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Trial Management in the UK and Ireland:

A Cross-sectional Survey of Workforce, Training, and Professional Recognition

Prepared by

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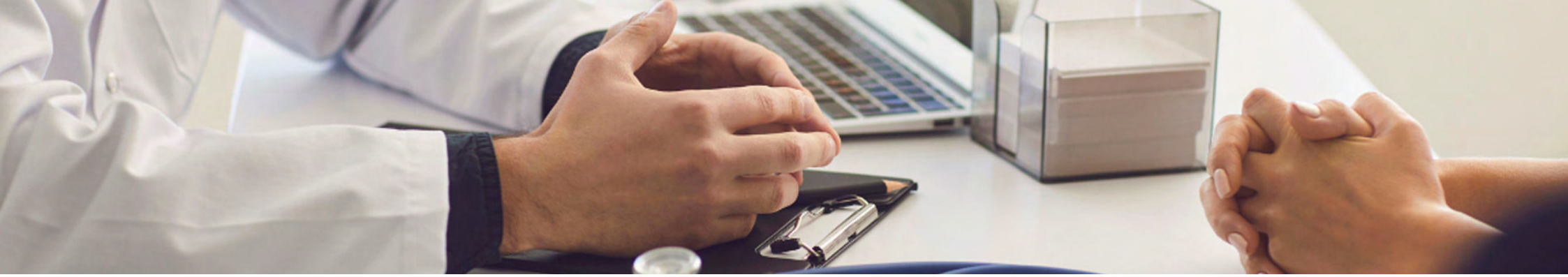

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Background

Trial Managers (TMs) play a central role in the successful delivery of clinical trials, particularly in academic and publicly funded research environments. Over time, the scope of trial management has expanded substantially, now encompassing responsibilities such as coordination of complex multi-centre studies, regulatory compliance, site engagement, recruitment oversight, and stakeholder communication. Despite this expansion, there is increasing concern that expectations placed upon TMs are not matched by commensurate authority, resources, or formal recognition. Previous literature has highlighted variability in trial management training, reliance on experiential learning, and under-utilisation of operational expertise at early trial stages. However, empirical data examining these issues across national contexts remain limited. This study aimed to explore the roles, training experiences, challenges, and priorities of TMs working in academic clinical trials, and to examine similarities and differences between respondents in the United Kingdom and Ireland.

Methods

A cross-sectional survey was conducted using a structured questionnaire distributed to individuals performing trial management functions. Participants were recruited regardless of job title, acknowledging that trial management responsibilities are conducted under varied roles across different national contexts. The survey captured data on respondent demographics, country of employment, professional role, level of education and qualifications, trial experience, training access and frequency, perceived adequacy of training, decision-making autonomy, involvement across trial lifecycle stages, and challenges encountered in day-to-day trial delivery. The survey included Likert-scale items, multiple-choice questions, and open-text responses to allow both quantitative summarisation and qualitative insight.

Responses were analysed descriptively. Quantitative data were summarised using frequencies and proportions, while thematic synthesis was applied to free-text responses to identify recurring patterns related to training needs, autonomy, resourcing, and professional identity. Comparisons between UK- and Ireland-based respondents were conducted exploratorily to identify similarities and differences in emphasis, acknowledging unequal sample sizes and the descriptive nature of the analysis.

Results

Respondents were predominantly based in the UK, with a smaller but substantive proportion from Ireland, and most worked in academic clinical trial settings managing single-centre, multi-centre, and multinational trials. Across both countries, findings were remarkably consistent. Trial management roles were widely reported to have expanded in scope and complexity, with expectations closely resembling full project management. Practical, experiential knowledge was consistently valued more highly than formal education; however, respondents strongly expressed the need for formal recognition, accreditation, and structured career pathways.

Training was commonly described as ad hoc, infrequent, and heavily reliant on on-the-job learning and peer support. There was strong, cross-national support for national or international training frameworks, centralised guidance, and improved trial management and IT systems. Trial Managers in both countries reported limited autonomy and late involvement in trial design and funding stages, despite widespread recognition of their importance to feasibility, recruitment, and delivery.

Differences by country were subtle but notable. UK respondents more frequently highlighted challenges related to workload, bureaucracy, and scale, while Irish respondents more often emphasised limited institutional capacity and reliance on individual expertise. These differences reflected variations in infrastructure rather than fundamental divergence in experience.

Conclusions

Trial Managers in both the UK and Ireland are widely recognised as critical to trial success, yet remain under-resourced, under-recognised, and under-utilised—particularly at early trial stages. The strong alignment of findings across countries suggests that these challenges are systemic rather than context-specific, supporting the case for coordinated, cross-national approaches to training, role definition, and workforce development in trial management

Introduction

There is a lack of published literature available to guide trial managers on how to successfully run a clinical trial (1)(2)(3). An editorial in *Trials* by Treweek and Littleford highlighted this dearth of research on the management of clinical trials (1). Clinical trial managers are an important member of the trial team (1)(3). They have a wealth of knowledge and expertise accrued and more attention needs to focus on learning from their experience (1). Additionally, the trial managers role has a complex list of key responsibilities, however, there is limited guidance published in this area (2)(4) and there is no standardised structured career path for trial managers (5). We know that well designed trials by a multidisciplinary team are the basis for addressing important clinical questions, but what is required to successfully manage and thus deliver a clinical trial is less well defined (1)(2). According to Farrell *et al.*, many clinical trials fail to deliver because of the lack of a structured, practical, business-like approach to trial management (2). Therefore, more emphasis needs to be placed on the importance of the management role within clinical trials. It is postulated that trials with a dedicated trial manager may have a higher rate of success due to successfully reaching their recruitment target (2)(4)(5)(6). Ideally clinical trial managers should begin their involvement early on in the trial design phase and funding application process (2). Treweek and Littleford highlighted the need for a more collaborative effort around the management of clinical trials (1). The sharing of knowledge, so that trial managers can learn from each other, could lead to more efficient and successful trials (1)(2)(4). However, so little is known about what trial managers do on a day-to-day basis, collaboration is futile without defining their roles and responsibilities. The purpose of our study is to establish the training level of clinical trial managers, their approaches to clinical trial management and in their view, the important factors that successfully deliver a clinical trial. This mixed-methods research will provide us with information regarding how trial managers deliver successful clinical trials. Furthermore, it will indicate how they address day to day challenges in their job and what areas of trial management need more research.

Methods

It should be noted that this report has been prepared in part using AI (Claude.ai and Microsoft Copilot, March - April 2026) while every effort has been made to check and validate the findings. From the paragraph beginning “Survey respondents were also asked if they thought trial managers should have more training.” (page 12, questions 16-31), AI was used to analyse, summarise data, and draft text while the outputs were checked against analysis completed in SPSS by HB. From section ‘Successful recruitment in trials’ (page 21, questions 32-44) AI was used solely, also to identify illustrative quotes included in the appendices, while checking against raw data. AI was also used to draft the summary and the summary of the findings.

The survey was distributed online to members of the UK Trial Managers’ Network (UKTMN) and Trial Methodology Research Network Ireland (TMRN) mailing list (2926 members) and via social media (4649 followers) The aim of the survey was to gather information on the background, the opinion on the role of trial managers, their approaches to management and important factors that successfully deliver a clinical trial. The survey covered 45 questions spanning respondent characteristics, qualifications, training, decision making, involvement in trial phases, perceptions of the trial manager role, and views on resources and professional guidelines. The survey is available in Appendix 3.

Results

Two hundred and eighteen responses to the survey were received, n=184 (84%) from the UK and n=34 (16%) from Ireland. All survey respondents were included in the analysis.

Job Title

Figure 1 shows the range of job titles provided by respondents. The majority (n=204, 94%) reported to fulfil the role of trial manager in their job, n=170 (92%) in the UK and n=34 (100%) in Ireland. One respondent answered 'no', they did not fulfil the role of trial manager in their job and one respondent did not answer the question. Twelve respondents, all based in the UK, responded 'other' which included: an oversight of trial manager role (n=8); trial manager role combined with oversight (n=1); Data management role (n=1); support role (n=1); fulfilling the role occasionally when needed (n=1).

Figure 1: Word-cloud showing the range in job titles of all respondents (n=218).

There were differences between the two countries in terms of the job titles listed thus they are reported separately for each country. In the UK participants, the top three job titles were Trial Manager (n=40, 22%), Clinical Trial Manager (n=23, 13%) and Senior Trial Manager (n=20, 11%). The remaining job titles varied and included variations of Trial Manager e.g. Clinical Project Manager (n=3), Clinical Trials Coordinator (n=2), Clinical Trials Manager (n=6), Clinical Trial Project Manager (n=1) or variations with an emphasis on research e.g. Clinical Research Assistant (n=1), Research Associate (n=7), Research Facilitator (n=1), Research Fellow (n=5), Research Fellow and Trial Manager combined (n=3) and Research Fellow Senior Trial Manager combined (n=1) (total n= 18, 10%).

The top three job titles in responses from Irish participants were Clinical Research Nurse (n=3, 9%), Project Manager (n=3, 9%) and Research Nurse (n=3, 9%). The remaining job titles also varied, and responses included Health Care Professionals such as GP (n=1), Consultant (n=1), Clinical Nurse Manager (n=1), Nurse Manager (n=1), and Allied Health Professionals such as Physiotherapist (n=1) (total n=5, 15%). One respondent from Ireland reported to be a Postdoctoral Researcher and another three also had job titles with emphasis on research, as Research Co-ordinators (total n=4, 12%).

Experience

Their characteristics are presented in Table 1. In terms of experience of managing trials, most participants had experience running single centre, multicentre trials and multinational trials (n=58) The highest proportion of respondents from the UK had experience of single and multicentre trials (n=48, 26%) while the highest proportion of respondents from Ireland had experience of single centre, multicentre and multinational trials (n=13, 38%).

Almost all participants (n=215, 99%) were educated to at least undergraduate-degree level, of these, n=148 (67%) had a postgraduate qualification. The relative frequencies were similar across the two countries, most had a masters degree (n=67 UK, n=16 Ireland).

Table 1 Characteristics of survey respondents by country and total

	Ireland	UK	Total
Location			
Country	34	184	218
Fulfil trial manager role?			
Yes	34	170	204
No	0	1	1
*Other	12	0	12
Missing	0	1	1
*Oversight of Trial Managers (n=8) Trial Manager and oversight of TMs (n=1) Trial Manager and Data Manager (n=1) Support Trial Managers (n=1) Sometimes have Trial Manger role (n=1)	0	12	12
Trial management experience	(%)	(%)	(%)
Single centre	7 (21)	3 (2)	10 (5)
Multicentre	5 (15)	47 (26)	52 (24)
Multinational	5 (15)	8 (4)	13 (6)
Single centre, multicentre	1 (3)	48 (26)	49 (22)
Multicentre, multinational	3 (9)	33 (18)	36 (17)
Single centre, multicentre, multinational	13 (38)	45 (24)	58 (27)
Highest level of education	(%)	(%)	(%)
PhD	6 (18)	53 (29)	59 (27)
Masters	16 (47)	67 (36)	83 (38)
Other postgraduate qualification e.g. PG Certificate, PG Diploma	2 (6)	4 (2)	6 (3)
Undergraduate degree	10 (29)	57 (31)	67 (31)
Secondary education	0 (0)	3 (2)	3(1)

Confidence in qualifications, training received and unmet needs

Overall, n=45 (21%) people reported to have a professional management or clinical trial qualification, n=30 (16%) from the UK and n=15 (44%) from Ireland.

Of these respondents, six (3%) reported having both a clinical trial and a professional management qualifications (n=3, 2% UK, n=3, 9% Ireland).

Of those who reported to have a qualification (n = 45), 27 reported to have a clinical trials qualification (n=15 UK, n=12 Ireland), most had a masters degree, n=16, (n=11 UK, n=5 Ireland) then in descending order, a certificate, n=6 (n=2 UK, n=4 Ireland); a diploma, n=3 (n=2 UK, n=1 Ireland); two people who had responded they had a clinical trials qualification did not indicate which qualification they had, both were from Ireland. One person from the UK listed two clinical trials qualifications, only the highest level achieved has been counted.

In terms of project management qualifications, 24 (11%) people responded they had one (n=18 UK, 6 Ireland). Most had a PRINCE2 qualification, n=10 (n=10 UK, n=0 Ireland); Institute of Leadership and Management (ILM) qualification, n=4, (n=4 UK, n=0 Ireland); diploma, n=4, (n=1 UK, n=3 Ireland); certificate, n=2 (n=2 UK, n=1 Ireland); Masters, n=2, (n=1 UK, n=1 Ireland); undergraduate degree, n=1, (n=0 UK, n=1 Ireland). Two people, one from the UK and one from Ireland, listed two project management qualifications, only the highest level achieved has been counted.

Another nine people listed qualifications which were either not relevant to the survey question as it was not clear how the qualifications related to clinical trials and/or project management (e.g. Information Management; Professional Diploma in Public Relations and; Senior Nursing Management course) or could not be assessed for the level and type of qualification achieved

Of the 45 people who responded that they had a professional management and/or clinical trial qualification, on a five point Likert scale, strongly agree to strongly disagree, most agreed (n=17, 9 UK, 8 Ireland) their qualification equipped them with all the skills to be a successful trial manager while five (n=2 UK, n=3 Ireland) strongly agreed. Thirteen (10 UK, 3 Ireland) disagreed with the statement, n=2 strongly disagreed (n=2 UK, n=0 Ireland) and eight (n=7 UK, n=1 Ireland) neither agreed or disagreed.

All respondents were asked whether they felt confident in their level of training when conducting a clinical trial. Table 2 shows the responses to this statement with the majority either in the strongly agree or agree categories.

Table 2 Respondents' level of agreement with the statement "I feel confident in my level of training when conducting a clinical trial".

	Ireland (%)	UK (%)	Total (%)
Strongly agree	11(32)	34 (18)	45 (21)
Agree	20 (59)	103 (56)	123 (56)
Neither agree nor disagree	1 (3)	24 (13)	25 (11)
Disagree	2 (6)	22 (12)	24 (11)
Strongly disagree	0 (0)	1 (0.5)	1 (0.5)

A total of n=141 (65%) (n=125 UK, n=16 Ireland) responded to the question of whether they had received additional training from specific providers and some listed several. Table 3 presents the findings. Most responded they had received training from the UK Trial Managers Network, n=96 (44%) (n=91 UK, n=5 Ireland) or other, n=38 (17%) (n=29 UK, n=9 Ireland). In terms of other providers most responses were unspecific e.g. 'Internal training', n= 24 (n=18 UK, n=6 Ireland) or 'variety of providers', n=11 (n=9 UK, n=2 Ireland). The full list of those named are included in table 3.

Table 3 Whether respondents had received additional training from one of the specified providers (n=141). Note, respondents could list several additional training courses attended.

Training provider	Ireland (n=16)	UK (n=125)	Total (n=141)
UK Trial Managers Network	5	91	96
The Association of Clinical Research professionals	2	4	6
The Society of Clinical Research Associates	0	1	1
Other	9	29	38
Additional providers listed by respondents:			
-Institute of Clinical Research	0	7	7
-Edinburgh Clinical Trials Management Course	0	5	5
Funder (NIHR, MRC, Welcome Trust, CRUK)	0	4	4
-NIHR/IRNM	2	2	4
-Pharma School	0	4	4
-CRF	0	2	2
-MHRA/EMEA	0	2	2
-The British Association for Research Quality Assurance (BARQA)	0	2	2
-Royal College of Surgeons in Ireland	2	0	2
-Society for Clinical Trials	0	1	1
-Project Management Institute	1	0	1
-Oxford Centre for Statistics in Medicine	1	0	1
-Clinical Research Development Ireland	1	0	1
-Local R&D	0	1	1
-Internal training [+GCP]	6	18	24
-Variety of providers	2	9	11
-On the job training	0	7	7
-External training	0	2	2

In terms of the frequency of additional training, most respondents reported that they complete additional training once a year or less. Attendance at additional training appears similar between the two countries (Table 4). The main mode of accessing training was online, n=168 (77%) (n=140 UK, n=28 Ireland), in person either on site at their home facility, n=124 (57%) (n=107 UK, n=17 Ireland) or at another site requiring travel, n=89 (41%) (n=78 UK, n=11 Ireland). Eight (4%) respondents did not provide an answer to this question (n=7 UK, n=1 Ireland).

Table 4 Frequency by which respondents reported attending additional training.

	Ireland (%) (n=34)	UK (%) (n=184)	Total (%) (n=218)
Less than once a year	9 (26)	53 (29)	62 (28)
Once per year	11 (32)	51 (28)	62 (28)
Twice per year	3 (9)	36 (20)	39 (18)
Three times per year	1 (3)	14 (8)	15 (7)
More than three times per year	10 (29)	30 (16)	40 (18)

Respondents were asked to rate the trial management training they had received on a five-point scale ranging from poor to excellent, responses are listed in table 5. The majority thought their training was either very good or good, though a significant portion in the UK also thought it was fair or poor.

Table 5 Respondents' rating of the trial management training they have received by country and in total (rated on a five-point rating scale from poor to excellent).

Rating	Ireland (%) (n=34)	UK (%) (n=184)	Total (%) (n=218)
Excellent	0 (0)	5 (3)	5 (2)
Very good	10 (29)	30 (16)	40 (18)
Good	17 (50)	85 (46)	102 (47)
Fair	3 (9)	53 (29)	56 (26)
Poor	4 (12)	11 (6)	15 (7)

In terms of training provision, most, n=134 (61%) (n=113 UK, n=21 Ireland) responded that there are elements lacking in current training while n=76 (35%) (n=64 UK, n=12 Ireland) were neutral and n=8 (4%) (n=7 UK, n=1 Ireland) did not think current training is lacking.

Table 6 shows the elements respondents listed as lacking in the current training provision. Elements relating to Research Governance were listed most often as lacking and included tasks such as trial set-up and approvals, safety, SAE reporting, monitoring, audit, closedown and archiving. Equally frequently listed were elements of a generic nature and more practical 'how to' trial management using case studies e.g. how to submit a Research Ethics amendment. Project management was the third most listed element lacking from training and this included contracts, risk assessment and vendor assessment. A smaller number of respondents listed research skills which included grant writing, costing, dissemination, trial design and methodology. A small number also listed budget management which we kept as a separate category as it, at some institutions, counts towards promotion. Lastly, leadership was listed including managing difficult situations, assertiveness, conflict resolution, negotiation, people and large research team management and expectation management. The final other category included statistics, IT and software, social media and communication, introductory training, biobanking and social care research.

Table 6 Elements identified by survey respondents as lacking in currently available training.

Elements lacking from training	Ireland	UK	Total
Research Governance	6	33	39
Generic and practical trial management	5	34	39
Project Management	4	18	22
Research skills	1	12	13
Budget management	3	10	13
Leadership	2	7	9
Other (Statistics, IT/software, social media and communication, Intervention, introductory, biobanking, social care research)	2	13	15

This question about elements lacking in the available training also received comments from 67 (31%) respondents (n=58 UK, n=9 Ireland). The responses highlight widespread concern about the lack of structured, formalised training for TMs, with many respondents noting that training tends to be ad hoc, infrequent, and largely dependent on individual circumstance rather than any defined programme. Several respondents called for regular continuing professional development (CPD) that keeps pace with changes in governance, GCP, legislation, and best practice.

A recurring and significant tension runs through the responses around the question of standardisation. While many respondents expressed a clear need for a structured training programme and competency framework, others acknowledged that the sheer variability of the TM role — differing across trials, institutions, and trial units — makes standardisation inherently difficult. This creates something of a circular problem: the lack of professional standardisation makes it hard to design training, yet the absence of training perpetuates the lack of professional identity and consistency.

Closely related to this is the question of professional recognition. Several respondents noted that trial management is not regarded as a formal profession, which has knock-on effects for access to training, funding, and career development. There is no clear entry point into the role, with many respondents describing having learned primarily through experience, mistakes, and being "thrown in at the deep end." This is reinforced by institutional failures, i.e., a lack of investment in TMs in terms of both time and money, leaving individuals to pursue self-learning in their own time, which is often not feasible given heavy workloads and understaffing. The consequence of this professional isolation is perhaps best illustrated by one respondent who, despite four years of coordinating studies, had never encountered the European Clinical Research Infrastructure Network (ECRIN). This highlights how awareness of key professional networks and resources can remain entirely absent through no fault of the individual, but simply due to a lack of structured exposure.

There is also a distinction between those who feel that on-the-job training is an inadequate substitute for formal training, and those who acknowledge that some aspects of the role are genuinely best learned through experience. This is not necessarily a contradiction, rather, it suggests that an effective training approach would combine structured formal learning with supported practical experience, rather than relying on one or the other.

Where training does exist, it is often designed from a Principal Investigator (PI) perspective rather than a trial management one, meaning the specific practical needs of TMs are not addressed. Training is frequently described as introductory and lacking in depth or practical application.

Finally, respondents pointed to the need for a more coordinated national approach to TM training, something akin to established frameworks in other parts of the research sector, alongside greater institutional commitment to investing in this workforce.

Survey respondents were also asked if they thought trial managers should have more training. A total of n=185 (85%) (n=156 UK, n=29 Ireland) responded yes, while n=9 (4%) said no (n=7 UK, n=2 Ireland) and n=24 (11%) (n=21 UK, n=3 Ireland) commented on the question, indicating that the need is highly context-dependent. Key themes in the comments were:

- Training needs vary by individual experience and background (most common theme)
- On-the-job learning seen as more valuable than formal training
- Training should be trial-specific rather than generic
- Concern about funding constraints in academic settings
- One comment called for a structured career pathway rather than just more training, noting the role evolved organically without strategic planning

Following on, respondents were asked who should provide training for them. The majority responded that their employer should provide training, n=53 (n=49 UK, n=4 Ireland). Overall, respondents listed 16 named potential training providers and another six unnamed potential providers in addition to an 'other' category where potential providers could not be categorised (e.g. 'other organisations'; organisations involved in trials' and; 'national/international

organisations'). The full list of potential named and unnamed providers is available in table 7 below.

Table 7 Who should provide training for trial managers, listed by survey respondents. Note that respondents often listed more than one training provider.

Named Providers	Ireland	UK	Total
Employer	4	49	53
Trial Managers Network	2	37	39
CTUs/CRFs/CRC	5	24	29
Higher Education Institutions	5	20	25
Funders	4	20	24
Regulators	0	19	19
Professional/accredited body	3	15	18
Trial managers	1	12	13
NHS/HSE	2	5	7
UKCRC/HRB NCTO	2	3	5
NIHR CRN/IRNM	1	3	4
Sponsor	1	2	3
Mentor	0	3	3
Chief Investigator	0	2	2
Local sites	1	1	2
Local R&D	0	1	1
Unnamed Providers			
Multiple providers	1	7	8
Qualified providers	1	6	7
Academic/industry	2	3	5
External	1	3	4
Self-directed learning	0	3	3
Shadowing	0	1	1
Other	5	18	23

Tools and Resources Used in Trial Management

Respondents were asked whether they use an online toolkit or resources from the European Clinical Research Infrastructure Network (ECRIN). The ECRIN toolkit is used to support the planning, setup, conduct, and management of clinical trials, especially multinational studies in Europe. Of the 218 respondents nearly three quarters of respondents (74%) have little to no engagement with the ECRIN toolkit, with only 4% using it frequently. N=108 (50%) (n=94 UK, n=14 Ireland) said they had never used it, n=53 (24%) (n=43 UK, n=10 Ireland) said rarely, and n=45 (21%) (n=38 UK, n=7 Ireland) said sometimes. Only n=9 (4%) (n=7 UK, n=2 Ireland) said they use it frequently, and n=3 (1%) (n=2 UK, n=1 Ireland) had used it once.

Successful Trial Delivery

Respondents were asked how important they believe an efficient, well-trained management team is to the success of a clinical trial and answered on a five-point-scale, ranging from Very important; Of Little Importance; Moderately Important; Important; Very Important. Answers ranged from moderately important to very important with none selecting unimportant. A total of n=197 (90%) (n=170 UK, n=27 Ireland) rated it as very important, and n=19 (9%) (n=12 UK, n=7 Ireland) as important. Only n=2 (0.9%) (both UK) rated it as moderately important.

Respondents were asked to rank, in order of importance, their top five team members from a list of roles (selecting trial managers was not permitted). All rankings of team members roles' importance are listed in table 8. The PI was the most common first choice, selected as the top pick by n=110 (n=94 UK, n=16 Ireland) respondents, followed by the Research Nurse as first choice by n=70 (n=58 UK, n=12 Ireland) — together accounting for 83% of all first-place selections.

Table 8 Ranked team roles by country and total, rank 1 is most important.

	Rank 1			Rank 2			Rank 3			Rank 4			Rank 5		
Role	**Ireland n=34**	**UK n=184**	**Total (%) n=218**	**Ireland n=34**	**UK n=184**	**Total (%) n=218**	**Ireland n=34**	**UK n=184**	**Total (%) n=218**	**Ireland n=34**	**UK n=184**	**Total (%) n=218**	**Ireland n=34**	**UK n=184**	**Total (%) n=218**
Principal Investigator	16	94	110 (50)	7	22	29 (13)	4	14	18 (8)	2	13	15 (7)	0	13	13(6)
Research nurse	12	58	70 (32)	12	63	75 (34)	7	23	30 (14)	0	11	11 (5)	0	9	9 (4)
Data Manager	2	8	10 (5)	3	28	31 (14)	6	42	48 (22)	6	46	52 (24)	9	19	28 (13)
Statistician	0	7	7 (3)	0	27	27 (12)	1	34	35 (16)	3	41	44 (20)	4	23	27 (12)
Administrative staff	0	7	7 (3)	1	21	22 (10)	3	28	31 (14)	2	22	24 (11)	4	33	37 (17)
Monitor	0	2	2 (0.9)	4	2	6 (3)	5	7	12 (6)	10	19	29 (13)	6	26	32 (15)
IT Programmer	0	3	3 (0.1)	0	13	13 (6)	1	20	21 (10)	2	15	17 (8)	2	21	23 (11)
Pharmacy Support	0	0	0 (0)	0	0	0 (0)	6	8	14 (6)	5	11	16 (7)	5	19	24 (11)
Sub PI	0	0	0 (0)	6	4	10 (5)	1	7	8 (4)	3	4	7 (3)	4	10	14 (6)
Other	4	5	9 (4)	0	3	3 (1)	0	1	1 (0.5)	0	1	1 (0.5)	0	7	7 (3)
Health Economist	0	0	0 (0)	1	1	2 (0.9)	0	0	0 (0)	1	1	2 (0.9)	0	4	4 (2)

Informed Decisions for Trial Management

Respondents were asked to list and/or describe where they obtain the information used to make informed decisions as trial managers. All informed decision-making information sources are listed in table 9. A total of n=210 (96%) respondents answered this question (n=177 UK, n=33 Ireland). It should be noted that n=12 respondents left comments indicating they found the question unclear or did not understand it.

The two most commonly cited sources were Regulators (HRA/MHRA) (n=72; n=67 UK, n=5 Ireland) and Colleagues (n=71; n=67 UK, n=4 Ireland), suggesting that both formal regulatory guidance and informal peer support are equally central to how trial managers inform their decision-making. SOPs (n=48; n=43 UK, n=5 Ireland), online resources (n=43; n=41 UK, n=2 Ireland) and personal experience (n=41; n=33 UK, n=8 Ireland) were also frequently cited. Senior staff (n=28) and the GCP/MHRA Grey Guide (n=24) featured prominently too.

One notable country difference was the Protocol, cited by n=7 Irish respondents but only n=2 UK respondents, and Trial Forge/TMRN which was cited more by Irish respondents (n=3) than UK (n=1).

Training Needs According to Trial Phase

Respondents were asked to rank five trial stages in order of training need, with 1 indicating the greatest need and 5 the least, the responses are summarised in table 10.

The Initiation phase was identified as the stage most in need of additional training, selected as the single greatest training need by n=71 (33%) respondents (n=66 UK, n=16 Ireland), and ranked second by a further n=97 (44%) (n=82 UK, n=15 Ireland). Planning was consistently identified as the second greatest training need, ranked first by n=59 (27%) (n=50 UK, n=9 Ireland) and second by n=56 (26%) (n=47 UK, n=9 Ireland). Together, Initiation and Planning were clearly seen as the two phases where trial managers feel most in need of further training.

The remaining three stages were ranked lower in terms of training need. Executing ranked third overall, while Monitoring and Controlling and Analysing and Reporting were ranked fourth and fifth respectively. Notably, n=125 respondents ranked Analysing and Reporting as the least in need of additional training.

Table 9 List of where trial managers get information to make informed decisions in their role. Note, multiple responses were permitted. N/A = Not applicable

Information Source	Ireland	UK	Total
Regulators (HRA/MHRA)	5	67	72
Colleagues	4	67	71
SOPs	5	43	48
Online (general)	2	41	43
Experience	8	33	41
Senior staff	5	23	28
GCP/MHRA Grey Guide	5	19	24
Sponsor	2	21	23
CI/PI	3	17	20
As required	2	13	15
Trial team	4	12	16
UKTMN	N/A	12	12
REC (Research Ethics Committee)	1	9	10
CT Toolkit	1	9	10
NIHR	N/A	9	9
Protocol	7	2	9
Literature	3	5	8
IRAS (ethics application system)	N/A	7	7
CTU	0	7	7
TMG meeting	1	6	7
Training	1	6	7
Research Governance	2	4	6
UKTMN Guide	0	6	6
QA Manager/Department	3	3	6
Funder	2	3	5
Monitor	2	3	5
Statistician/Methodologist	1	3	4
Trial Forge/TMRN	3	1	4
ECRIN	1	1	2

Table 10 Ranking of trial stages most in need of additional training — UK respondents (n=184). Rank 1 indicates most training need.

	Rank 1			Rank 2			Rank 3			Rank 4			Rank 5		
Phase	**Ireland n=34**	**UK n=184**	**Total (%) n=218**	**Ireland n=34**	**UK n=184**	**Total (%) n=218**	**Ireland n=34**	**UK n=184**	**Total (%) n=218**	**Ireland n=34**	**UK n=184**	**Total (%) n=218**	**Ireland n=34**	**UK n=184**	**Total (%) n=218**
Initiation	14	57	71 (33)	11	48	59 (27)	4	21	25 (11)	2	27	29 (13)	3	29	32 (15)
Planning	15	82	97 (44)	9	47	56 (26)	7	31	38 (17)	1	16	17 (8)	2	8	10 (5)
Executing	4	22	26 (12)	6	48	54 (25)	10	61	71 (33)	8	35	43 (20)	6	22	28 (13)
Monitoring and controlling	1	18	19 (9)	5	26	31 (14)	9	50	59 (27)	16	68	84 (39)	3	20	23 (11)
Analysing and reporting	0	5	5 (2)	3	15	18 (8)	4	21	25 (11)	7	38	45 (21)	20	105	125 (57)

Decision Making

When asked whether they have autonomy in decision making in their role, or if they are required to get PI/Sub-PI approval, the responses were split. N=110 (50%) (n=97 UK, n=13 Ireland) reported having autonomy, while n=108 (50%) (n=87 UK, n=21 Ireland) said they require PI or Sub-PI approval.

Involvement in the Different Stages of a Trial

Respondents were asked whether they are currently involved in designing clinical trials, and whether they would like to be. Table 11 provides the findings. In the UK, 35% are always or frequently involved in the UK, but that proportion is lower in Ireland (21%). At the opposite end of the scale, almost a third are rarely or never involved in both the UK (31%) and Ireland (30%).

Table 11 Reported level of involvement in clinical trial design among trial managers, by country and total.

Involvement	Ireland (%) (n=34)	UK (%) (n=184)	Total (%) (n=218)
Always	3 (9)	19 (10)	22 (10)
Frequently	4 (12)	47 (26)	51 (23)
Sometimes	17 (50)	59 (32)	76 (35)
Rarely	5 (15)	35 (19)	40 (18)
Never	5 (15)	22 (12)	27 (12)
Once	0 (0)	2 (1)	2 (1)

Despite this variability in current involvement, the desire to be involved was near-universal — n=208 (95%) (n=175 UK, n=33 Ireland) said yes, they would like to be involved in trial design, with only n=10 (5%) (n=9 UK, n=1 Ireland) saying no.

Of the n=177 respondents who provided a reason, the overwhelming theme was the value of practical, on-the-ground experience that trial managers could bring to the design process which was cited by 95 respondents. Common sentiments included the ability to identify feasibility issues, flag unrealistic timelines and recruitment targets, and prevent problems before they arise. A further theme around preventing the need for amendments later in the trial was evident in 13 responses. Twenty-two respondents cited career development, ownership and job satisfaction as motivations, noting that involvement from the outset gave them greater investment in the trial's success. A small number (approximately 15) said they did not feel it was their expertise or that clinicians and statisticians should lead on design.

Respondents were also asked about their current involvement in writing the trial protocol, and whether they would like to be involved.

On current involvement, the picture is different between the two countries. The majority of UK respondents reported regular involvement — n=67 said always, n=52 frequently and n=49 sometimes — with only n=14 saying rarely or never. In contrast, Irish respondents were far less likely to be involved, with "sometimes" and rarely or never being the most common responses (n=12, n=11 respectively). Table 12 provides the full overview of respondents' reported level of current involvement in trial protocol writing.

Table 12 Reported level of involvement in writing of the trial protocol among trial managers, by country and total.

Involvement	Ireland (%) (n=34)	UK (%) (n=184)	Total (%) (n=218)
Always	2 (6)	67 (36)	69 (32)
Frequently	9 (26)	52 (28)	61 (28)
Sometimes	12 (35)	49 (27)	61 (28)
Rarely	5 (15)	9 (5)	14 (6)
Never	4 (12)	5 (3)	9 (4)
Once	2 (6)	2 (1)	4 (2)

Despite this disparity in current involvement, the desire to be involved in protocol writing was near-universal — n=202 (93%) (n=171 UK, n=31 Ireland) said yes, with only n=9 (4%) (n=6 UK, n=3 Ireland) saying no. Seven (3%) respondents (UK) did not answer.

Respondents were asked whether they are currently involved in the funding application phase of a clinical trial, and whether they would like to be.

Table 13 shows that current involvement was notably lower than for either trial design or protocol writing. Almost half of respondents reported little or no involvement — n=55 said never and n=47 rarely — making these the two most common responses when combined (n=102, 47%; n=87 UK, n=15 Ireland). Only n=19 (9%) (n=16 UK, n=3 Ireland) reported always being involved, and n=36 (17%) (n=29 UK, n=7 Ireland) frequently. The pattern was broadly similar across both countries, with neither showing a clear majority of regular involvement.

Table 13 Reported level of involvement in funding applications among trial managers, by county and total.

Involvement	Ireland (%) (n=34)	UK (%) (n=184)	Total (%) (n=218)
Always	3 (9)	16 (9)	19 (9)
Frequently	7 (21)	29 (16)	36 (17)
Sometimes	8 (24)	49 (27)	57 (26)
Rarely	7 (21)	40 (22)	47 (22)
Never	8 (24)	47 (26)	55 (25)
Once	1 (3)	3 (2)	4 (2)

The desire to be involved in the funding application was high — n=188 (86%) (n=166 UK, n=22 Ireland) said yes, and n=30 (14%) (n=18 UK, n=12 Ireland) said they would not like to be involved. Irish respondents were proportionally much less keen, with n=12 out of 34 saying no compared to n=18 out of 184 in the UK.

Of the n=188 respondents who said they would like to be involved in the funding application phase, n=185 provided a first reason and n=113 provided a second reason, generating 298 comments in total. Note that individual responses frequently covered more than one theme.

The most prominent theme, raised in approximately 97 comments, was ensuring adequate and realistic costing and resources. Respondents consistently noted that PIs and CIs tend to underestimate the time, staffing and financial resources required to run a trial, and that trial manager involvement at the funding stage would help prevent trials being underfunded or unrealistically resourced from the outset.

Closely related was the theme of practical experience and feasibility input, cited in approximately 85 comments. Respondents felt their hands-on experience of running trials gave them unique insight into what is and is not deliverable, and that this knowledge should inform the application before commitments are made to funders.

Better understanding of the trial from the outset featured in around 70 comments, with respondents noting that involvement at the funding stage provides a stronger foundation for managing the trial later and helps avoid the difficulties of taking on a trial where key decisions were made without their input.

Sense of ownership and investment was cited in approximately 33 comments, with respondents noting that involvement from the earliest stage increases their engagement and motivation.

Career development and progression featured in around 29 comments, with several respondents noting that funding application experience is increasingly expected for senior roles but rarely accessible to trial managers.

Successful Recruitment in Trials

Respondents were asked whether they thought a trial manager has an important role in the successful recruitment of trial participants. The majority of respondents, n=202 (93%), answered yes (n=171 UK, n=31 Ireland), while n=16 (7%) answered no (n=13 UK, n=3 Ireland).

Those who answered yes were invited to provide up to two reasons for their view. Table 14 shows the reasons. Of the 202 (93%) respondents who said yes, n=191 (88%) provided a first reason (n=164 UK, n=27 Ireland) and n=151 (69%) provided a second reason (n=133 UK, n=18 Ireland), generating 342 statements in total (UK: 297, Ireland: 45). Individual statements could capture more than one theme. Ten themes were identified and are described below and listed in table 14 with frequency of occurrence.

1. Central coordination and communication was the most frequently cited theme (n=91, 26.6%; UK: n=81, 27.3%; Ireland: n=10, 22.2%). Respondents described the TM as the central link between the trial management group (TMG), principal investigators, and recruiting sites, responsible for ensuring information, queries, and feedback flowed in both directions, and for reporting recruitment progress to the TMG, TSC, and CI.
2. Training and supporting site staff was the second most frequently cited theme (n=53, 15.5%), and the most frequently cited theme among UK respondents (n=52, 17.5%). Respondents cited TM-delivered training on eligibility criteria, trial procedures, and documentation as central to recruitment outcomes. This theme was cited by only n=1 Irish respondent (2.2%).
3. Monitoring and oversight of recruitment was cited in n=49 statements overall (14.3%; UK: n=46, 15.5%; Ireland: n=3, 6.7%), and encompassed tracking of recruitment figures, review of screening logs, identification of underperforming sites, and early detection of recruitment shortfalls.
4. Motivation and maintaining momentum was raised in n=48 statements overall (14.0%; UK: n=44, 14.8%; Ireland: n=4, 8.9%). Strategies mentioned by respondents included newsletters, inter-site competitions, league tables, sharing of site successes, and direct encouragement from the TM to site teams.
5. Site engagement and relationship-building was identified in n=35 statements overall (10.2%; UK: n=32, 10.8%; Ireland: n=3, 6.7%), with respondents describing regular contact with sites and the maintenance of strong working relationships as key to active recruitment.
6. Strategic planning and feasibility was cited in n=34 statements overall (9.9%; UK: n=27, 9.1%; Ireland: n=7, 15.6%), covering target-setting, timeline management, site selection, and recruitment campaign planning, including involvement in feasibility assessments. This was the second most frequently cited theme among Irish respondents.
7. Trial design and protocol input was mentioned in n=29 statements overall (8.5%; UK: n=25, 8.4%; Ireland: n=4, 8.9%), with respondents referencing TM involvement in reviewing eligibility criteria, identifying problematic trial procedures, and advocating for protocol amendments.
8. Designing recruitment materials and processes was raised in n=28 statements overall (8.2%; UK: n=26, 8.8%; Ireland: n=2, 4.4%), including development of participant information sheets (PIS), consent documentation, patient-facing advertising materials, and the recruitment pathway.
9. Knowledge and experience was cited in n=16 statements overall (4.7%; UK: n=13, 4.4%; Ireland: n=3, 6.7%), with respondents referencing cross-trial experience and knowledge of effective recruitment strategies in specific settings.
10. Problem-solving and troubleshooting was identified in n=14 statements overall (4.1%; UK: n=14, 4.7%; Ireland: n=0), with respondents describing the TM's role in responding to recruitment difficulties and implementing solutions in collaboration with the wider team.

A further 80 statements (23.4%) were general in nature and did not map to a specific theme, including responses such as "overall responsibility" and "the trial manager is the one who makes it work."

Table 14 Themes identified in reasons given by respondents for believing the TM has an important role in successful recruitment (n=202 respondents, 342 total statements)

Theme	Ireland n=34	UK n=184	Total n=218
Central coordination and communication	10	81	91
Training and supporting site staff	1	52	53
Monitoring and oversight of recruitment	3	46	49
Motivation and maintaining momentum	4	44	48
Site engagement and relationship-building	3	32	35
Strategic planning and feasibility	7	27	34
Trial design and protocol input	4	25	29
Designing recruitment materials and processes	2	26	28
Knowledge and experience	3	13	16
Problem-solving and troubleshooting	0	14	14
Total statements	**45**	**297**	**342**

Current Timing of Involvement in a Trial

Respondents were asked at what stage of the clinical trial their involvement as a trial manager is currently sought, all responses are summarised in table 15. Of the 218 respondents, n=211 (97%) provided a response (n=179 UK, n=32 Ireland) and n=7 (3%) did not answer the question. Responses were free-text and were coded into categories; individual responses sometimes referenced more than one stage.

Table 15 Showing TMs current timing of involvement in a trial, by country and total. A total of n=211 responded in free-text and some provided several stages.

Stage of Involvement	Ireland n=32	UK n=179	Total (%) n=211
Set-up, initiation, and regulatory approvals	9	56	65 (30%)
All stages / throughout the trial lifecycle	8	38	46 (21%)
Funding or grant application stage	8	31	39 (18%)
After funding awarded but before protocol development or set-up	1	30	31 (14%)
Protocol development or planning stage	1	28	29 (13%)
Execution, recruitment, or delivery phase	3	19	22 (10%)
Varies depending on the trial	2	8	10 (5%)

Several respondents added qualifying remarks to their responses. Six UK respondents noted that earlier involvement was preferable to their current situation, with comments including that involvement from the funding application stage is where it is "most helpful," and that being involved "from the beginning" reflects an expectation to manage all aspects rather than standard practice. One respondent noted that their involvement across all stages was not considered reflective of trial managers more broadly, given their more senior role.

Daily Challenges in Trial Management

Respondents were asked to identify three day-to-day challenges they face as a trial manager and their responses are listed in Box 1. Response rates were n=218 (100%) for challenges one and two, and n=216 (99%) for challenge three (n=2 missing, both UK). After excluding non-substantive responses (e.g. "n/a", "nil"), a total of 646 statements were available for analysis. These were coded into ten themes; individual statements could capture more than one theme.

1. Recruitment Challenges & Site Engagement: Includes slow/low recruitment, unrealistic targets, poor site engagement, protocol limitations, site staff turnover.
2. Resources, Staffing & Workload Pressures: Under-resourcing, insufficient admin support, multiple trials per manager, unrealistic budgets.
3. Regulatory, Governance & Institutional Delays: Slow approvals, contracting delays, bureaucratic processes.
4. Communication Problems & Stakeholder Responsiveness: Unresponsive PIs/teams, unclear expectations, poor communication across teams.
5. Protocol Complexity & Amendments: Overly complex protocols, frequent amendments, feasibility problems.
6. Data Management, Database Build & IT Limitations: Slow database builds, outdated IT, data entry delays.
7. Administrative & Documentation Burden: Heavy paperwork, TMF/ISF maintenance, email burden.
8. Role Clarity, Autonomy & Recognition: Lack of autonomy, unclear roles, limited recognition/career progression.
9. Training Gaps & Professional Development Needs: Lack of structured training, reliance on on-the-job learning.
10. Multi-tasking, Time Management & Competing Priorities: Managing multiple deadlines, juggling tasks, unpredictable workloads.

Box 1 List of themes identified in respondents' descriptions of day-to-day challenges.

To identify which types of challenges were considered most significant, respondents were asked to rank the challenges 1-3 where 1 indicated the most significant. The analysis counted the number of times each challenge theme was assigned rank 1 (most significant) to 3 across all three challenges reported and these are listed in table 16.

The highest Rank 1 challenge was Recruitment Challenges & Site Engagement (n=43; 19.7%), followed by Multi-tasking/Time Management (n=32; 14.7%) and Communication/Stakeholder Responsiveness (n=29; 13.3%). Resources/Staffing pressures were more commonly positioned as Rank 2 and Rank 3 (both n=35; 16.1%), suggesting that resourcing is widely experienced as a persistent constraint, but not always perceived as the single most acute day-to-day issue. Regulatory/governance delays were spread across ranks, with a slight increase at Rank 3 (n=23; 10.6%). Patterns were broadly similar by country, although Irish respondents more frequently ranked Time Management and Resources as Rank 1 compared with UK respondents.

Table 16 Challenge themes ranked by significance (Rank 1 = most significant, Rank 3 = least significant), by country and total.

Theme	Rank 1			Rank 2			Rank 3		
	Ireland n=34	UK n=184	Total (%) n=218	Ireland n=34	UK n=184	Total (%) n=218	Ireland n=34	UK n=184	Total (%) n=218
Recruitment Challenges & Site Engagement	6	37	43 (19.7%)	5	35	40 (18.3%)	6	25	31 (14.2%)
Resources, Staffing & Workload Pressures	6	19	25 (11.5%)	8	27	35 (16.1%)	9	26	35 (16.1%)
Regulatory, Governance & Institutional Delays	5	15	20 (9.2%)	1	18	19 (8.7%)	5	18	23 (10.6%)
Communication Problems & Stakeholder Responsiveness	5	24	29 (13.3%)	3	20	23 (10.6%)	2	21	23 (10.6%)
Protocol Complexity & Amendments	1	4	5 (2.3%)	1	3	4 (1.8%)	0	5	5 (2.3%)
Data Management, Database Build & IT Limitations	0	11	11 (5.0%)	1	18	19 (8.7%)	2	10	12 (5.5%)
Administrative & Documentation Burden	0	2	2 (0.9%)	1	5	6 (2.8%)	0	10	10 (4.6%)
Role Clarity, Autonomy & Recognition	0	8	8 (3.7%)	1	5	6 (2.8%)	1	9	10 (4.6%)
Training Gaps & Professional Development Needs	0	2	2 (0.9%)	0	3	3 (1.4%)	0	1	1 (0.5%)
Multi-tasking, Time Management & Competing Priorities	7	25	32 (14.7%)	5	26	31 (14.2%)	0	24	24 (11.0%)
Other / Unclassified	3	36	39 (17.9%)	7	23	30 (13.8%)	8	32	40 (18.3%)

Respondents were also asked how they address their ranked challenges, as listed in table 16, and the strategies of how TMs address them are described below and summarised in a matrix of ranked challenge and strategies to address them in table 17. Open-ended text responses were thematically analysed. The dominant strategies used are summarised with attention to how approaches differ when the theme is ranked as a primary (Rank 1) versus secondary or tertiary (Ranks 2–3) challenge. Also see appendix 1 for the analysis including illustrative verbatim quotes.

1. Recruitment & Site Engagement
(Rank 1: n=28 | Rank 2: n=22 | Rank 3: n=12 | % Rank 1: 45.2%)

How challenges are addressed - When recruitment and site engagement are ranked highly, responses focus on active, relational strategies rather than passive monitoring.

Key approaches include:

- Frequent, proactive communication with sites (regular calls, emails, newsletters, site visits)
- Tailored support for low-recruiting sites, including targeted retraining or troubleshooting
- Escalation to CI/PI or senior CTU staff when sites are persistently under-performing
- Sharing best practice between sites, particularly where peer comparison can motivate improvement
- Adjusting recruitment strategies (opening additional sites, revising workflows, engaging CRNs)

When ranked lower (Ranks 2–3), recruitment tends to be addressed through monitoring and incremental adjustment rather than intensive intervention.

2. Resources & Staffing Constraints
(Rank 1: n=30 | Rank 2: n=18 | Rank 3: n=8 | % Rank 1: 53.6%)

How challenges are addressed - This theme is most often ranked as the *top* challenge, and responses reflect clear structural and pragmatic coping strategies:

- Prioritisation of critical tasks, with non-essential activities delayed or deprioritised
- Justifying additional resources via escalation to senior management, funders, or sponsors
- Redistribution of workload within the trial team where possible
- Personal workload compensation, including unpaid overtime (particularly when ranked Rank 1)
- Early planning and realistic costing in future grants as a preventative strategy

Lower-ranked responses tend to frame resourcing issues as accepted constraints, managed through experience rather than resolvable problems.

3. Regulatory, Approvals & Governance Delays
(Rank 1: n=26 | Rank 2: n=16 | Rank 3: n=6 | % Rank 1: 54.2%)

How challenges are addressed - Highly ranked regulatory challenges are addressed through anticipation, persistence, and relationship management:

- Early engagement with regulatory bodies and R&D offices
- Building extra time into project plans to absorb predictable delays
- Persistent follow-up (“chasing”) via multiple communication routes
- Clear documentation and version control to avoid rework or resubmissions
- Escalation to sponsor or senior CI/CTU leadership when blockages persist

When ranked lower, delays are framed as an *inevitable feature* of the system, managed rather than solved.

4. Communication & Collaboration Difficulties
(Rank 1: n=20 | Rank 2: n=20 | Rank 3: n=14 | % Rank 1: 37.0%)

How challenges are addressed - Across all ranks, communication challenges are addressed through process-based and interpersonal strategies:

- Establishing clear communication structures (scheduled meetings, agreed response times)
- Clarifying decision-making authority early in the trial
- Frequent summarisation of actions and decisions (clear minutes, action logs)
- Diplomacy and negotiation skills, especially with senior investigators
- Direct conversations replacing prolonged email exchanges where conflict arises

When ranked lower, communication problems are often addressed reactively rather than systematically.

5. Data & Database Management Issues
(Rank 1: n=18 | Rank 2: n=14 | Rank 3: n=9 | % Rank 1: 43.9%)

How challenges are addressed - Responses emphasise a blend of technical workarounds and coordination:

- Close collaboration with database developers/statisticians
- Use of data flow diagrams or logic checks to minimise downstream issues
- Incremental fixes rather than full redesigns in under-resourced settings
- Additional training for site staff to reduce data queries
- Manual oversight, including spot checks and log tracking when systems are limited

Lower-ranked responses accept database constraints as fixed, relying heavily on manual quality control.

6. Administrative Burden & Documentation
(Rank 1: n=8 | Rank 2: n=15 | Rank 3: n=28 | % Rank 1: 15.7%)

How challenges are addressed - This theme is rarely a top-ranked challenge but frequently present as background workload.

Strategies include:

- Strict organisation and filing systems
- Templates, checklists, and SOPs to improve efficiency
- Delegation to administrative staff where available
- Batching of tasks (e.g. reporting, amendments)
- Acceptance and endurance when ranked Rank 3

When ranked highest, responses often explicitly link admin burden to insufficient resourcing.

7. Workload, Prioritisation & Multitasking
(Rank 1: n=22 | Rank 2: n=24 | Rank 3: n=16 | % Rank 1: 35.5%)

How challenges are addressed - Workload issues are addressed primarily through self-management strategies:

- Task lists, planners, and trackers
- Weekly or daily prioritisation reviews
- Negotiating deadlines upward when possible
- Reducing scope where permissible
- Personal strategies (experience, resilience, time management)

Rank-1 responses frequently acknowledge unsustainability, with few structural solutions offered.

8. Protocol Complexity & Amendments
(Rank 1: n=14 | Rank 2: n=17 | Rank 3: n=9 | % Rank 1: 35.0%)

How challenges are addressed - Approaches focus strongly on early mitigation:

- Early trial manager involvement in design to prevent later amendments
- Clear documentation of impacts to inform CI decisions
- Limiting amendments through robust initial planning
- Improving protocol clarity and training at site initiation

Lower-ranked responses tend to frame amendments as unavoidable and managed case-by-case.

9. Training, Knowledge Gaps & Support Needs
(Rank 1: n=10 | Rank 2: n=12 | Rank 3: n=9 | % Rank 1: 32.2%)

How challenges are addressed - Training gaps are largely addressed informally:

- Peer learning and mentorship
- Self-directed learning using guidance and networks
- On-the-job experience
- Ad hoc training for site staff

High-ranked responses explicitly note lack of structured or role-specific training, with limited practical solutions available.

10. Role Clarity, Autonomy & Professional Recognition
(Rank 1: n=7 | Rank 2: n=9 | Rank 3: n=14 | % Rank 1: 23.3%)

How challenges are addressed - This theme is most often addressed through individual coping rather than systemic change:

- Building credibility through competence and experience
- Clear articulation of impacts to CI/PI
- Escalation for authority where possible
- Acceptance of limited autonomy, particularly when ranked lower

When ranked Rank 1, responses reflect frustration and reliance on informal negotiation rather than formal power.

Overall, across all themes, responses show that trial managers primarily address challenges through personal experience, proactive communication, and adaptability, rather than structural supports. Issues ranked most significant (especially resources, regulation, and recruitment) elicit active, time-intensive strategies, while lower-ranked challenges are often managed through acceptance and endurance rather than resolution - the higher the perceived significance of a challenge, the more proactive and escalation-based the response.

Table 17 How trial managers address challenge themes according to ranked significance (rank 1 = most significant challenge).

Challenge theme	Rank 1 (most significant)	Rank 2 (moderately significant)	Rank 3 (least significant)
Recruitment & Site Engagement	Active, relational strategies: frequent proactive contact with sites (calls, emails, newsletters, site visits); tailored support for low-recruiting sites; escalation to CI/PI or senior CTU staff for persistent under-performance; sharing best practice between sites; adjustment of recruitment strategies (e.g., opening additional sites, revising workflows, engaging CRNs).	Monitoring with targeted troubleshooting and incremental adjustment, rather than sustained intensive intervention; selective retraining, site support, and sharing of best practice where needed.	Routine monitoring and incremental encouragement; lower-ranked recruitment challenges are generally managed with limited intervention and acceptance of some variability in site performance.
Resources & Staffing Constraints	Clear structural and pragmatic coping strategies: prioritisation of critical tasks, delaying non-essential activities; escalation to senior management, funders, or sponsors to justify additional resources; redistribution of workload within the team; personal workload compensation including unpaid overtime; and early planning / realistic costing in future grants as prevention.	Workload redistribution and short-term coping within the team; pragmatic management of constrained resources using experience and prioritisation.	Resourcing issues are treated more as accepted constraints than resolvable problems, with adaptation and endurance within fixed limits.
Regulatory, Approvals & Governance Delays	Anticipation, persistence, and relationship management: early engagement with regulatory bodies and R&D offices; building extra time into project plans; persistent follow-up (“chasing”) through multiple routes; clear documentation and version control; escalation to sponsor or senior CI/CTU leadership when blockages persist.	Persistent follow-up and buffering of timelines, with delays managed as predictable system pressures rather than fully preventable problems.	Delays are framed as an inevitable feature of the system and are managed rather than solved.
Communication & Collaboration Difficulties	Process-based and interpersonal strategies used actively: establishing clear communication structures (scheduled meetings, agreed response times); clarifying decision-making authority early; diplomacy and negotiation skills, especially with senior investigators; and replacing prolonged email exchanges with direct conversations when conflict arises.	Process improvements such as clearer summaries of actions and decisions, minutes, and action logs; selective direct conversations to resolve emerging issues.	Communication problems are more often addressed reactively than systematically, relying on interpersonal workarounds rather than formal structures.

Data & Database Management Issues	A blend of technical coordination and hands-on oversight: close collaboration with database developers/statisticians; use of data flow diagrams or logic checks; additional training for site staff to reduce queries; and manual oversight including spot checks and log tracking when systems are limited.	Incremental fixes rather than full redesigns in under-resourced settings, with targeted coordination and site training where needed.	Database constraints are more often accepted as fixed, with reliance on manual quality control and workarounds.
Administrative Burden & Documentation	When ranked highest, responses explicitly link administrative burden to insufficient resourcing, alongside attempts to streamline work and seek support.	Strict organisation and filing systems; use of templates, checklists, and SOPs; delegation to administrative staff where available; and batching of routine tasks such as reporting or amendments.	Acceptance and endurance of administration as background workload intrinsic to the role.
Workload, Prioritisation & Multitasking	Primarily self-management strategies: task lists, planners, and trackers; weekly or daily prioritisation reviews; negotiating deadlines upward where possible; reducing scope where permissible; and personal coping strategies. Rank 1 responses frequently acknowledge unsustainability and a lack of structural solutions.	Time-management and balancing strategies used to manage competing demands, with continued prioritisation and deadline negotiation where feasible.	Personal coping, resilience, and adaptation dominate; overload is more likely to be normalised as part of trial management.
Protocol Complexity & Amendments	Strong focus on early mitigation: early trial manager involvement in design; clear documentation of amendment impacts to inform CI decisions; limiting amendments through robust initial planning; and improving protocol clarity and training at site initiation.	Amendments are managed pragmatically and case by case, with documentation used to support decisions and minimise avoidable changes.	Amendments are more often framed as unavoidable and managed as they arise.
Training, Knowledge Gaps & Support Needs	Reliance on informal solutions: peer learning and mentorship, self-directed learning using guidance and networks, on-the-job experience, and ad hoc training for site staff. High-ranked responses explicitly note the lack of structured or role-specific training.	Informal mentoring, peer support, and ad hoc learning continue to be the main strategies.	Experience-based coping with minimal expectation of formal support.

Role Clarity, Autonomy & Professional Recognition	Addressed mainly through individual coping and informal negotiation: clear articulation of impacts to CI/PI; escalation for authority where possible; and frustration about limited formal power when this is the top-ranked challenge.	Influence is pursued informally through competence, credibility, and experience.	Acceptance of limited autonomy and professional recognition is more common when lower-ranked.

When asked what the most important responsibility of a trial manager is, responses conceptualised the Trial Manager as the individual with overarching responsibility for trial delivery, combining regulatory oversight, recruitment management, communication, and problem solving. Rather than a single discrete task, participants described the TM role as integrative and cross-cutting, spanning operational, regulatory, and interpersonal domains. The findings suggest that TMs view themselves as central to safeguarding both the scientific and operational success of clinical trials. The themes and illustrative verbatim quotes are available in appendix 2.

Theme 1: Ensuring Successful Trial Delivery
The most pervasive theme related to overall trial delivery. Respondents described the TM as having ultimate responsibility for ensuring that trials are delivered to time, target, and within budget. This theme captures the CTM's role as the central coordinator, responsible for tracking progress, anticipating risks, and ensuring milestones are met throughout the trial lifecycle.

Example responses referred to:

- Delivering the trial to time and target
- Keeping the trial on track overall
- Ensuring milestones and funder deadlines are achieved

Theme 2: Regulatory Compliance and Governance
Many respondents emphasised responsibility for ensuring compliance with regulatory, ethical, and governance requirements. This included adherence to ICH-GCP principles, maintenance of documentation, management of approvals and amendments, and safeguarding trial integrity. Respondents often framed compliance as a non-negotiable foundation of successful trial conduct.

Example responses referred to:

- Ensuring GCP compliance
- Maintaining regulatory approvals and documentation
- Operating within ethical and legal frameworks

Theme 3: Recruitment Oversight and Site Performance
Another prominent theme focused on recruitment. Respondents commonly identified monitoring and supporting recruitment as a core TM responsibility, including identifying underperforming sites, troubleshooting recruitment barriers, and implementing strategies to improve accrual. This theme highlighted the CTM's role as an active facilitator of recruitment rather than a passive overseer.

Example responses referred to:

- Monitoring recruitment rates
- Supporting sites to recruit participants
- Addressing barriers to recruitment

Theme 4: Communication and Central Coordination
Trial Managers were repeatedly described as the main point of contact and communication hub for the trial. Responsibility for maintaining clear, timely, and effective communication between stakeholders (sites, investigators, sponsors, funders) was seen as essential to smooth trial operation and problem resolution.

Example responses referred to:

- Acting as the central point of contact
- Coordinating communication between teams
- Liaising across multiple stakeholders

Theme 5: Problem Solving and Risk Management
Respondents highlighted the TM's responsibility for identifying problems early and implementing solutions. This included anticipating risks, responding to unexpected challenges, and adopting a proactive rather than reactive approach to trial management. This theme often overlapped with senior or experienced respondents' descriptions of the role.

Example responses referred to:

- Troubleshooting issues as they arise
- Anticipating and mitigating risks
- Fire-fighting and crisis management

Theme 6: Leadership, Oversight and Team Support
Finally, many responses framed the TM role in terms of leadership and oversight. This included supporting and motivating site staff, guiding junior team members, and maintaining oversight of multiple trial activities. While not always described as formal management, respondents emphasised influence, authority, and responsibility for maintaining team functioning.

Example responses referred to:

- Leading and supporting trial teams
- Providing training and guidance
- Maintaining oversight of delegated tasks

Resources for Trial Managers

Respondents were asked whether they thought there are adequate resources available for trial managers. A total of 156 (72%) participants responded, 62 replied yes (n=51 UK, n=11 Ireland) and 94 replied no (n=88 UK, n=6 Ireland). If respondents answered 'no' to this question they were asked to list the resources lacking in the next question. These responses were content analysed and are reported in table 18 below. Please note, the resource categories are not mutually exclusive — many responses referenced multiple resource gaps. Counts therefore refer to number of respondents mentioning each category.

Table 18 Resources reported as lacking by respondents, who think there is not adequate resources available for trial managers (n = 94). Note that responses could reference multiple resource gaps.

Resource category	Description	Ireland (n=6)	UK (n=88)	Total (n=94)
Staffing and capacity	Insufficient TM numbers, unrealistic workloads, multiple trials, lack of cover	3	65	68
Training and professional development	Lack of role-specific training, CPD, leadership or management training	3	44	47
Administrative support	Lack of admin staff; TMs undertaking clerical or routine work	2	40	42
Funding and protected time	TM roles under-costed, <1.0 FTE posts, inadequate grant funding	1	38	39
Tools, systems, and infrastructure	Inadequate IT systems, databases, trial management tools	2	29	31
Guidance, standardisation, and role recognition	Lack of clear guidance, standard processes, career pathways	1	23	24

Views on Trial Management Guidelines

The vast majority of respondents thought that the publication of standard trial management guidelines would be beneficial with 180 (83%) (n=151 UK, n=29 Ireland) respondents answering positive ('yes') and 33 (15%) (n=29 UK, n=4 Ireland) did not think so ('no') while 5 (2%) (n=4 UK, n=1 Ireland) did not respond.

The majority of respondents were also willing to give their time to the process of drafting guidelines for standard trial management, n=143 (66%) (n=118 UK, n=25 Ireland), while n=61 were not (n=55 UK, n=6 Ireland) and 14 did not respond (n=11 UK, n=3 Ireland).

When Should TMs Be Involved in Trials

When asked at what stage trial managers should be involved in trials, responses from both Ireland and the UK were highly consistent. Three dominant themes emerged:

1. **Early involvement is essential**
   - The most common view was from the funding and design stage, or "as early as possible".
   - Respondents emphasised feasibility, realistic timelines, appropriate costing, and avoidance of later amendments.
2. **Ongoing involvement across the lifecycle**
   - Many respondents stressed continuous involvement, not a single stage: design → set-up → recruitment → delivery → close-out
   - Trial managers described themselves as the "thread" across the whole trial.
3. **Implementation / set-up stage**
   - Some respondents focused specifically on post-funding, pre-recruitment, particularly:
     - regulatory submissions
     - site set-up
     - database and document development

Overall, there was a strong consensus that late involvement is inefficient and undermines trial delivery.

Perceived Responsibility for Recruitment Shortfalls

When asked whether they feel personally responsible if a trial does not recruit to target, respondents most commonly selected either "Yes" or "Sometimes", with each accounting for n=95 (44%) (n=16 Ireland, n=79 UK) and n=96 (44%) (n=15 Ireland, n=81 UK) of responses, respectively. See full details of responses in table 19. Taken together, 88% of respondents reported feeling at least some responsibility for under-recruitment.

Table 19 Respondents' perceived responsibility for recruitment shortfalls.

Response	Ireland n=34	UK n=184	Total (%) n=218
Yes	16	79	95 (44)
Sometimes	15	81	96 (44)
No	3	21	24 (11)
Never	0	1	1 (0.5)
Missing	0	2	2 (0.9)

How TMs Spend Their Time

Respondents were asked to describe how they spend their time. Across both countries, respondents described the trial manager role as broad, fragmented and highly variable, with time distributed across multiple overlapping activities rather than a small number of discrete tasks. Although many attempted to provide percentage breakdowns, a common theme was the difficulty of doing so meaningfully, as workload shifts substantially depending on trial stage, urgency of issues, and organisational context. The themes from the open-ended responses are described below.

1. Administrative and Regulatory Work (Dominant Time Component)

The most consistently reported activity across both countries was administrative and regulatory work, commonly described as the largest proportion of time.

This included:

- ethics and regulatory submissions
- amendments and approvals
- maintenance of trial master files and site files
- reporting to funders, sponsors and oversight committees

Many respondents estimated this component as 30–60% (and sometimes more) of their workload. Administrative activity was frequently characterised as essential but burdensome, repetitive, and increasingly complex. Several respondents reflected that this work crowded out time for strategic oversight, problem-solving, or professional development.

2. Communication and Coordination

Communication was described as a constant, cross-cutting activity, rather than a standalone task.

Respondents highlighted:

- emails, calls and meetings with sites, investigators, sponsors and regulators
- acting as the central coordination point for trial teams
- managing expectations and chasing information or decisions

This component was often estimated at 20–40% of time, but many noted that communication is embedded within almost every other task. Across both countries, trial managers portrayed themselves as the hub of information flow, maintaining trial momentum through frequent interaction.

3. Site Management, Recruitment and Operational Support

A substantial proportion of time was devoted to supporting trial sites and recruitment activities, though this varied widely by trial phase.

Activities included:

- responding to site queries
- training and supporting site staff
- monitoring performance and data quality
- troubleshooting recruitment or retention issues

Some respondents emphasised being directly involved in operational delivery, while others focused more on oversight and coordination. Regardless, site-related work was consistently described as resource-intensive and reactive, particularly during recruitment and follow-up phases.

4. Meetings

Meetings formed a notable component of trial managers' workloads, including:

- trial management group meetings
- oversight and governance meetings
- internal team and stakeholder meetings

For some (particularly those in senior or coordinating roles), meetings dominated large parts of the working week. Respondents often commented on the volume of meetings relative to their perceived added value, especially when meetings were frequent or poorly focused.

5. Additional Responsibilities and Role Breadth

Across both countries, respondents described undertaking a wide range of additional roles, including:

- data management and database oversight
- budget and financial monitoring
- line management and staff training
- problem-solving and "fire-fighting"

This breadth reinforced a sense that the trial manager role is expansive rather than narrowly defined, with expectations extending well beyond core project management.

6. Variability and Workload Pressure

A strong cross-cutting theme was the variability of time use:

- workload changed markedly by trial stage (set-up, recruitment, follow-up, close-out)
- priorities shifted rapidly in response to urgent issues
- many respondents reported working beyond contracted hours

Several explicitly noted that their estimated percentages added up to more than 100%, reflecting workload intensity and perceived role overload rather than poor estimation.

Overall, the responses from both UK and Ireland depict the trial manager role as:

- administratively heavy, with regulatory processes dominating time
- communication-intensive, requiring constant coordination across stakeholders
- operationally critical, particularly for site support and recruitment
- highly variable, making rigid role definitions or time allocations unrealistic

The combined analysis highlights a role characterised by high responsibility, broad scope and sustained workload pressure, with limited protected time for strategic reflection or development.

Summary of Findings

Across the survey findings, there is remarkable consistency across both UK and Ireland: trial management roles are expanding in scope and complexity; expectations increasingly resemble full project management, without equivalent authority or support; and practical experience is valued more highly than formal education by employers, alongside a strong desire for formal recognition of that expertise by TMs. Across both countries, respondents emphasise experiential learning, peer support, and “learning by doing” as the primary means of skill development, reflecting shared structural characteristics of academic trial delivery systems.

There is also a shared appetite across countries for national or international training frameworks, more centralised guidance and resources, and improved IT and trial management systems. Respondents from both the UK and Ireland highlight fragmentation of guidance, duplication of effort, and inefficiencies arising from locally developed processes, reinforcing the need for harmonisation beyond individual institutions. Similarly, respondents in both settings strongly advocate for earlier and more meaningful Trial Manager involvement in trial design and funding stages, viewing late involvement as a key driver of downstream feasibility, recruitment and resourcing problems.

Some nuanced differences by country are evident, although they are differences of emphasis rather than direction. UK-based respondents more frequently describe challenges related to scale, workload volume, and bureaucratic burden, reflecting the size and complexity of the UK research infrastructure and approval systems. In contrast, Irish respondents more often emphasise limited local capacity, reliance on individual expertise, and variability between institutions, suggesting that constraints of scale and resourcing play a relatively larger role. However, these differences do not alter the core finding: in both countries, Trial Managers feel required to compensate for systemic gaps through individual effort and informal problem-solving.

Overall, Trial Managers in both the UK and Ireland are widely recognised as critical to trial success, particularly in recruitment, site engagement, and operational delivery. However, they remain under-resourced, under-recognised, and under-utilised, most notably at the design and funding stages where their expertise could prevent many of the challenges reported later in trial conduct. The strong alignment of findings across countries suggests that these issues are systemic rather than country-specific, and that solutions are likely to be most effective if developed collaboratively at national and international levels rather than within individual institutions.

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Appendix 1: Strategies Used to Address Ranked Challenge Themes

This document presents a synthesis of responses to Q35 (ranked challenge themes) and Q36 (how challenges are addressed), mapping how trial managers describe addressing key challenge themes when these are ranked as most significant (Rank 1), moderately significant (Rank 2), or least significant (Rank 3). Table 17 summarises cross-cutting patterns by rank, followed by illustrative anonymised quotes extracted from the open-ended text responses to Q36 in the survey (table 16a is the same as in the results section but is included here for completeness).

Table 17 How trial managers address challenge themes according to ranked significance (rank 1 = most significant challenge).

Challenge Theme	Rank 1 (most significant)	Rank 2 (moderately significant)	Rank 3 (least significant)
Recruitment & Site Engagement	Active, relational strategies: frequent proactive contact with sites (calls, emails, newsletters, site visits); tailored support for low-recruiting sites; escalation to CI/PI or senior CTU staff for persistent under-performance; sharing best practice between sites; adjustment of recruitment strategies (e.g., opening additional sites, revising workflows, engaging CRNs).	Monitoring with targeted troubleshooting and incremental adjustment, rather than sustained intensive intervention; selective retraining, site support, and sharing of best practice where needed.	Routine monitoring and incremental encouragement; lower-ranked recruitment challenges are generally managed with limited intervention and acceptance of some variability in site performance.
Resources & Staffing Constraints	Clear structural and pragmatic coping strategies: prioritisation of critical tasks, delaying non-essential activities; escalation to senior management, funders, or sponsors to justify additional resources; redistribution of workload within the team; personal workload compensation including unpaid overtime; and early planning / realistic costing in future grants as prevention.	Workload redistribution and short-term coping within the team; pragmatic management of constrained resources using experience and prioritisation.	Resourcing issues are treated more as accepted constraints than resolvable problems, with adaptation and endurance within fixed limits.
Regulatory, Approvals & Governance Delays	Anticipation, persistence, and relationship management: early engagement with regulatory bodies and R&D offices; building extra time into project plans; persistent follow-up ("chasing") through multiple routes; clear documentation and version control; escalation to sponsor or senior CI/CTU leadership when blockages persist.	Persistent follow-up and buffering of timelines, with delays managed as predictable system pressures rather than fully preventable problems.	Delays are framed as an inevitable feature of the system and are managed rather than solved.
Communication & Collaboration Difficulties	Process-based and interpersonal strategies used actively: establishing clear communication structures (scheduled meetings, agreed response times); clarifying decision-making authority early; diplomacy and negotiation skills, especially with senior investigators; and replacing prolonged email exchanges with direct conversations when conflict arises.	Process improvements such as clearer summaries of actions and decisions, minutes, and action logs; selective direct conversations to resolve emerging issues.	Communication problems are more often addressed reactively than systematically, relying on interpersonal workarounds rather than formal structures.

Data & Database Management Issues	A blend of technical coordination and hands-on oversight: close collaboration with database developers/statisticians; use of data flow diagrams or logic checks; additional training for site staff to reduce queries; and manual oversight including spot checks and log tracking when systems are limited.	Incremental fixes rather than full redesigns in under-resourced settings, with targeted coordination and site training where needed.	Database constraints are more often accepted as fixed, with reliance on manual quality control and workarounds.
Administrative Burden & Documentation	When ranked highest, responses explicitly link administrative burden to insufficient resourcing, alongside attempts to streamline work and seek support.	Strict organisation and filing systems; use of templates, checklists, and SOPs; delegation to administrative staff where available; and batching of routine tasks such as reporting or amendments.	Acceptance and endurance of administration as background workload intrinsic to the role.
Workload, Prioritisation & Multitasking	Primarily self-management strategies: task lists, planners, and trackers; weekly or daily prioritisation reviews; negotiating deadlines upward where possible; reducing scope where permissible; and personal coping strategies. Rank 1 responses frequently acknowledge unsustainability and a lack of structural solutions.	Time-management and balancing strategies used to manage competing demands, with continued prioritisation and deadline negotiation where feasible.	Personal coping, resilience, and adaptation dominate; overload is more likely to be normalised as part of trial management.
Protocol Complexity & Amendments	Strong focus on early mitigation: early trial manager involvement in design; clear documentation of amendment impacts to inform CI decisions; limiting amendments through robust initial planning; and improving protocol clarity and training at site initiation.	Amendments are managed pragmatically and case by case, with documentation used to support decisions and minimise avoidable changes.	Amendments are more often framed as unavoidable and managed as they arise.
Training, Knowledge Gaps & Support Needs	Reliance on informal solutions: peer learning and mentorship, self-directed learning using guidance and networks, on-the-job experience, and ad hoc training for site staff. High-ranked responses explicitly note the lack of structured or role-specific training.	Informal mentoring, peer support, and ad hoc learning continue to be the main strategies.	Experience-based coping with minimal expectation of formal support.
Role Clarity, Autonomy & Professional Recognition	Addressed mainly through individual coping and informal negotiation: clear articulation of impacts to CI/PI; escalation for authority where possible; and frustration about limited formal power when this is the top-ranked challenge.	Influence is pursued informally through competence, credibility, and experience.	Acceptance of limited autonomy and professional recognition is more common when lower-ranked.

Illustrative and Anonymised Quotes

Recruitment & Site Engagement

- “Regular contact with sites is essential – if recruitment drops, I phone rather than email and escalate quickly if needed.” (Trial manager)
- “If one site is struggling, we share ideas from higher recruiting sites to try to unblock issues.” (Academic CTU staff)

Resources & Staffing Constraints

- “You prioritise what absolutely must be done and accept that some things will slip without more staff.” (Trial manager)
- “I often end up working additional hours because there is no flexibility in funding.” (Senior trial manager)

Regulatory, Approvals & Governance Delays

- “Early contact with R&D helps, but a lot of time is still spent chasing approvals.” (Research fellow)
- “We build extra time into timelines because governance delays are inevitable.” (CTU manager)

Communication & Collaboration Difficulties

- “Having clear actions and decision points avoids long email chains and confusion.” (Project manager)
- “Sometimes it takes a direct conversation rather than more emails to resolve things.” (Trial coordinator)

Data & Database Management Issues

- “We work very closely with the database team and manually check data when systems are limited.” (Trial manager)

Administrative Burden & Documentation

- “There is a lot of paperwork, so templates and checklists are essential to stay on track.” (Trial coordinator)

Workload, Prioritisation & Multitasking

- “I use daily task lists and constantly reassess priorities – it is the only way to cope.” (Trial coordinator)
- “Juggling multiple studies means something is always competing for attention.” (Project manager)

Protocol Complexity & Amendments

- “Better planning early on avoids amendments later, but it does not always happen.” (Senior trial manager)

Training, Knowledge Gaps & Support Needs

- “Most of what I have learned is through experience and asking colleagues when issues arise.” (Trial manager)

Role Clarity, Autonomy & Professional Recognition

- “You often need to demonstrate the impact before your perspective is taken seriously.” (Trial manager)

Appendix 2: Thematic Analysis of Open-ended Text Responses to "Most Important Responsibility of a Trial Manager"

This appendix presents the findings of an inductive thematic analysis of responses to Question 37 of the TM Survey: "What is the most important responsibility of a Trial Manager (TM)?". Question 37 was an open-text question and was analysed using a reflexive thematic analysis approach to identify shared patterns of meaning across responses.

The quotations below are reproduced verbatim from responses and are illustrative of each theme. Minor punctuation standardisation was applied where necessary, but wording and meaning have been preserved.

Results: Identified Themes

Theme 1: Ensuring Successful Trial Delivery

The most pervasive theme related to overall trial delivery. Respondents described the TM as having ultimate responsibility for ensuring that trials are delivered to time, target, and within budget. This theme captures the CTM's role as the central coordinator, responsible for tracking progress, anticipating risks, and ensuring milestones are met throughout the trial lifecycle.

Example responses referred to:

- Delivering the trial to time and target
- Keeping the trial on track overall
- Ensuring milestones and funder deadlines are achieved

Illustrative quotes:

"Ensuring delivery of the trial to time and target whilst ensuring regulatory compliance with the utmost scientific and ethical rigour."
(Senior Trial Manager)

"Driving a project forward and making sure all milestones are met so the trial does not drift."
(Trial Manager)

"Ensuring the trial is delivered successfully – if a trial fails, responsibility often sits with the trial manager."
(Clinical Trials Manager)

Theme 2: Regulatory Compliance and Governance

Many respondents emphasised responsibility for ensuring compliance with regulatory, ethical, and governance requirements. This included adherence to ICH-GCP principles, maintenance of documentation, management of approvals and amendments, and safeguarding trial integrity. Respondents often framed compliance as a non-negotiable foundation of successful trial conduct.

Example responses referred to:

- Ensuring GCP compliance
- Maintaining regulatory approvals and documentation
- Operating within ethical and legal frameworks

Illustrative quotes:

"To ensure that the trial is GCP compliant and safeguard participants."
(Clinical Trial Manager)

"Ensuring the trial adheres to all ethical, legal and regulatory requirements at every stage."
(Senior Clinical Trials Coordinator)

"Making sure regulatory approvals are in place and that the study is conducted strictly according to protocol."
(Trial Manager)

Theme 3: Recruitment Oversight and Site Performance

Another prominent theme focused on recruitment. Respondents commonly identified monitoring and supporting recruitment as a core CTM responsibility, including identifying underperforming sites, troubleshooting recruitment barriers, and implementing strategies to improve accrual. This theme highlighted the CTM's role as an active facilitator of recruitment rather than a passive overseer.

Example responses referred to:

- Monitoring recruitment rates
- Supporting sites to recruit participants
- Addressing barriers to recruitment

Illustrative quotes:

"Monitoring recruitment and identifying sites that are struggling so support can be put in place early."
(Senior Trial Manager)

"If recruitment is not working, it is the trial manager's role to identify the problem and resolve it."
(Trial Manager)

"Keeping sites engaged and motivated – without recruitment there is no trial."
(Clinical Trial Coordinator)

Theme 4: Communication and Central Coordination

Clinical Trial Managers were repeatedly described as the main point of contact and communication hub for the trial. Responsibility for maintaining clear, timely, and effective communication between stakeholders (sites, investigators, sponsors, funders) was seen as essential to smooth trial operation and problem resolution.

Example responses referred to:

- Acting as the central point of contact
- Coordinating communication between teams
- Liaising across multiple stakeholders

Illustrative quotes:

"Being the central point of contact between sites, investigators, sponsors and funders."
(Trial Manager)

"Facilitating communication between all stakeholders so everyone understands what is required and when."
(Project Manager)

"Linking all aspects of the trial together and making sure nothing is missed."
(Senior Trial Manager)

Theme 5: Problem Solving and Risk Management

Respondents highlighted the TM's responsibility for identifying problems early and implementing solutions. This included anticipating risks, responding to unexpected challenges, and adopting a proactive rather than reactive approach to trial management. This theme often overlapped with senior or experienced respondents' descriptions of the role.

Example responses referred to:

- Troubleshooting issues as they arise
- Anticipating and mitigating risks
- Fire-fighting and crisis management

Illustrative quotes:

"Identifying issues early and finding solutions before they become major problems."
(Senior Trial Manager)

"Fire-fighting when unexpected challenges arise while keeping the trial moving forward."
(Clinical Trials Manager)

"Anticipating risks and mitigating them wherever possible."
(Trial Manager)

Theme 6: Leadership, Oversight and Team Support

Finally, many responses framed the CTM role in terms of leadership and oversight. This included supporting and motivating site staff, guiding junior team members, and maintaining oversight of multiple trial activities. While not always described as formal management, respondents emphasised influence, authority, and responsibility for maintaining team functioning.

Example responses referred to:

- Leading and supporting trial teams
- Providing training and guidance
- Maintaining oversight of delegated tasks

Illustrative quotes:

"Providing leadership and support to sites and junior staff to ensure high-quality trial conduct."
(Senior Trial Manager)

"Supporting and motivating the trial team to maintain momentum and standards throughout the study."
(Trial Manager)

"Maintaining oversight of all trial activities and ensuring delegated tasks are completed appropriately."
(Clinical Trials Unit Manager)

Summary Interpretation

Overall, responses conceptualised the trial manager as the individual with overarching responsibility for trial delivery, combining regulatory oversight, recruitment management, communication, and problem solving. Rather than a single discrete task, participants described the TM role as integrative and cross-cutting, spanning operational, regulatory, and interpersonal domains. The findings suggest that TMs view themselves as central to safeguarding both the scientific and operational success of clinical trials.

Appendix 3: The Survey

Participant ID: _____

Study Title: Trial managers: an undervalued resource in the clinical trials team?

Name of Chief Investigator: Dr Frances Shiely. Contact No. +353 (0)877835193

Data Controller: University College Cork

Data Protection Officer: DPO, Office of Corporate & Legal Affairs, University College Cork, Western Road, Cork, E: foi@ucc.ie Tel: +353 21 4903949

You are being asked to participate in a research study. The study is seeking your opinion on the role of trial managers, your approaches to management and important factors that successfully deliver a clinical trial. In order to decide whether or not you want to be a part of this research study, you should understand enough about its risks and benefits to make an informed judgment. This process is known as informed consent. This consent form gives detailed information about the research study. I am happy if you wish to contact me and I will also discuss the study with you in detail. When you are sure you understand the study you can tick the box at the end to say you understand and are happy to progress to the questionnaire. This will mean you have given your informed consent.

NATURE AND DURATION OF PROCEDURE(S):

We would like you to fill in this survey online. We ask you to be as truthful as possible. We will also conduct a telephone interview with a small number of clinical trial managers (10% of the total answering the questionnaires). If you are willing to be part of this small group, we ask that you voluntarily give your telephone number on this survey. This is not compulsory and there is no requirement for you to do so. We will call and if it is not a suitable time, we can call you back at a time convenient to you. We would like to record this interview so that we can transcribe it and then analyze your responses in different themes. This will be totally anonymous. When we refer to the interview in a journal article or a conference presentation, we will only say, Participant no. 1 suggested ..... etc. Your participation is totally voluntary and you do not have to agree to doing this study. If you do agree, and at any stage during the interview you wish to stop, that is totally okay too.

POTENTIAL RISKS AND BENEFITS:

There are really no risks to you participating in this research. The survey will take about 20 minutes to complete. Your help now would benefit trial managers in the future. It will assist the conduct of trials, as it will provide us with information that will aid trial managers in successfully conducting clinical trials.

POSSIBLE ALTERNATIVES:

You may choose not to participate in this study. Participation is completely voluntary.

AGREEMENT TO CONSENT

The research project and the treatment procedures associated with it have been fully explained to me. I have had the opportunity to ask questions via telephone call concerning all aspects of the project. I am aware that participation is voluntary and that I may withdraw my consent at any time. I am aware that my decision not to participate or to withdraw will not restrict my access to health care services normally available to me. Confidentiality of records concerning my involvement in this project will be maintained in an appropriate manner. When required by law, the records of this research may be reviewed by government agencies and sponsors of the research.

I, the undersigned, hereby consent to participate as a subject in the above described study conducted by the HRB Clinical Research Facility at University College Cork. I understand by ticking the boxes below and progressing forward online here, this is recognized as giving my consent to continue. I understand that if I have any questions concerning this research, I can contact the Chief Investigator listed above. I understand that the study has been approved by the Cork Research Ethics Committee of the Cork Teaching Hospitals (CREC) and if I have further queries concerning my rights in connection with the research, I can contact CREC at Lancaster Hall, 6 Little Hanover Street, Cork, +353-21-4901901.

I have read and understand the study: Yes □ No □

I agree to participate in this research: Yes □ No □

I agree to being contacted to conduct a sort 10 minute telephone interview, and will provide my telephone voluntarily. Yes □ No □
Phone number with country code: _____

I consent to allow my interview to be audio-recorded (if I give my phone number to allow the researchers contact me) Yes □ No □

I understand that my anonymised data will be stored at University College Cork for up to 10 years Yes □ No □

Questionnaire for Participants

Location. Please Tick one.

□ Ireland

□ United Kingdom

□ Other

Section 1. Training and Experience

1. What type of clinical trials do you manage?

□ Academic clinical trials

□ Commercial clinical trials

□ Both

2. Have you experience managing single centre, multicentre or multinational trials? Please tick all that apply

□ Single Centre

□ Multicentre

□ Multinational

3. What is the highest level of qualification that you have?

□ Primary education

□ Secondary education

□ Third level degree

□ Masters

□ PhD

□ Other

4. Do you have a professional management qualification?

□ Yes

□ No

5. If you answered yes, what type of qualification?

_____

Please circle one for each question:

6. I believe that this professional management qualification equipped me with all of the skills to be a successful trial manager?

Please circle

□ Strongly Agree □ Agree □ Neither Agree nor Disagree
□ Disagree □ Strongly disagree

7. I feel confident in my level of training when conducting a clinical trial

□ Strongly Agree □ Agree □ Neither Agree nor Disagree
□ Disagree □ Strongly Disagree

8. Have you received additional training from (please tick one or more)

□ The Trial Managers Network

□ The Association of Clinical Research Professionals

□ The Society of Clinical Research Associates

□ Other

9. On average, how often do you complete additional training?

□ Once per year

□ Twice per year

□ Three times per year

□ More than three times per year

10. Where do you receive this additional training?

□ Online

□ Onsite at your home facility

□ Another site which required travel

11. Do you use an online toolkit or resources from the European Clinical Research Infrastructure Network (ECRIN) to guide you in managing clinical trials?

□ Always □ Frequently □ Sometimes □ Rarely □ Once
□ Never

12. How well would you describe the clinical trial managers training that you received?

□ Poor □ Fair □ Good □ Very Good □ Excellent

13. Do you think there are elements lacking in the current training for clinical trial managers?

□ Yes

□ Neutral

□ No

14. If you answered yes, in your opinion what elements are lacking?

_____

15. Do you think Clinical Trial Managers should have more training?

□ Yes

□ No

□ Other

16. In your opinion, who should provide this training?

_____

Section 2. Clinical Trial Management

17. How important do you believe an efficient well-trained management team is in the conduct of a successful clinical trial?

□ Very important □ Of Little Importance □ Moderately Important
□ Important □ Very Important

18. If you could select only five members of your clinical trial team to run an efficient clinical trial, select in order of importance, 1 being the most important and 5 being the least important, the 5 members of the team you would select.

□ Principal Investigator (PI)

□ Sub PI

□ Research nurse

□ Statistician

□ Data manager

□ Data assistants

□ IT programmer

□ Monitor

□ Health economist

□ Pharmacy support

□ Administrative staff

□ Other

19. Where do you obtain the information that you use to make informed decisions as a trial manager?

_____

20. Below are five stages in the conduct of a clinical trial. In your view, which of these stages needs most training? Please rank these in order from 1 to 5, 1 being the stage in most need of additional training and 5 being the least in need of additional training to help trial managers.

□ Initiating phase

□ Planning phase

□ Executing phase

□ Monitoring and controlling phase

□ Analysing and reporting phase

Section 3. Important factors of Clinical Trial Management

21. Do you have autonomy in decision making in your role as a clinical trial manager, or are you required to get PI/sub-PI approval before making a decision?

□ Autonomy

□ Require PI/sub PI approval

22. In your work as a trial managers, are you involved early on in the trial design phase?

□ Always □ Frequently □ Sometimes □ Rarely □ Once
□ Never

23. Would you like to be involved early on in the trial design phase of a clinical trial?

□ Yes

□ No

Why (optional)

_____

24. In your work as a trial manager, are you involved early on in funding application phase?

□ Always □ Frequently □ Sometimes □ Rarely □ Once
□ Never

25. Would you like to be involved early on in the funding application phase of a clinical trial?

□ Yes

□ No

Why (optional) _____

26. Do you think a clinical trial manager has an important role in the successful recruitment of trial participants?

□ Yes

□ No

27. In your current role as a clinical trial manager, at what stage of the clinical trial is your involvement sought?

_____

28. What are three day-to-day challenges that you face as a trial manager?

_____

29. Can you rank these challenges in order of significance i.e. having the largest effect on the success of the trial. 1 being the most significant challenge, 3 being the least significant challenge.

1._____

2._____

3._____

30. As a trial manager, how would you address these challenges?

1._____

2._____

3._____

31. What is the most important responsibility of a Clinical Trial Manager?

_____

32. Do you think there are adequate resources available for trial managers?

□ Yes

□ No

33. If you answered no, what resources are lacking?

_____

34. Do you think the publication of standard trial management guidelines would make your job easier?

□ Yes

□ No

35. Would you be willing to give your time to the process of drafting these guidelines?

□ Yes

□ No

36. At what stage of a clinical trial, e.g. funding stage, design stage, post-funding stage, implementation stage, etc. would you like to be called on to share your area of expertise?

_____

37. In your role as a trial manager, do you feel responsible if the clinical trial fails to meet its recruitment target?

- □ Yes
- □ No
- □ Sometimes
- □ Never

38. In your role as a trial manager, how do you spend your time? Can you divide this by 100% into portions? E.g. 15% on paperwork, 10% on meetings, 20% dealing with international sites. These are just some examples. Please try to include all aspects of your role which help us understand the day to day job of a clinical trial manager.

_____

Thank you for taking the time to complete this questionnaire.