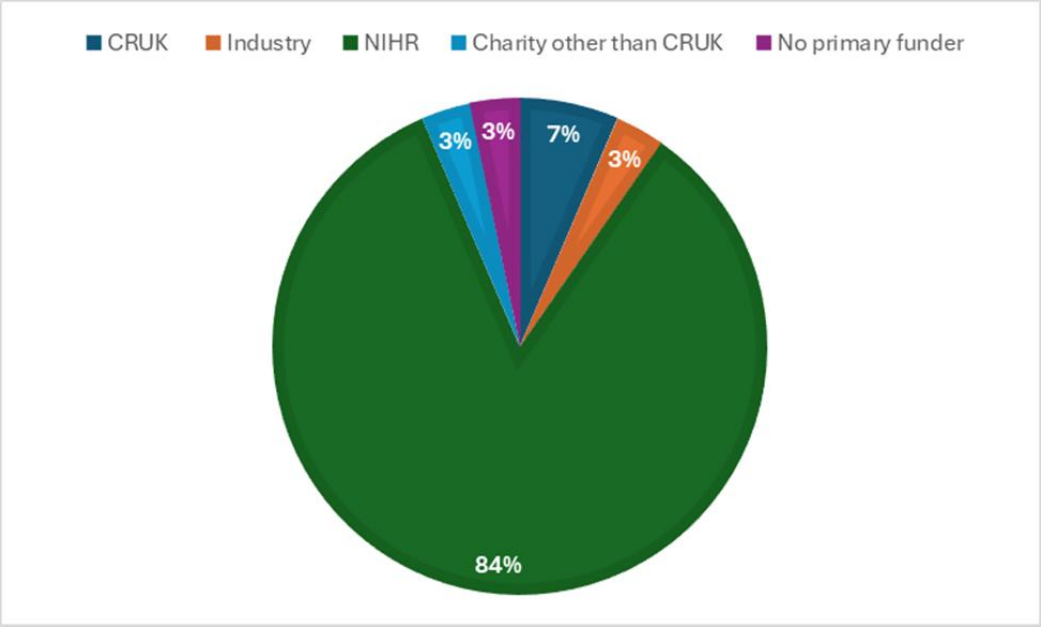

Figure 4 – Breakdown of main funder for CTUs

Units were also asked to state who else funded the trials on their portfolios; charities other than CRUK were most commonly cited followed by the MRC. 26 units (84%) cited charity funding other than from CRUK as one of their sources of funding. Figure 5 shows the sources that were cited by more than one unit. 11 (35%) units cited in addition to their main funder they had three other funders (where charities other than CRUK, the BHF, MRC and Wellcome were one category that could be selected). Four (13%) units cited at least five other funders in addition to their main funder. Figure 5 lists the options selected by units where at least two units selected that option.

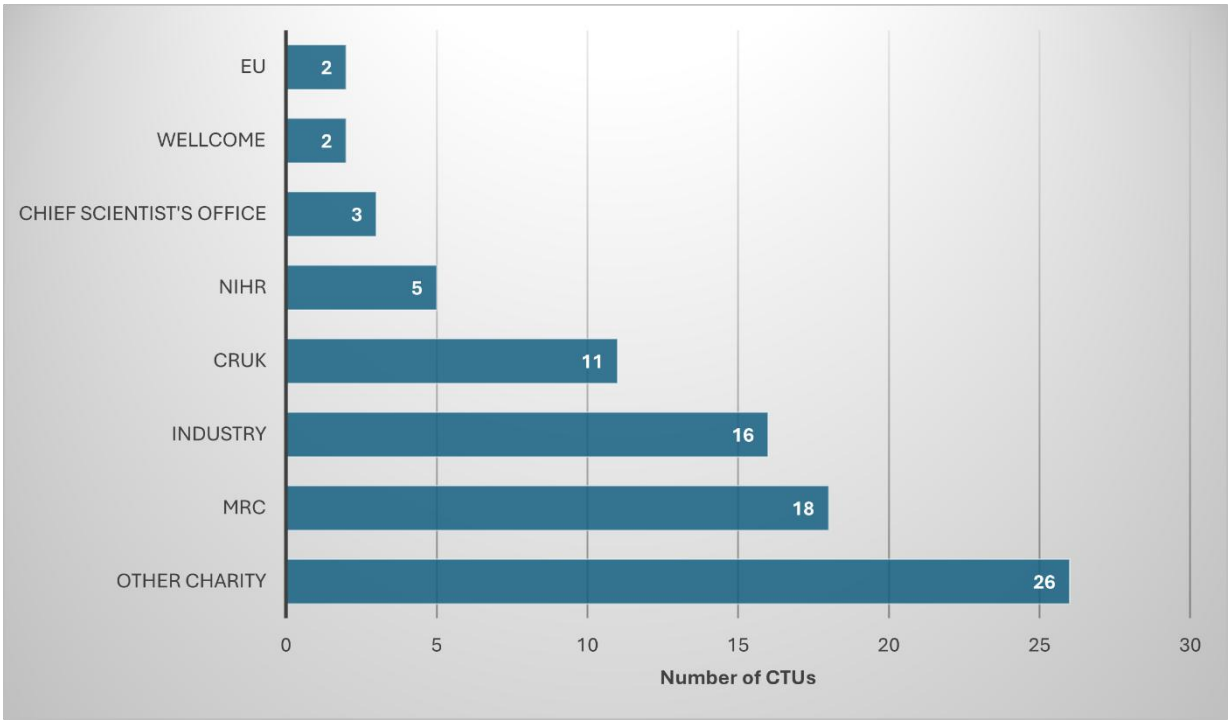

Figure 5 – Other sources of funding cited by units after their main funder

(Funders that were only cited by one unit were the UKRI, NHS Blood and Transplant, the Ministry of Defence, Health and Care Research Wales, the British Heart Foundation, Internal University Pump Priming.)

3. Work in the period from funding award to funding start (Pre-award activity)

CTUs were asked typically how much time their CTU likes to have between awards being awarded and the start date of funding. Only two CTUs said they generally had less than three months for this, most units – 20 (65%) stated they usually have between three and six months, whilst seven (23%) stated between seven and nine months, and two units between 10 and 12 months.[2]

Importantly CTUs were asked if they generally do any work on the study during this time. 26 (84%) of units stated that they did undertake work during this time. Only four (13%) stated they did not work on trials during this time.

Of the 26 CTUs that stated that they undertake pre-award activity, 16 (61%) stated that they always did and 10 (38%) stated only sometimes if resources were available. 7 of the 26 CTUs had a dedicated person or team to oversee this activity from the following disciplines - trial management/operations professionals, statisticians/methodologists and data management. Pre-award activity was generally funded via CTU core budget (5/7, 71%) and host institution (2/7, 29%). 18 (69%) units stated pre-award activity was solely undertaken by individuals within their unit, whilst eight (31%) stated that the work was undertaken by staff within and outside of their CTU.

[2] The need for grant related posts to only be recruited to once funding has been secured, posts advertised, appointed to and individuals working their notice to join a study would support these time periods.

Respondents from those 10 CTUs that sometimes undertook work if resources were available were asked to explain how their CTU prioritise which trials receive support/work. The common themes were staff availability/capacity. The full quotes are included below.

- *Not so much about prioritisation more about timing, staff availability and type/amount work required. (Respondent 16)*
- *Co-applicants input during this time and some funded studies request pre-contract funding for operational staff. Those are prioritized. (Respondent 21)*
- *There is no prioritisation; it is just done when feasible to do so. (Respondent 23)*
- *Determined by available resource within the allocated team, requirements of the funder in terms of set up time and profile of the trial. (Respondent 27)*
- *Studies prioritised based on grant start date, funders requirements (e.g. start-up tasks or if ethics required prior to grant start date) (Respondent 18)*
- *Often it depends on whether there is capacity within the team. It is rare that more than one study starts at the same time, however if we had to prioritise, we would prioritise if they had RCT funding available. After this we may give priority to a 'local' study lead (Respondent 26)*
- *Availability of the staff who will be working on the project, who the CTRU lead is. Where the risk of delay would have a more significant impact. (Respondent 9)*
- *All studies will receive support from core staff whilst we recruit trial specific staff onto the project. (Respondent 19)*
- *On the basis of trial complexity. (Respondent 17)*
- *Usually on the basis of if costing allocation post-fund date (e.g., FTE percentage for a given role) is elevated for a period of time to allow for cost recovery of any work-up elements in the post-award / pre-fund stage. (Respondent 11)*

Tasks that were cited by the seven units as being undertaken in the pre-award period are listed in Figure 6. All CTUs used this time to draft protocols, and the majority also utilised this time to draft PIS/participant materials and engaged with sites/undertake feasibility.

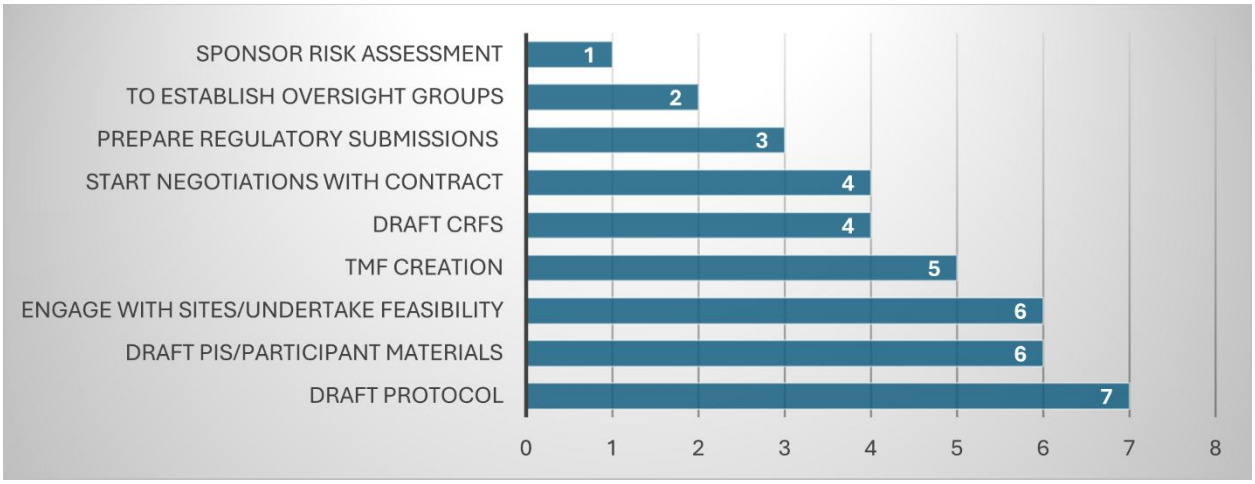

Figure 6 – Tasks undertaken by CTUs in the period prior to grant start post confirmation of funding

The rationale for undertaking pre-award activities was explored and presented in Figure 7 with the majority who responded 21 /26(81%) stating this was due to insufficient time within the

awarded period.[3] 6 / 26 (19%) others also reported that it was a requirement of the funder for some uncosted pre-work – with one funder being named in the responses as needing to have obtained ethics approval prior to the start of the grant. Figure 7 lists all the reasons cited by units.

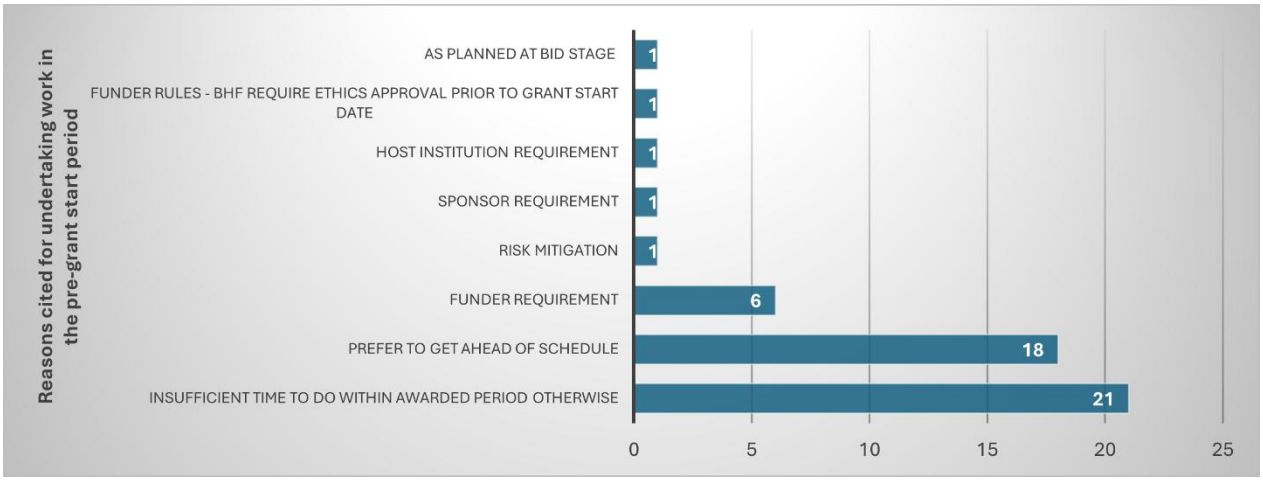

Figure 7 – Reasons cited by CTUs for undertaking work in the pre-grant start period

4. Funded trial set-up

Units were asked to describe their funded trial set-up periods defined as the duration from the grant start date to opening of recruitment. All 31 CTUs include a funded set-up period in their grants with the majority of CTUs (20/31, 65%) not being required to comply to a time limit imposed by the funder for the duration of the set up period Eight (26%) stated they had experience of limits imposed by funders, which respondents stated to be CRUK (12 month maximum), NIHR (between 6 and 12 months), Brain Tumour Charity (12 month maximum) and Industry (although exact time periods were not specified).

30 of the 31 (97%) units were happy to share the typical duration and results are presented in Figure 8 and they acknowledged this period varied depending on the trial complexity with 20 (66%) extending the duration if complex. The most common duration of the funded set-up period was between 7 to 9 months (13/31 (42% units cited this). It was noted that complexity was not necessarily about regulated trials, rather it could be complex interventions/site set-ups and approvals that were required.

[3] This is due to perhaps grant limitations or wanting to be more competitive and not costing all the work required. With the current financial pressures on Universities and therefore CTUs this will not be sustainable.

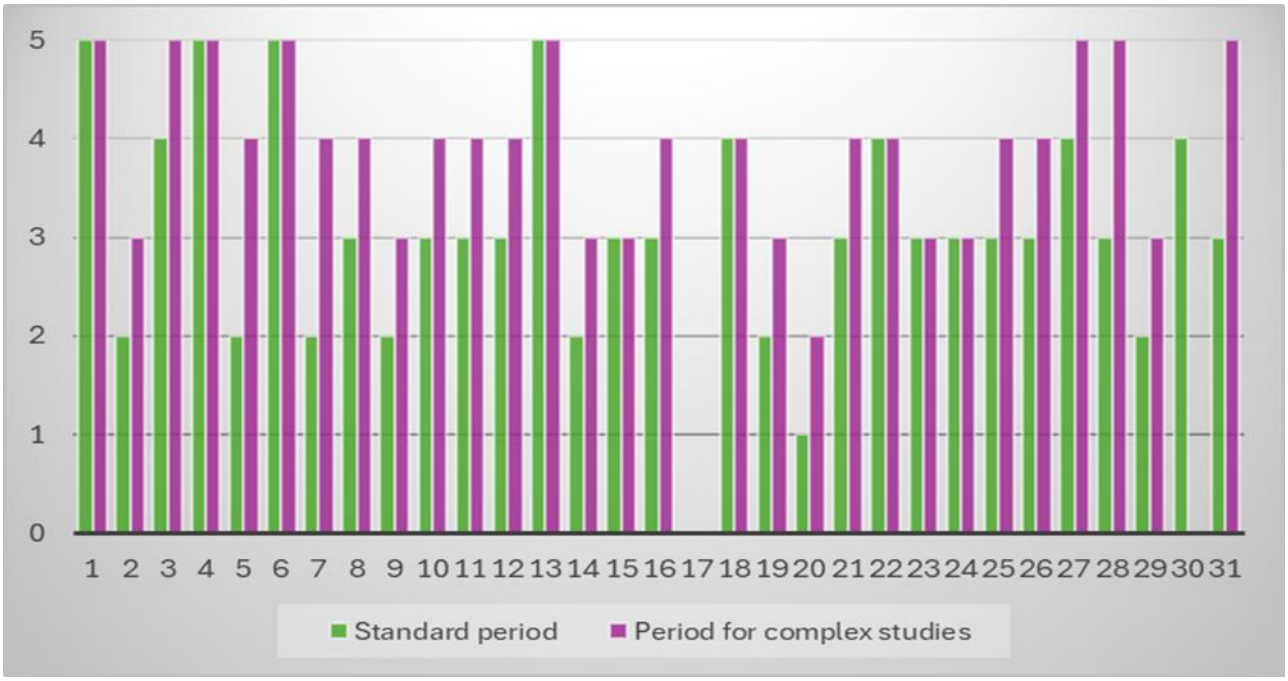

Figure 8 – Typical duration in months from grant start to planned opening to recruitment – for a standard study in green and a complex study in purple. The responses were transposed into categories – Category 1 represented – 0-3 months, category 2 represented 4-6 months, category 3 represented 7-9 months, category 4 – 10-12 months and category 5 – Over 12 months.

Note: Respondent 17 preferred not to give this information and respondent 30 did not want to give an answer with regards to a complex study

5. Embedded pilots

Units were asked if they generally included embedded pilots in their grant applications. 19 (61%) units cited that they generally included in their grant applications time and funding for an embedded pilot, which are often welcomed by funder to ensure deliverability of the trial. Units were asked what criteria they use for continuation of their pilots with the most common being number of sites opened (16/19 (84%) units used this) and the number of participants randomised (15/19 (79%) units used this). All the reasons given are listed in Figure 9.

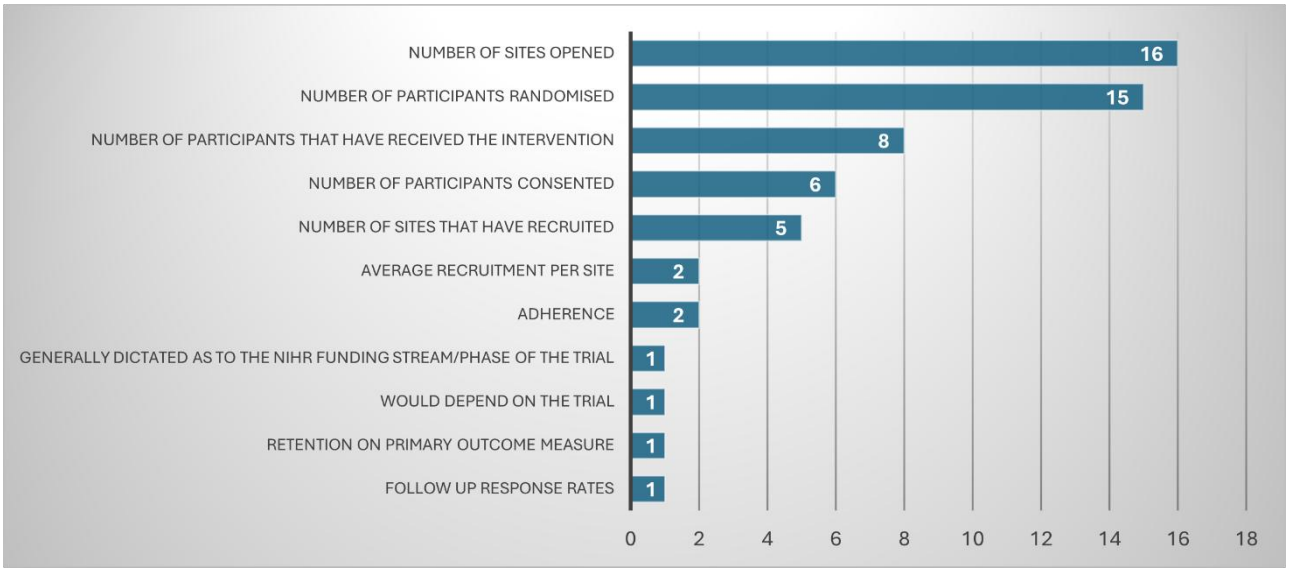

Figure 9 – Criteria listed that have been used in embedded pilots to measure against

6. Recruitment duration

All trials involve set-up, recruitment and follow-up periods. Units were asked how they typically determine the length of time needed for recruiting the required numbers of participants. The top two primary sources used for this was the opinion of the Chief Investigator (28/31, 90%) and the use of site feasibility questionnaires (26/31, 84%) there was just one unit that did not cite the use of either of these. Figure 10 gives all reasons reported.

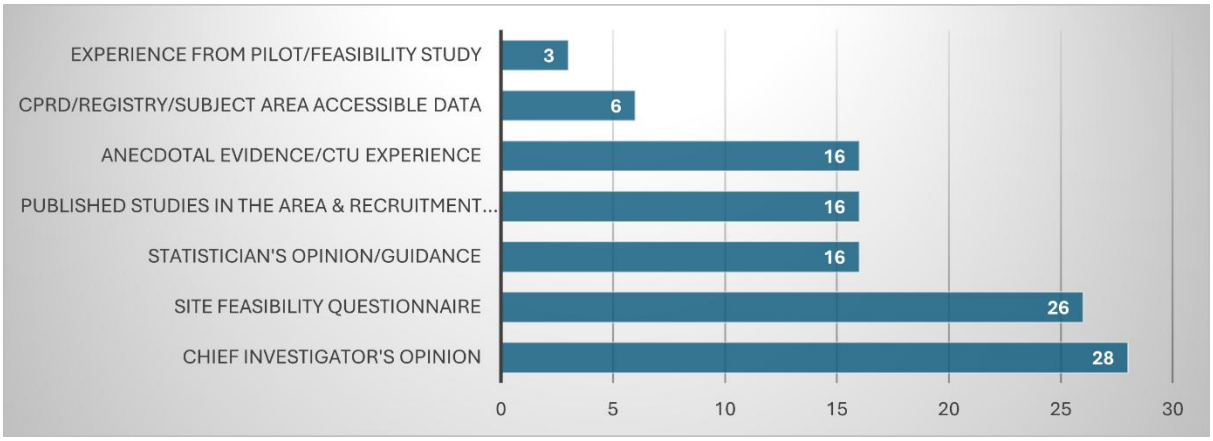

Figure 10 – Factors used to determine how long to set a recruitment period for a trial – units were able to select multiple reasons

How units decided upon how many sites to include as opposed to the length of time allocated for recruitment was also questioned – there were 4 main factors identified – optimal study duration, ability for sites to be able to deliver the trial, typical numbers that could be recruited and previous experience in the clinical area. All reasons are listed in Figure 11.

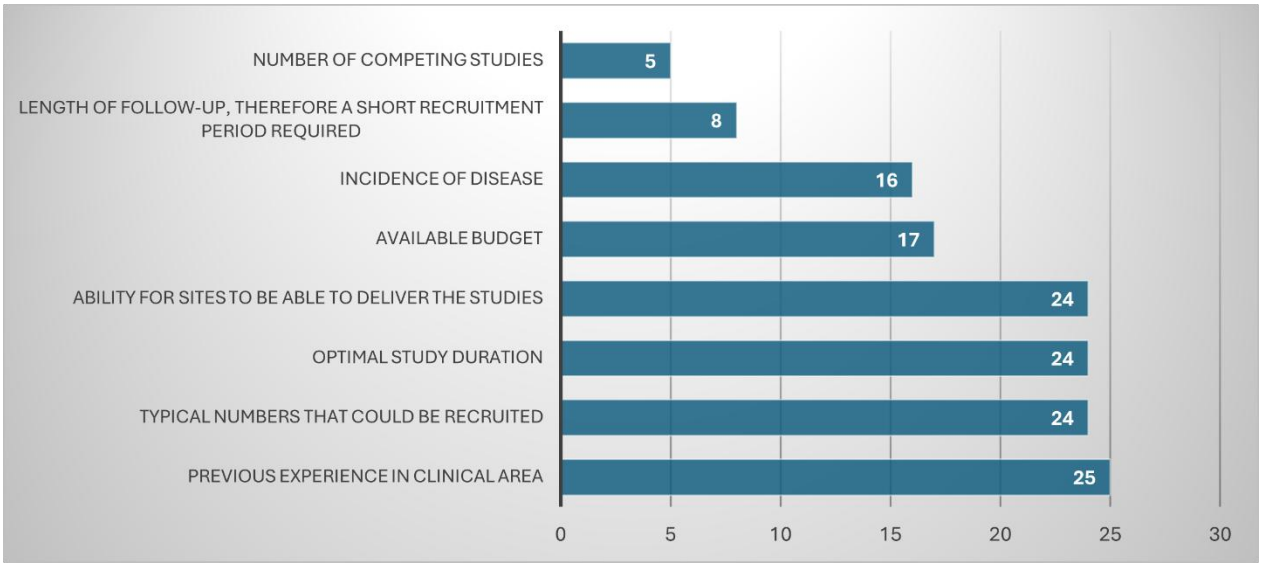

Figure 11 – Reasons/evidence used to determine the number of sites needed to recruit to target

Units stated for the majority of trials (59%) on their portfolios they had planned recruitment periods of between 13 to 24 months with 27% being 25 to 36 months and 14% being 37 to 48 months long.

7. On time and target delivery of trials and implications

It is well published that seemingly a lot of trials do not deliver to time and target.[4] [5] [6] Respondents were asked to approximate what percentage of trials on their portfolios had closed within the original number of recruiting months stated in their funding applications. Three units absented from answering this question. For the remaining 28 units, 13 (46%) stated that less than a quarter of their portfolio had delivered on time, only 2/29 (7%) stated between 76 and 100% delivered on time. Figure 12 shows this breakdown from the units, which is the inverse of what both CTUs and funders would like.

[4] Sully, B.G.O., Julious, S.A. & Nicholl, J. A reinvestigation of recruitment to randomised, controlled, multicenter trials: a review of trials funded by two UK funding agencies. *Trials* **14**, 166 (2013). https://doi.org/10.1186/1745-6215-14-166

[5] Walters SJ, Bonacho dos Anjos Henriques-Cadby I, Bortolami O, et al. Recruitment and retention of participants in randomised controlled trials: a review of trials funded and published by the United Kingdom Health Technology Assessment Programme. BMJ Open 2017;7:e015276. doi:10.1136/bmjopen-2016015276

[6] Knowlson C, et al. Recruitment patterns in multicentre randomised trials fit more closely to Price's Law than the Pareto Principle: A review of trials funded and published by the United Kingdom Health Technology Assessment Programme,
Contemporary Clinical Trials, 2022;113

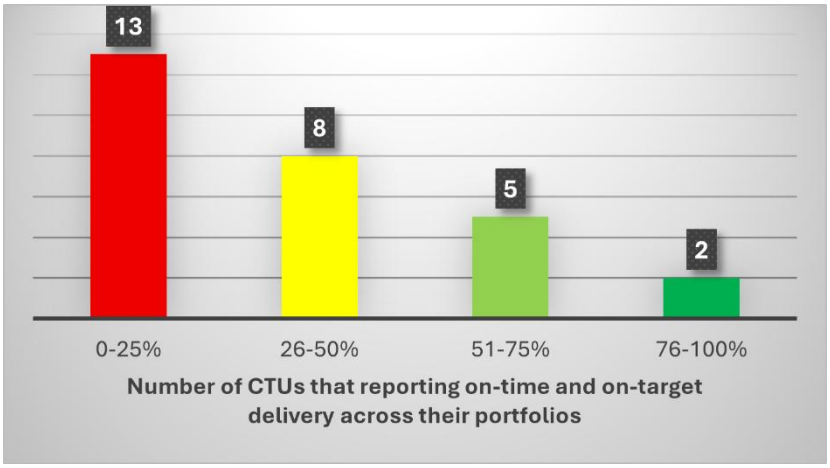

Figure 12 – Percentage of CTU portfolio that has been deliver on time – where 76-100% is delivery on time

The average "unfunded" set up time and funded set up time was compared. The most common combination was 3-6 months "unfunded" set up time followed by 7 to 9 months funded set up time. Table 1 lists all the combinations reported by units.

		Unfunded months			
		Less than 3m	3-6 m	7-9 m	10-12m
Funded months	0-3m		1		
	4-6m		5	2	
	7-9m	1	7	4	1
	10-12m		3	1	1
	12m+	1	3		
	Prefer not to say		1		

Table 1 – Average timing combinations for grants reported by units

Table 2 compared the data in Table 1 against successful delivery (on time and on target, Figure 13). Respondents could select success rates within the ranges of 0-25%, 26-50%, 51-75% or 76-100%. In Table 2 these ranges were converted to 1,2,3 or 4 values accordingly. Table 2 data indicates that a 3 to 6 month (up to 9 months) unfunded set up period followed by a 7 to 9 month funded set up period was necessary.

		Unfunded months			
		Less than 3m	3-6 m	7-9 m	10-12m
Funded months	0-3m		2		
	4-6m		3	2	
	7-9m	1	4	3	1
	10-12m		1	1	2
	12m+	1	3		
	Prefer not to say		4		

Table 2 – Successful delivery reported levels of trials – on time and on target using these time combinations.

Note: Where multiple CTUs reported using the same combination, the highest success score has been used in this table

Units were asked of those trials that they did not deliver on time, what percentage of these trials was a time only extension requested, and if it was granted by the funder. Units were also asked to report on the percentage of these trials that did not deliver on time, what percentage of these was a cost and time extension requested, and if it was granted by the funder.

For the time only extensions the most common length requested for the extension was between three to six months, whereas for the costed extension the most common length of the extension was for over 12 months – this is unsurprising given the staff and resource costs this extended period would incur. Table 3 shows the frequencies stated of the number of months requested for extensions – time only (uncosted) and costed.

Number of months requested for extension	Time only extensions (uncosted) (n=31)	Time and financial extensions (costed) (n=31)
Less than 3 months	3	1
3 – 6 months	13	2
7 – 9 months	5	3
10 – 12 months	2	6
Over 12 months	4	12
Prefer not to say	4	7

Table 3 – Average length of extensions requested from funders

Units were asked to state what they considered the most common reasons for their trials not recruiting as per their original predictions. The biggest issue cited was study burden for sites but of note is the unrealistic targets initially predicted 17 units selected this.

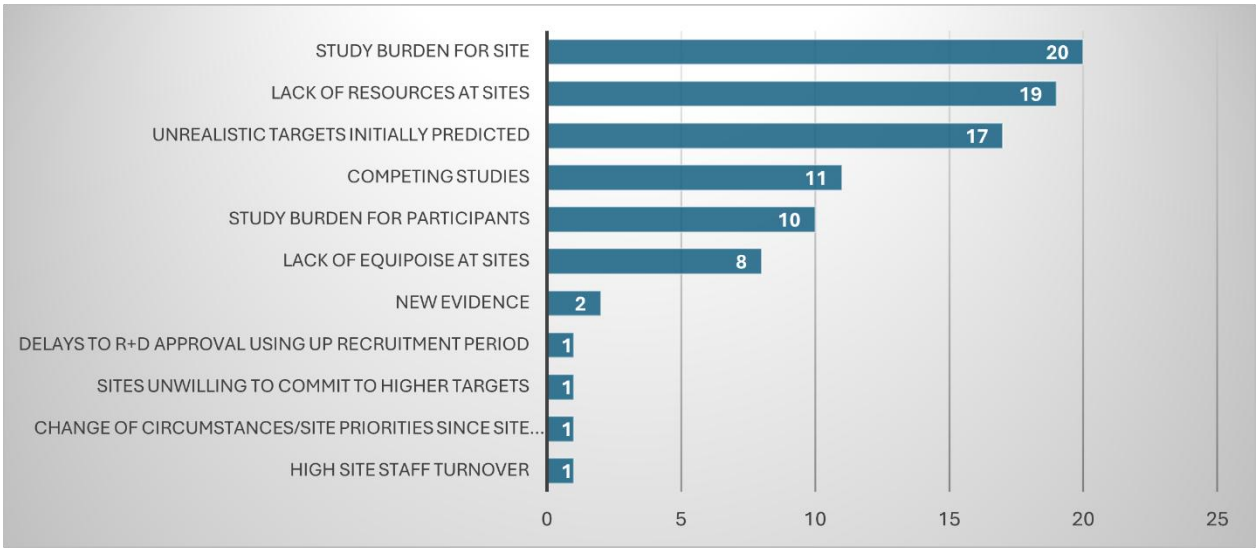

Figure 13 – Reasons cited by units as the main reasons a trial did not deliver to time and target

8. Burden of extension requests

For those trials not delivering on time, extensions are generally sought – either funded or unfunded, with funder extensions generally being for short periods of time. Units were asked to quantify the burden extension requests placed on them. Units were unanimous that extension requests did result in a burden to them, and for just under half of respondents (48%) this was classed as a least a major burden. Figure 15 shows the spread of responses.

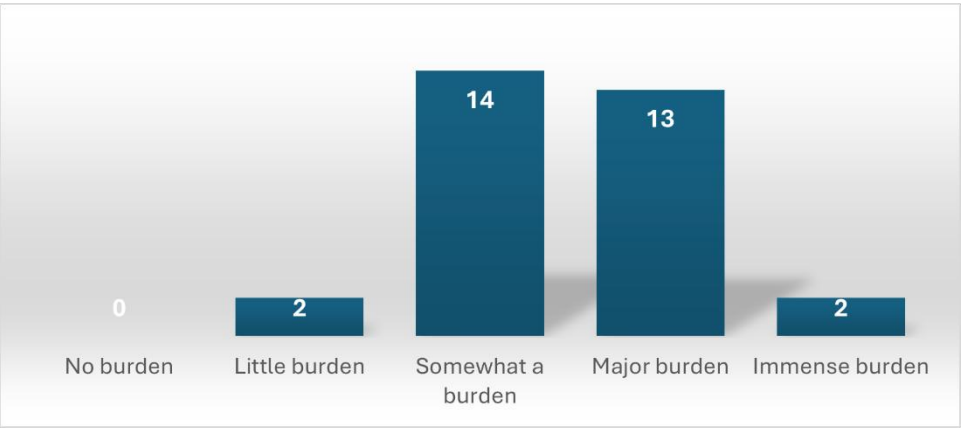

Figure 14 – CTU categorisation of the burden associated with extension requests, n=31

Units were also asked who was usually involved in the process of applying for an extension. All 31 units responded to this question, and the leading parties involved in this are the Chief Investigator, Senior Trial Manager and Trial Manager as the parties most closely involved with the trial and have the greatest understanding of what has been occurring to date. It is notable how many members of CTU staff are potentially involved – the responses received included 13 different job roles. Figure 15 lists all roles cited.

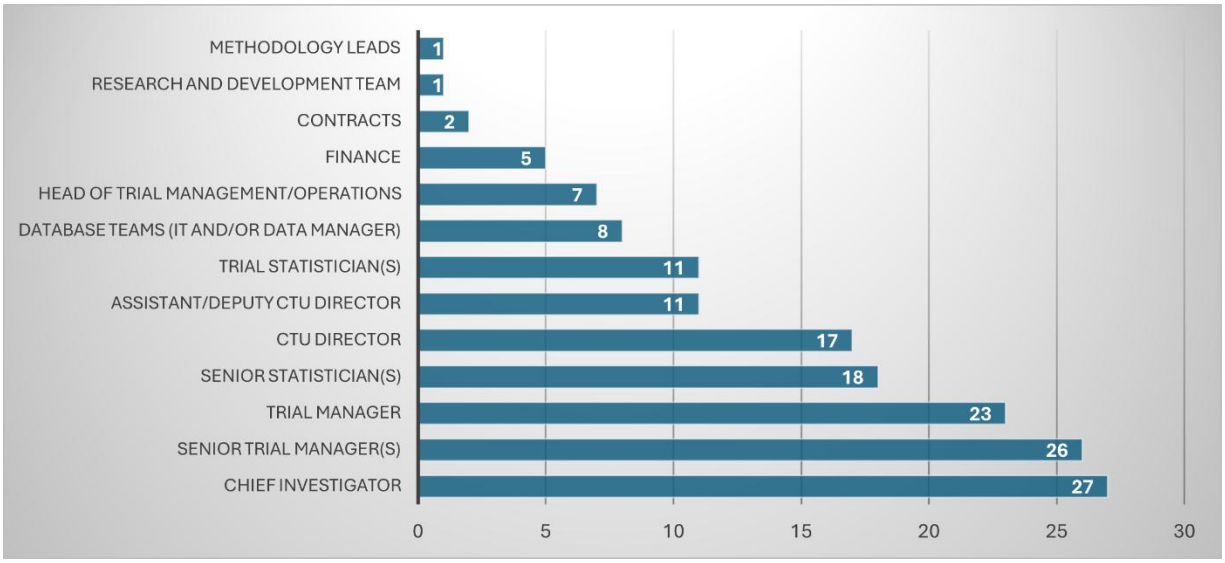

Figure 15 – Those within a CTU that undertake work in applying for permissions for extensions (multiple selects were permitted)

9. Sankey diagrams

The authors have undertaken an exploratory look at some of the data to see if there were any patterns in the data provided by units.

Exploration 1 – is there a relationship between the length of time between the grant being awarded and started, the funded time for set-up and the % of trials delivering on time?

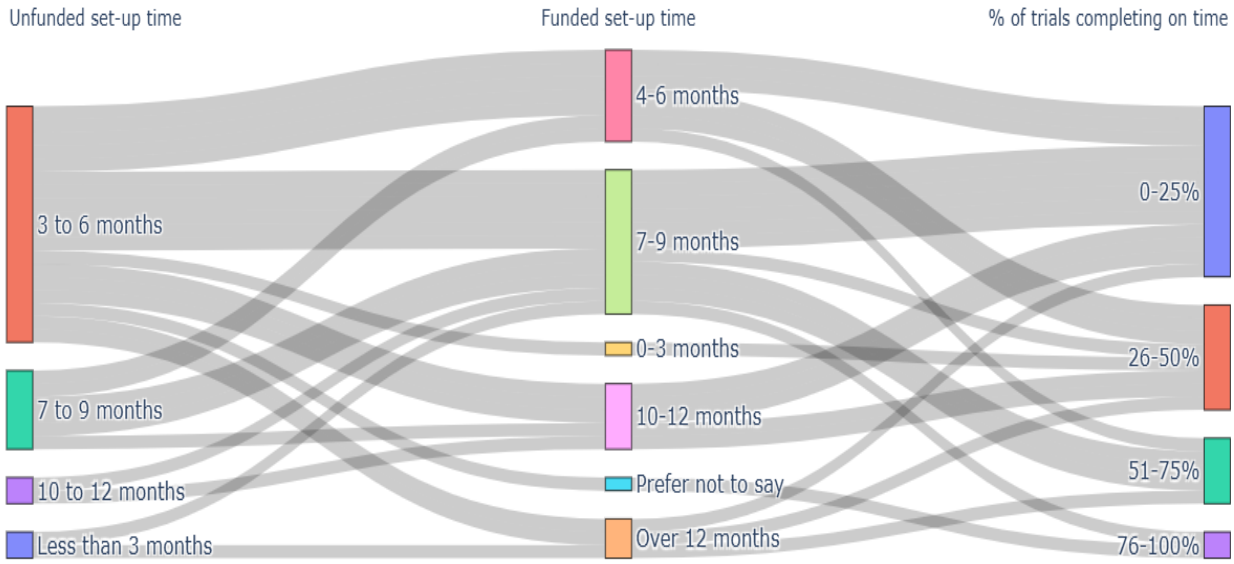

Figure 16 – Relationship between time from grant award to grant start (unfunded set-up time), funded set-up time and % of trials completing on time

There were only 2 units that reported that at least 76% of the trials on their portfolios complete on time. Both units reported quite different pathways – one stated that generally took less than 3 months of unfunded set-up then had 7-9 months (so between 10-12 months – which is what anecdotally is being told by units across the country as being what is needed to set-up a trial; the other stated they usually have 3-6 months of unfunded set-up then did not state their funded set-up time so we cannot comment on that relationship. However, there are strong relationships shown between those trials that had 3 to 6 months of unfunded set-up, 7-9 months of funded set-up and ended with only 25% of their trials completing on time.

It must be noted that these correlations do not consider the type of trials and clinical areas that units are undertaking which will impact the delivery.

Exploration 2 – is there a relationship between the percentage of trials completed on time, the length of time only extension requested, and the percentage of extension requests approved by the funder.

It was not surprising that by far the largest category of the percentage of time only requests were approved by the funder – everyone involved in studies wants to deliver what has been funded. What is seemingly quite worrying is that units reporting the lowest quartile of their trials completing on time (0-25%) numbered the most responses (46%) of units had selected this answer and many stated pretty long extensions that were ultimately approved by the funder.

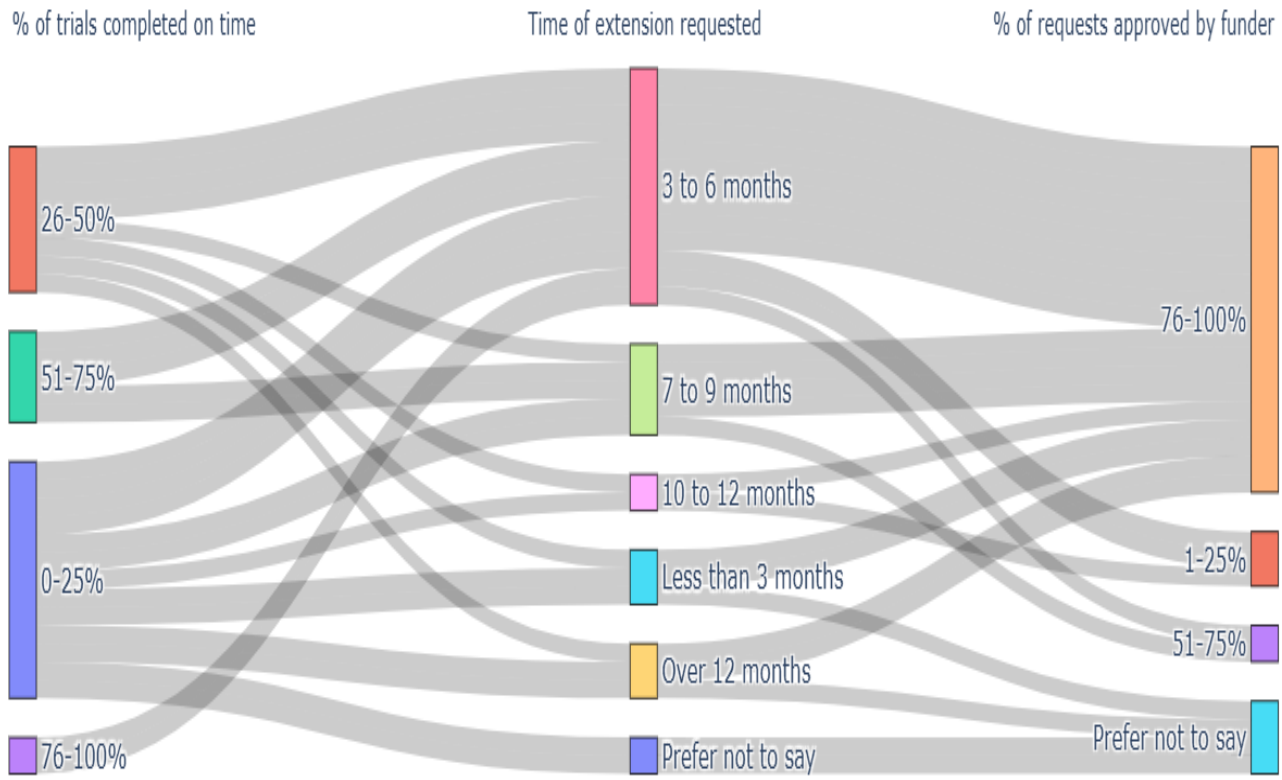

Figure 17 – Sankey diagram showing the relationship between the percentage of trials not delivering on time, length of time only extension requests and whether these were granted by the funder.

Exploration 3 – is there a relationship between the percentage of trials completed on time, the length of costed extensions requested, and the percentage of extension requests approved by the funder.

It was not surprising that the approval of costed funding request differed to those uncosted request with less being approved. However, what was interesting was units that delivered the lowest number of trials completing on time the majority of costed funding requests were being approved by the funder.

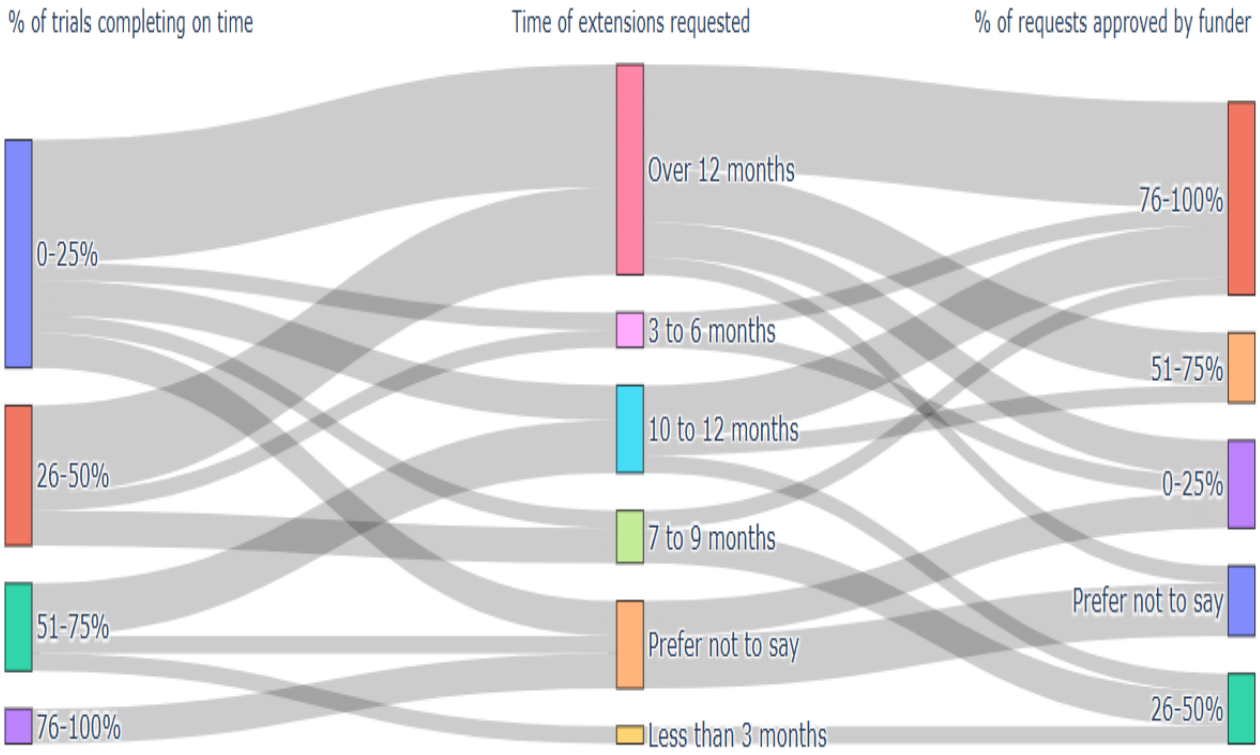

Figure 18 – Sankey diagram showing the relationship between the percentage of trials not delivering on time, length of time and cost extension requests and whether these were granted by the funder.

10. Conclusions

This survey records for the first time the amount of notionally unfunded work UKCRC registered CTUs undertake. However, this work is being paid by someone, either other funder, host organisations or by individuals either delivering unpaid overtime.

Registered UKCRC CTUs are required by many funders to be key collaborators of grant applications; being heavily involved in the development of research questions leading to robust funding applications that stand-up to close peer-review scrutiny and for those studies funded, they lead, manage and deliver those studies. This survey set out to look at the delivery of funding studies following on from a previous study to look at the main inefficiencies of trial conduct back in 2013.[7]

What is clear from this survey is that the majority of CTUs are undertaking study activities unfunded by the study funder to try to set studies up. These altruistic endeavours cannot be relied upon especially in the current financial crisis that is currently facing Universities and NHS Organisations, the main host of CTUs, this is not sustainable. [8] 68% of units who responded to the survey stated the main reason was that there was insufficient time to undertake all activities within the awarded period otherwise. This is concerning as the authors could not find many grant schemes that put limits around recruitment periods – what is the limiter is funding limits. The average UK salary for full-time employees in the UK (April 2015)

[7] Duley, L., Gillman, A., Duggan, M. *et al.* What are the main inefficiencies in trial conduct: a survey of UKCRC registered clinical trials units in the UK. *Trials* **19**, 15 (2018).
[8] https://www.universitiesuk.ac.uk/what-we-do/creating-voice-our-members/media-releases/universities-grip-financial-crisis-what

was £27,600[9] which has risen to £37,430[10] (April 2024) – a 36% increase – the final costs of grants have not increased in line with this as units are concerned that putting in the true cost of a grant may make a funding proposal uncompetitive compared to applications from other units. Taking a snapshot of trial manager salaries across the UK – a search for Trial Manager positions was conducted in August 2025 on jobs.ac.uk, had trial manager posts being advertised encompassing a salary range from £38,674 to £49,023, (noting that both included geographical allowances i.e. London or Oxford. There is clear guidance from the main funder cited in this survey – the NIHR of what can be claimed for a grant, and they are very clear that research costs are to be reimbursed -however if units are not claiming all costs that is not the fault of the funder.[11] It will be interesting over the next five years if the average cost of a project submitted to funders increases.

Despite 84% of CTUs undertaking pre-award activities, nearly half of respondents reported that at least 26% of their portfolio had not been delivered on time resulting in a need to apply either a time or time and costed extension which over 50% of CTUs stated was a major or immense burden to them and required the input of many stakeholders across the Unit and externally to gather the required details to submit to the funder. If awarded these extensions often require additional activities to be undertaken by the CTU (e.g. substantial amendments, database changes). The studies that seem to be meeting targets more often are either the largest units or those potentially more specialist units. However, is the reliance on undertaking pre-award activities just compounding the issue of meeting targets both in set-up and ultimate delivery of trials?

Funders cannot expect substantial unfunded work to be routinely undertaken and should review funding applications to assess feasibility of set-up based on the progress reports that they will be routinely receiving from various studies who are seeing issues in getting studies open. There is currently no feedback to the CTU network of issues being consistently reported – which might be useful on a national scale that could impact on newer grant applications being developed. With longer set-up and recruitment periods comes additional costs and although many CTUs are aware that their initial funding application is unlikely to be sufficiently long enough they are wanting to ensure their bid is as attractive as possible to the funder so are submitting perhaps overly ambitious applications. The volume of trials that are not meeting their recruitment target is considerable and there is correlation between sufficient funded time being allocated to meeting recruitment targets. This was definitely made worse due to the COVID-19 pandemic effect and knock on effect on the NHS to have the resource to deliver trials, and government numbers have shown that we have not yet recovered to pre-pandemic levels of recruitment to trials.[12] [13] Funders perhaps need to consider the funding envelope and conditions of the award in light of these findings. For those CTUs that cited that they had some funded support apart from the funding stream to undertake pre-award activity the set-up period was generally shorter (three to six months 5/7 (71%) recruitment was better 4/7 (57%), these units all cited that at least 26% of trials recruited within original timeframe.

[9] Office for National Statistics (ONS), released 18 November 2015, ONS website statistical bulletin
[10] Office for National Statistics (ONS), released 29 October 2024, ONS website, statistical bulletin, Employee earnings in the UK: 2024.
[11] https://www.nihr.ac.uk/research-funding/application-support/guidance/finance-guidance-for-applicants#tab-375176
[12] Lorenc A, Rooshenas L, Conefrey C et al. Non-COVID-19 UK clinical trials and the COVID-19 pandemic impact, challenges and possible solutions. *Trials* 2023; 24:424
[13] Management information on recruitment to clinical research studies. Updated 24 September 2024 https://www.gov.uk/government/publications/management-information-on-recruitment-to-clinical-research-studies/management-information-on-recruitment-to-clinical-research-studies

It takes many months to set up a trial, typically trials within a CTUs portfolio are complex often regulated trials which require dedicated, highly trained staff to deliver. The recent BMJ paper clearly outlined the workforce challenges and system inefficiencies health research is facing in England [14]specifically the increasing regulation, staff shortages and inefficiencies all of which negatively impact on delivering robust research and add burden and costs to CTUs. The NHS 10-year health plan[15] has set-out to slash the reported 250 days it takes to open a trial in the NHS – this is 8 months – of which we cannot seek approval without an approved trial – therefore currently setting up a trial with a period of 7-9 months is set to fail.

CTUs need to develop cost-efficient trials that can deliver timely answers/evidence on the scientific questions they have set out to meet. To do this, whilst the research environment continues to evolve with improvements in national systems [16] but also significant challenges there needs to be allowances made by funders to allow realistic efficient costs to be provided to CTUs to apply for, set-up and deliver studies to enable the UK to continue to be a world leader in delivering clinical research. CTUs all need to be costing and requesting the true cost of delivering studies in this current climate and funders need to carefully review all funding applications to ensure they are deliverable within the timeframe with particular focus on set-up and recruitment. Evidence is always required to support the clinical question, but there is rarely evidence requested on the predications made in the number of months stated for set-up and recruitment – perhaps there needs to be more focus on this by funders if this can receive more scrutiny at the funding request this could lead to less funding extension request and work for both CTUs and funders.

Finally, it should be noted that this report and the conclusions drawn have been made on the responses from 31 out of the 50 registered CTUs. Therefore, they may be reporting bias in the findings presented. However, the results of this survey and previous published research cited in this paper previously 5,6,7 seem to mirror each other and talking to trial managers from across the UK this does seem to be the current state of academic trial delivery.

The UKCRC CTU Operations Group look to contribute to addressing the findings of this survey in aiming to work with funders and CTUs on creating tools/checklist to enable better evidencing of study operational aspects.

[14] Crowe S, Pagel C, Ramnarayan P, Taylor J A. Health research in England is grinding to a halt. *BMJ* 2025; 390: r1386

[15] Policy Paper: 10 Year Health Plan for England: fit for the future https://www.gov.uk/government/publications/10-year-health-plan-for-england-fit-for-the-future

[16] The Research Systems programme - Health Research Authority https://www.hra.nhs.uk/about-us/partnerships/research-systems-programme/

Appendix 1 – Survey Questions

2. Please select the name of your CTU *

- ◯ Barts and the London Pragmatic CTU
- ◯ Barts Clinical Trials Unit
- ◯ Birmingham Clinical Trials Unit
- ◯ Brighton and Sussex Clinical Trials Unit
- ◯ Bristol Trials Centre
- ◯ CaCTUS (Cancer Clinical Trials Unit Scotland)
- ◯ Cambridge Clinical Trials Unit (CCTU)
- ◯ Cambridge Epidemiology & Trials Unit
- ◯ Cancer Research UK Clinical Trials Unit (CRCTU)
- ◯ Centre for Healthcare Randomised Trials (CHaRT)
- ◯ Centre for Trials Research
- ◯ Comprehensive CTU @UCL
- ◯ CR UK & UCL Cancer Trials Centre
- ◯ Derby Clinical Trials Support Unit (DCTSU)
- ◯ Diabetes Trials Unit, University of Oxford
- ◯ Edinburgh Clinical Trials Unit
- ◯ Exeter Clinical Trials Unit
- ◯ Glasgow Clinical Trials Unit
- ◯ Hull Health Trials Unit
- ◯ Imperial Clinical Trials Unit
- ◯ Intensive Care National Audit & Research Centre (ICNARC) CTU
- ◯ Keele Clinical Trials Unit
- ◯ King's Clinical Trials Unit at King's Health Partners
- ◯ Lancashire Clinical Trials Unit
- ◯ Leeds Clinical Trials Unit
- ◯ Leicester Clinical Trials Unit
- ◯ Liverpool Trials Collaborative
- ◯ London School of Hygiene & Tropical Medicine
- ◯ Medical Research Council Clinical Trials Unit at UCL
- ◯ Newcastle Clinical Trials Unit (NCTU)

- ◯ NHS Blood and Transplant Clinical Trials Unit
- ◯ North Wales Organisation for Randomised Trials in Health (NWORTH)
- ◯ Northern Ireland Clinical Trials Unit
- ◯ Norwich Clinical Trials Unit
- ◯ Nottingham Clinical Trials Unit
- ◯ NPEU Clinical Trials Unit
- ◯ Oxford Clinical Trial Service Unit & Epidemiological Studies Unit (CTSU)
- ◯ Oxford Clinical Trials Research Unit (OCTRU)
- ◯ Oxford Primary Care and Vaccines Collaborative Clinical Trials Unit
- ◯ Papworth Trials Unit Collaboration
- ◯ Peninsula Clinical Trials Unit
- ◯ PRIMENT Clinical Trials Unit at UCL
- ◯ Royal Marsden Clinical Trials Unit (RM-CTU)
- ◯ Sheffield Clinical Trials Research Unit
- ◯ Southampton Clinical Trials Unit
- ◯ Swansea Trials Unit
- ◯ Tayside Clinical Trials Unit
- ◯ The Institute of Cancer Research Clinical Trials & Statistics Unit (ICR-CTSU)
- ◯ Warwick Clinical Trials Unit
- ◯ York Trials Unit

Pre Award Questions

The questions in this section relate to the period of time between a grant being awarded/confirmed and the start of the grant.

3. At any one time how many **funded** studies do you have within your portfolio where you are the lead CTU (i.e. co-ordinating the running of the study)? (This does **not** include archived studies, but does include those at any point (set-up, recruitment, follow-up, analysis) of an open grant) *

0–4	5–9	10–15	16–29	30–49	+50	Prefer not to say
◯	◯	◯	◯	◯	◯	◯

4. Of the above studies: *

	0–4	5–9	10–15	16+	Prefer not to say
In the past year, how many of the studies did you add to your CTU portfolio?	○	○	○	○	○
Of the studies added in the past year, how many are regulated (e.g. CTIMP, device IVDD)?	○	○	○	○	○
Of the studies added to your CTU portfolio in the last year, how many are global / International studies (i.e. not recruiting in the UK)?	○	○	○	○	○

5. Who is the primary (**that is the largest in number rather than income**) funder of your CTU portfolio? *

- ○ NIHR
- ○ MRC
- ○ CRUK
- ○ Other Charity
- ○ Industry
- ○ Other
- ○ Prefer not to say

6. If other, please state who the primary funder is

7. Where else do you receive funding for your studies? *Please tick all that apply, and if selecting other, please specify who in the text box that states Other* *

- [ ] NIHR
- [ ] MRC
- [ ] CRUK
- [ ] Other Charity
- [ ] Industry
- [ ] Prefer not to say
- [ ] Other

8. Typically how much time does your CTU like to have between the award being awarded and the start date of the funding? *

- ◯ Less than 3 months
- ◯ 3 to 6 months
- ◯ 7 to 9 months
- ◯ 10 to 12 months
- ◯ Over 12 months
- ◯ Prefer not to say

9. Does you CTU generally do any work on the study during this time? *

- ◯ Yes – always
- ◯ Yes – sometimes (if resources are available)
- ◯ No
- ◯ Unsure
- ◯ Prefer not to say

10. As you answered sometimes to doing some work between a grant being awarded and the start date of the funding, how does your CTU prioritise which studies receive this support? *

11. Who supports this pre award activity? *

- ◯ Staff within the CTU
- ◯ Staff outside the CTU
- ◯ Staff within and outside the CTU
- ◯ Other
- ◯ Prefer not to say

12. If other, please state who supports the pre award activity *

13. Is there a dedicated person or team within your CTU who is there to oversee pre-award activity? *

- ◯ Yes
- ◯ No
- ◯ Unsure
- ◯ Prefer not to say

14. What type of role(s) are they in? *Please tick all that apply, and if selecting other, please specify who in the text box that states Other* *

- ☐ Trial Management / Operations
- ☐ Statistics / Methodology
- ☐ Data management / data architecture
- ☐ Prefer not to say
- ☐ Other

15. Please select any tasks that you might undertake in this period. *Please tick all that apply, and if selecting other, please specify what in the text box that states Other* *

- [ ] Sponsor risk assessment
- [ ] To establish oversight groups
- [ ] Draft protocol
- [ ] Draft PIS/Participant materials
- [ ] Draft CRFs
- [ ] Start negotiations with contract
- [ ] Engage with sites/undertake feasibility
- [ ] TMF creation
- [ ] Prepare regulatory submissions
- [ ] Prefer not to say
- [ ] Other

16. Is this pre-award activity funded from somewhere? *

- ◯ Yes
- ◯ No
- ◯ Unsure
- ◯ Prefer not to say

17. If funded, where are these funds from? *Please tick all that apply, and if selecting other, please specify who in the text box that states Other* *

- [ ] Part of core CTU budget
- [ ] From host institution
- [ ] RSS
- [ ] Prefer not to say
- [ ] Other

18. Why are these activities completed pre-grant start? *Please tick all that apply, and if selecting other, please specify why in the text box that states Other* *

- [ ] Funder requirement
- [ ] Host institution requirement
- [ ] Sponsor requirement
- [ ] Insufficient time to do within awarded period otherwise
- [ ] Prefer to get ahead of schedule
- [ ] Prefer not to say
- [ ] Other

Post Award Questions

These questions relate to after grant funding has started but the study is not yet open to recruitment

19. Do you always include a set-up period within your funded grant ? (e.g. obtaining ethical approval/ building database) *

- ◯ Yes
- ◯ No
- ◯ Unsure
- ◯ Prefer not to say

20. Does your CTU manage trials that has maximum set-up period that is imposed by the funder? *

- ◯ Yes
- ◯ No
- ◯ Unsure
- ◯ Prefer not to say

21. Please could you list funders that have maximum requirements and the number of months that they state *

22. What tasks are included within the funded set-up period? *Please tick all that apply, and if selecting other, please specify what in the text box that states Other* *

- ☐ Approvals
- ☐ Contracts
- ☐ Protocol development
- ☐ Database
- ☐ Site engagement
- ☐ Risk assessment
- ☐ Prefer not to say
- ☐ Other

23. What is the typical duration of the period from grant start to opening to recruitment? *

0-3 months	4-6 months	7-9 months	10-12 months	Over 12 months	Prefer not to say
○	○	○	○	○	○

24. Does this period vary in length depending on the study complexity? *(Note - complexity is not necessarily regulated trials, this could be complex intervention/site set-up/approvals that are required)* *

- ○ Yes (it can, but dependent upon other factors)
- ○ No
- ○ Unsure
- ○ Prefer not to say

25. For complex studies (as defined above), what is the typical duration of the period from grant start to opening to recruitment? *

0-3 months	4-6 months	7-9 months	10-12 months	Over 12 months	Prefer not to say
○	○	○	○	○	○

26. Do you generally include in your grant applications time and funding for an embedded pilot? *

- ○ Yes
- ○ No
- ○ Unsure
- ○ Prefer not to say

27. What stop/go criteria would you generally include in your pilot? *Please tick all that apply, and if selecting other, please specify what in the text box that states Other* *

- [ ] Number of sites opened
- [ ] Number of sites that have recruited
- [ ] Number of participants consented
- [ ] Number of participants randomised
- [ ] Number of participants having received the intervention
- [ ] We don't do pilots
- [ ] Unsure
- [ ] Prefer not to say
- [ ] Other

28. How would you say your CTU **typically determines the length of time** needed for sites to recruit to the required number of participants? *Please tick all that apply, and if selecting other, please specify what in the text box that states Other* *

- [ ] Site feasibility questionnaires
- [ ] Chief investigator's opinion
- [ ] Statistician's opinion/guidance
- [ ] Anecdotal evidence
- [ ] Published studies in the area and recruitment recorded
- [ ] CPRD/Registry/Subject area accessible data
- [ ] Unsure
- [ ] Prefer not to say
- [ ] Other

29. How does your CTU **decide how many sites to include as opposed to the length of time** you allocate for recruitment? *Please tick all that apply, and if selecting other, please specify what in the text box that states Other* *

- [ ] Length of follow-up – therefore a short recruitment period is required
- [ ] Number of competing studies
- [ ] Ability for sites to be able to deliver the studies (perhaps certain equipment or expertise is required)
- [ ] Available budget
- [ ] Previous experience of studies in a clinical area
- [ ] Incidence of disease
- [ ] Typical numbers that could be recruited
- [ ] Optimal study duration
- [ ] Unsure
- [ ] Prefer not to say
- [ ] Other

30. What would you say is the average planned **recruitment period** for studies on your portfolio? *

Up to 12 months	13 to 24 months	25 to 36 months	37 to 48 months	More than 49 months	Prefer not to say
○	○	○	○	○	○

Post the opening of study recruitment

These questions relate to after a study has been opened to recruitment

31. Approximately what % of the studies on your CTUs portfolio that have closed to recruitment recruited within the original number of recruiting months you stated to funder in the funding application? *

- ◯ 0-25%
- ◯ 26-50%
- ◯ 51-75%
- ◯ 76-100%
- ◯ Prefer not to say

32. Of those that did not recruit within the timeframe you specified, what % of those did you need to request a **time only** extension to complete recruitment? *

None	1-25%	26-50%	51-75%	76-100%	Prefer not to say
◯	◯	◯	◯	◯	◯

33. What is the length of a typical **time only** extension? *

- ◯ Less than 3 months
- ◯ 3 to 6 months
- ◯ 7 to 9 months
- ◯ 10 to 12 months
- ◯ Over 12 months
- ◯ Prefer not to say

34. Of those **time only** extensions you requested what % were **approved** by the funder? *

None	1-25%	26-50%	51-75%	76-100%	Prefer not to say
◯	◯	◯	◯	◯	◯

35. Of those that did not recruit within the timeframe you specified, what % of those did you need to request a **time and cost extension** to complete recruitment? *

0-25%	26-50%	51-75%	76-100%	Prefer not to say
◯	◯	◯	◯	◯

36. Of those **time and cost** extensions you requested what % were **approved** by the funder? *

0-25%	26-50%	51-75%	76-100%	Prefer not to say
○	○	○	○	○

37. What is the length of a typical **time and cost** extension? *

- ○ Less than 3 months
- ○ 3 to 6 months
- ○ 7 to 9 months
- ○ 10 to 12 months
- ○ Over 12 months
- ○ Prefer not to say

38. How significant is the burden to your CTU of managing the process of applying for an extension? *

Very little burden	Little burden	Somewhat a burden	Major burden	Immense burden	Prefer not to say
○	○	○	○	○	○

39. Which individuals within your CTU are usually involved in the process of applying for an extension? *Please tick all that are involved, and if selecting other, please specify who in the text box that states Other* *

- ☐ CTU Director
- ☐ Assistant/Deputy CTU Director(s)
- ☐ Chief Investigator
- ☐ Senior Statistician(s)
- ☐ Trial Statistician(s)
- ☐ Senior Trial Manager(s)
- ☐ Trial Manager
- ☐ Database teams (IT and/or Data Manager)
- ☐ Prefer not to say
- ☐ Other

40. What factors would you state to be the most common ones for your studies not recruiting as per your original predictions? *Please tick all that apply, and if selecting other, please specify what in the text box that states Other* *

- [ ] Study burden for site
- [ ] Study burden for participants
- [ ] Lack of resources at sites
- [ ] Competing studies
- [ ] Lack of equipoise at sites
- [ ] New evidence
- [ ] Unrealistic targets initially predicted
- [ ] Unsure
- [ ] Prefer not to say
- [ ] Other

41. Have you any comments that you wish to add regarding any of the questions asked in this survey?