

Where do we go from here? - Opportunities and barriers to the career development of Trial Managers: a survey of UK-based trial management professionals

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Keywords: clinical trial, trial management, trial manager, career development, survey, UKTMN, project management

Posted Date: October 22nd, 2019

DOI: <https://doi.org/10.21203/rs.2.16303/v1>

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Version of Record: A version of this preprint was published at Trials on May 6th, 2020. See the published version at <https://doi.org/10.1186/s13063-020-04316-z>.

Abstract

Background Clinical trials commonly have a dedicated trial manager and effective trial management is essential to the successful delivery of high quality trials. Trial managers have diverse experience and currently there is no standardised structured career pathway. The UK Trial Managers' Network (UKTMN) surveyed its members to understand what is important to them with respect to career development, since this would be important in the development of any initiative intended to develop a skilled workforce. **Methods** We conducted an online survey of UKTMN members, who are trial management professionals, working on academic-led trials in the UK. Members were asked what they perceive as opportunities and barriers to career development. Two reminders were sent to facilitate completion of the survey and responders were offered the opportunity to enter a prize draw for waived fees at the UKTMN annual meeting. **Data** was analysed descriptively using Stata (version 15.1) and free-text responses were reviewed for themes. **Results** The survey was sent to 819 UKTMN members; 433 responses were received, though 13 were from non-UKTMN members, thus 420 respondents' data were included in analyses. Respondents were representative of UKTMN membership, however more responses were received by trial managers based in registered Clinical Trials Units (CTUs). The top three opportunities for career development were: i) training, ii) helping design trials, iii) undertake relevant qualifications. The top three barriers were: i) funding, ii) few opportunities to get involved in development activities aside from managing a trial and iii) unclear organisational career pathway. Almost all respondents (401/420, 95.4%) considered career development either very or quite important. Although all respondents had a day-to-day role in managing trials, there was huge disparity between job titles. **Conclusion** Career development is important to trial managers yet there is a lack of a structured pathway. The enablers and disablers to career development for trial managers should be clearly considered by the clinical trial community and, in particular, employers, sponsors and funders in order to develop a highly skilled workforce of trial managers, who are key to the delivery of trials.

Background

Clinical trials are considered gold-standard for testing healthcare interventions in patients. In addition to clinical trials being led by a Chief Investigator (CI), these complex projects require expert project management and it is commonplace for trials to appoint a dedicated person to manage the trial. Effective trial management has been shown to be essential to the successful delivery of high quality trials (1) and the STEPS study, which investigated strategies to improve recruitment into randomised trials, showed that the appointment of a dedicated trial manager was one factor in trials that recruited more successfully (2). Indeed UK major public funding bodies such as the National Institute for Health Research (NIHR) recommend the appointment of a dedicated trial manager and send a general trial manager job description at the time of project activation. Treweek et al acknowledged that once clinical trial funding was awarded, the most important members of the team are "not the professors and investigators but the trial managers" who are key to delivering the goal (3) and Beaumont et al recently wrote that having an "expert" trial manager, who can overcome operational challenges, is often the difference between success and failure of a clinical trial (4). Over twenty years ago, one of the UK's largest funders of clinical trials at the time, the Medical Research Council (MRC), commissioned the development of the Trial Managers' Network in response to trials failing to deliver on time and budget and a lack of training identified for staff who were responsible for managing clinical trials. The network, now known as the UK Trial Managers' Network; (UKTMN) aims to facilitate the development and support of trial managers across the UK (5) and has long argued that there is a lack of recognition of the role of trial manager, particularly at an organisational level, and an absence of a structured career pathway. Trial managers come from a diverse range of backgrounds with no recognised career pathway so usually learn "on the job" (1) which the authors acknowledge is as an important part of career development, though also recognise this could be enhanced by technical and theoretical knowledge to underpin it. Recently there have been several publications acknowledging a lack of career development pathway for trial managers (6) (4) (7) and whilst some progress has been made in the development of academic career pathways in some universities, Beaumont et al recognised that not all trial managers may wish to pursue this and therefore alternative pathways should be considered. From our own experience

across several organisations and discussions with UKTMN members, where pathways do exist, there is disparity across organisations.

The UKTMN Executive Group, responsible for the strategic direction of the network, surveyed its membership (over 800 members) to understand what is important to them with respect to their own career development since this would be important for any initiative aimed at improving the development and retention of a skilled workforce. For the purpose of this manuscript, a trial management professional is someone who has day-to-day responsibility for the management of operational aspects of a clinical trial or other high quality clinical study, though the authors acknowledge there is significant disparity between job titles across the UK. For example, a trial coordinator in one organisation could have overall responsibility for a clinical trial, whereas in other organisations the role associated with this job title is a supportive one. UKTMN members are based in a variety of organisations, including universities, clinical trials units (CTU) and NHS Trusts.

Methods

We conducted an open survey of members of the UK Trial Managers' Network. Survey questions included a mixture of quantitative and free-text responses (additional file 1). The survey was built using Jisc Online Surveys[®] and prior to circulation a draft version of the survey was user-tested by six trial managers, all from a trial management background, in departments where authors were based. A link was circulated to all members in June 2019 and open for 20 calendar days, with two reminders circulated during this time. Survey questions and response categories were agreed by the authors. Adaptive questioning was used when required to increase the simplicity of completion and participants were able to review and edit their responses prior to final submission. Completion of the survey was voluntary and consent was assumed by completion of the survey.

To encourage completion of the survey, all participants were given the option of providing their email address and being entered into a prize draw to have their delegate fees waived at the forthcoming UKTMN annual meeting held later in 2019. Participants' contact details were not linked to other survey data when analysed and were stored in the password-protected Online Survey. For questions relating to career development opportunities that are considered important, participants were asked to rate each opportunity from 0-10 (0 being not important, 10 being the most important). These data are presented as mean (SD) scores. From a pre-populated list, defined by the authors, participants were also asked to state which issues they perceived as barriers to career development. For both opportunities and barriers to career development, analyses were undertaken for all responses and associations that were felt to potentially influence opinion; length of time in a trial management role; salary scale (used as a proxy for level of experience given the known disparity between job titles across organisations), whether participants had previously been promoted and whether they were currently based in a UK Clinical Research Collaboration (UKCRC) registered CTU.

Descriptive analyses were undertaken using Stata (version 15.1) with free-text responses being reviewed for themes using NVivo (version 12.1).

Results

The survey was sent to 819 UKTMN members and 433 responses were received. Thirteen responses were received by non-members of UKTMN, possibly due to the survey link being forwarded by members; their data were not included in analyses and thus data is presented on 420 participants (figure 1).

Limited data is collected at the time of applying for UKTMN membership, however, some comparisons between UKTMN members' characteristics and survey respondents could be made: characteristics of survey respondents reflect that of the overall UKTMN membership for geographical spread across the UK and job titles, though there were slightly more

responses from respondents who identified as a Senior Trial Manager (93/420, 22.1%) compared to UKTMN membership (109/819, 13.3%) (Table 1).

Table 1 - characteristics of survey respondents

Characteristic	n=420 (%)
Gender	
Female	364 (86.7)
Male	53 (12.6)
Prefer not to say	3 (0.7)
Based in a UKCRC registered CTU	
Yes	317 (75.5)
No	103 (24.5)
Location of CTU	
	n=317
London	49 (15.5)
West Midlands	44 (13.9)
Scotland	38 (12)
Oxfordshire	35 (11)
Yorkshire and the Humber	29 (9.2)
North West	29 (9.2)
South West	22 (6.9)
East Midlands	17 (5.4)
South East	15 (4.7)
Wales	14 (4.4)
East of England	14 (4.4)
South Central	7 (2.2)
Northern Ireland	3 (1.0)
North East	1 (0.3)
Employment status	
Full-time	313 (74.7)
Part-time	106 (25.3)
Missing	1 (0.2)
Organisation type	
University	356 (84.8)
NHS	60 (14.3)
Charity/Not for Profit	4 (0.1)
NHS Grade/pathway	
	n=60
Administrative/clerical	35 (58.3)
Managerial	19 (31.7)
Clinical	1 (1.7)
Nursing/healthcare professional	4 (6.7)
Research	1 (1.7)
Academic Grade/pathway	
	n=356
Professional/Administrative/Managerial/Academic-related	267 (75.1)
Research	67 (18.9)
Not known	20 (5.1)
Academic/Academic-related (research)	2
Length of time in a trial management role	
<1 year	32 (7.6)
1-2 years	66 (15.7)
3-5 years	126 (30)
6-10 years	89 (21.2)
>10 years	107 (25.5)
Funding for current position	
Grant/research funding	278 (66.2)
Combination of core/grant funding	77 (18.3)
Core-funded	41 (9.8)
Don't know	22 (5.2)
Institute-funding (based in a Charity)	1 (0.2)
No salary - honorary research fellow	1 (0.2)
Highest educational qualification	
PhD	111 (26.4)
Masters or other post-graduate qualification	138 (32.9)

	Undergraduate degree	147 (35)
	A levels or equivalent	16 (3.8)
	GCSEs or equivalent	6 (1.4)
	Vocational qualifications	1 (0.2)
	None of the above	1 (0.2)
Current job title		
	Trial manager	176 (41.9)
	Senior trial manager/team lead	93 (22.1)
	Trial coordinator	77 (18.3)
	Trial administrator/assistant	9 (2.1)
	Other	65 (15.5)
	<i>Project Manager</i>	11
	<i>Operations Manager</i>	11
	<i>Research Assistant/Associate/Fellow</i>	11
	<i>Assistant/Associate Trial Manager</i>	6
	<i>Senior Trial Coordinator</i>	6
	<i>Senior Research Fellow/Associate</i>	4
	<i>Programme Manager</i>	3
	<i>Data Manager</i>	3
	<i>Head of trial management</i>	2
	<i>Assistant Professor of Clinical Trials</i>	1
	<i>Compliance Manager</i>	1
	<i>Research Facilitator</i>	1
	<i>Senior Research Manager</i>	1
	<i>Senior Research Midwife</i>	1
	<i>TMF Manager</i>	1
	<i>Trial Director</i>	1
	<i>Trial Management Director</i>	1
Current salary range (full time equivalent)		
	<£18,000	1 (0.2)
	£18,000-£21,999	1 (0.2)
	£22,000-£24,999	8 (1.9)
	£25,000-£26,999	17 (4.1)
	£27,000-£31,999	70 (16.7)
	£32,000-£34,999	65 (15.5)
	£35,000-£39,999	114 (27.1)
	£40,000-£43,999	67 (16.0)
	>£44,000	61 (14.5)
	Prefer not to say	16 (3.8)
Ever experienced a promotion/progression to more senior role		
	Yes	224 (53.3)
	No	196 (46.7)
Reason for no experience of promotion/progression to more senior role n=196		
	No career pathway in my organisation	66 (33.7)
	Not in role long enough for this to be relevant	62 (31.6)
	Never been given the opportunity	50 (25.5)
	Not wanted to	18 (9.2)
If promoted/progressed, how this happened n=224		
	Via application to new/vacant position outside your organisation	159 (71)
	Via a promotional pathway in your organisation	65 (29)
Importance of career development		
	Very important	276 (65.7)
	Quite important	125 (29.8)
	Not very important	18 (4.3)
	Not important at all	1 (0.2)

There were also a higher number of responses from staff based in registered CTUs (317/420, 75.5%) compared with UKTMN membership (464/819, 56.7%). 356/420 (84.8%) of responders were based in Universities, with the remaining mainly based in the NHS, and almost all respondents were on a non-academic pay scale. Just under a third of participants had worked in a trial management role for between 3 and 5 years, with a further 20% with 6-10 years' experience. 278/420 (66.2%) participants were funded via grant or research funding with 41/420 (9.8%) being core-funded and 77/420 (18.3%) funded by a combination of the two. Almost all participants (396/420, 94.3%) were educated to at least undergraduate degree level, with 111/420 (26.4%) having a PhD and 138/420 (32.9%) having a masters or other postgraduate qualification. 176/420 (41.9%) participants referred to themselves as a trial manager, with other participants having a wide range of job titles. Nearly one third (114/420) had a salary between £35,000 and £39,999. Just over half of participants (224/420) answered yes to the question "have you ever experienced a promotion/progression to a more senior role". For the 196 participants who had never progressed, the main reason stated was "no career pathway in my organisation" (66/196, 33.7%) and 62/196 (31.6%) participants stated they had "not been in the role long enough for promotion to be relevant". For the 66/196 respondents who had not progressed because there was no career pathway in their organisation, just under half (30/66, 45.5%) were based in a registered CTU. For participants who had progressed (224/420), 29% had done this via a promotional pathway in the organisation, with the remaining 71% doing this via an application to a new or vacant position outside of the organisation. 401/420 (95.4%) considered career development as either 'very' or 'quite' important.

Opportunities

From a list of twelve potential opportunities considered important to career development, participants were asked to rate each one between 0 and 10 (0 being not important, 10 being the most important) (Table 2).

Table 2: Professional development opportunities

Opportunities that are considered important – mean (SD)	All respondents	Length of time in a trial management role		Salary scale		Previous promotion		Based in a registered CTU	
		<1-5 years	6->10 years	<£35,000	>£35,000	Yes	No	Yes	No
	n=420	n=224	n=196	n=162	n=242	n=224	n=196	n=317	n=103
To attend relevant training courses	8.3 (1.8)	8.4 (1.8)	8.2 (1.9)	8.4 (1.8)	8.3 (1.8)	8.3 (1.9)	8.4 (1.8)	8.4 (1.8)	8.1 (1.9)
To help in the design of trials	7.7 (2.4)	7.5 (2.5)	8.0 (2.2)	7.4 (2.6)	7.9 (2.2)	7.8 (2.3)	7.6 (2.4)	7.8 (2.3)	7.4 (2.6)
To undertake qualifications applicable to trial mgmt	7.5 (2.6)	7.3 (2.7)	7.8 (2.2)	7.9 (2.5)	7.3 (2.5)	7.8 (2.3)	7.6 (2.4)	7.8 (2.3)	7.4 (2.6)
To contribute to academic writing and publication	7.0 (2.9)	7.0 (2.5)	7.2 (2.7)	6.8 (2.6)	7.2 (2.3)	7.3 (2.8)	7.8 (2.4)	7.4 (2.7)	7.8 (2.3)
To join committees/groups related to trials	7.0 (2.5)	6.5 (2.6)	7.1 (2.7)	6.5 (2.5)	6.5 (2.5)	7.3 (2.7)	7.3 (2.7)	7.4 (2.6)	6.8 (2.9)
To assist with obtaining funding for trials	6.5 (2.6)	6.4 (2.7)	7.1 (2.6)	6.9 (2.4)	6.1 (2.8)	7.0 (2.7)	7.1 (2.7)	7.0 (2.6)	7.0 (2.6)
To work on more complex trials	6.1 (3.0)	6.1 (3.0)	7.2 (2.4)	5.9 (3.0)	6.3 (3.0)	7.0 (2.5)	7.1 (2.4)	7.0 (2.4)	7.0 (2.6)
To work in a variety of clinical areas	6.1 (3.0)	5.5 (3.2)	7.4 (2.8)	5.7 (3.1)	6.2 (2.9)	7.3 (2.7)	6.6 (3.0)	7.1 (2.8)	6.5 (3.0)
To contribute to methodological studies/SWATs	5.4 (2.9)	6.6 (2.5)	6.4 (2.8)	5.7 (2.8)	5.2 (3.0)	6.5 (2.8)	6.6 (2.5)	6.6 (2.6)	6.5 (2.7)
To present work at conferences		6.6 (2.5)	6.2 (2.8)			6.3 (2.7)	6.6 (2.6)	6.5 (2.7)	6.1 (2.6)
To work on trials outside the UK		5.8 (2.9)	6.5 (3.0)			6.2 (3.0)	6.0 (3.0)	6.3 (2.9)	5.7 (3.0)
To work on larger (sites and participants) trials		6.0 (2.9)	6.1 (3.1)			6.2 (2.9)	6.2 (2.9)	6.1 (3.0)	5.9 (3.0)
		5.4 (3.3)	5.5 (3.2)			5.6 (3.2)	5.3 (3.3)	5.5 (3.2)	5.3 (3.4)
		5.7 (2.7)	5.1 (3.0)			5.3 (3.0)	5.6 (2.8)	5.3 (2.9)	5.7 (3.0)

* for salary scale, the 16 respondents who answered “prefer not to say” were not included in this analysis.

The top three perceived most important opportunities were; 1) to attend relevant training courses (mean 8.3, SD 1.8), 2) to help in the design of trials (mean 7.7, SD 2.4) and to undertake relevant qualifications applicable to trial management

(mean 7.5, SD 2.6). The most important opportunity, for all, irrespective of possible associations previously described, was “to attend relevant training courses”. The top three opportunities by the characteristics described above are shown in Table 3. Participants were also asked to state any other opportunities they considered important with respect to career development; there were 35 responses in total, many of which were covered by the list of opportunities given, though several responses stated they would like the opportunity to develop leadership and line management responsibilities.

Table 3: Top 3 perceived enablers of career development

	Top three professional development opportunities		
	1	2	3
All respondents	Training	Trial design	Qualifications
Length of time in a trial management role			
<1-5 years	Training	Qualifications	Trial design
6->10 years	Training	Trial design	Qualifications
Salary scale			
<£35,000	Training	Qualifications	Trial design
≥£35,000	Training	Trial design	Academic writing
Previously promoted			
Yes	Training	Trial design	Qualifications, Academic writing, Assist with funding
No	Training	Qualifications	Trial design
Based in a registered Clinical Trials Unit			
Yes	Training	Trial design	Qualifications, Academic writing
No	Training	Qualifications	Trial design

Full wording for each opportunity as follows: “Training” – to attend relevant training courses; “Trial design” – to help in the design of trials; “Qualifications” – to undertake qualifications applicable to trial management; “Academic writing” – to contribute to academic writing and publications; “Assist with funding” – to assist with obtaining funding for trials.

Barriers

Participants were asked to select perceived barriers to career development from a list of nine, with the option of giving additional barriers not included in the list (Table 4). The top three perceived barriers were “funding” (256/420, 61%), “few opportunities to get involved in other activities aside from managing a clinical trial(s)” (249/420, 59.3%) and “unclear career pathway within the organisation” (247/420, 58.8%).

Table 4: Perceived barriers to professional development

Perceived barriers to career development	All responses	Length of time in a trial management role		Salary scale		Previous promotion		Based in a registered CTU	
		<1-5 years	6->10 years	<£35,000	>£35,000	Yes	No	Yes	No
	n=420 (%)	n=224 (%)	n=196 (%)	n=162 (%)	n=242 (%)	n=224(%)	n=196 (%)	n=317	n=103
Funding	256 (61.0)	132 (58.9)	124 (63.3)	103 (63.6)	141 (58.3)	136 (60.7)	120 (61.2)	186 (58.7)	70 (67.8)
Few opportunities	249 (59.3)	123 (54.9)	126 (64.3)	98 (60.5)	141 (58.3)	138 (61.7)	111 (56.6)	192 (60.6)	57 (55.3)
Working outside	247 (58.8)	122 (54.5)	125 (63.8)	84 (51.9)	151 (62.4)	124 (54.9)	124 (63.3)	170 (53.6)	77 (74.8)
Managing a trial(s)	237 (56.4)	106 (47.3)	131 (66.8)	82 (50.6)	142 (58.7)	135 (60.3)	102 (52.0)	178 (56.2)	59 (57.3)
Unclear career pathway in organisation	223 (53.1)	114 (50.9)	109 (55.6)	25 (15.4)	129 (53.3)	136 (60.7)	87 (44.4)	178 (56.2)	45 (43.7)
Recognition of role	155 (37.0)	94 (42.0)	61 (31.1)		66 (27.3)	77 (34.4)	78 (39.8)	113 (35.7)	42 (40.8)
Lack of time	63 (15)	31 (13.8)	32 (16.3)		37 (15.3)	36 (16.1)	27 (13.8)	45 (14.2)	18 (17.5)
Training	54 (12.9)	32 (14.3)	22 (11.2)		28 (11.6)	25 (11.2)	27 (14.9)	37 (11.7)	17 (16.5)
Geographical location	10 (2.4)	6 (2.7)	4 (2.0)		6 (2.5)	4 (1.8)	29 (14.9)	7 (2.2)	3 (2.9)
Size of organisation							6 (3.1)		
No barriers perceived									

* for salary scale, the 16 respondents who answered "prefer not to say" were not included in this analysis.

The top three barriers to career development, by the characteristics previously described, are shown in Table 5. Other barriers perceived, not included in the pre-populated list, included fixed-term contracts; line managers' insistence on the need to focus on "delivery of trials"; an assumption by the academic community that academic qualifications are needed to progress, when experience is often just as valuable and the job title 'trial manager' can imply an administrative, rather than professional role to many.

Table 5 - Top 3 perceived barriers to career development

	Top three perceived barriers to career development		
	1	2	3
All respondents	Funding	Few opportunities	Unclear career pathway
Length of time in a trial management role			
<1-5 years	Funding	Few opportunities	Unclear career pathway
6->10 years	Recognition	Few opportunities	Funding
Salary scale			
<£35,000	Funding	Few opportunities	Unclear career pathway, recognition, lack of time
≥£35,000	Unclear career pathway	Recognition	Funding, few opportunities
Previously promoted			
Yes	Few opportunities	Funding, lack of time	Recognition of role
No	Unclear career pathway	Funding	Few opportunities
Based in a registered Clinical Trials Unit			
Yes	Few opportunities	Funding	Recognition of role, lack of time
No	Unclear career pathway	Funding	Recognition of role

Full wording for each barrier as follows: "Funding" – funding; "Few opportunities" – few opportunities aside managing a trial(s); "unclear career pathway" – unclear career pathway in organisation; "recognition" – recognition of role; "lack of time" – lack of time.

Participants were asked to report how well supported they felt, with respect to professional development, by their line manager, department/unit (within the organisation) and the organisation itself. Nearly half of participants (194/420, 46.2%) felt "very well supported" by their line manager, though only a quarter (103/420, 24.5%) felt the same about their department/unit and less for their organisation (67/420, 16.0%).

115/420 (27.4%) participants provided free-text comments on other areas they felt related to career development for trial managers that hadn't been covered by previous questions. The main themes identified from free-text responses were 1) lack of recognition, understanding and value of the role of trial manager, 2) fixed/short-term contracts and funding, 3) lack of training and clear career pathway 4) disparity between organisations and 5) lack of time and capacity to focus on career development. Comments reflected the quantitative data and are shown in Table 6.

Table 6 – Themes identified from free-text comments

Theme	Example quotes
Lack of recognition, understanding and value of the role of trial manager	"trial managers are seen as less important than academics in the university setting"
	"I don't think trial management is seen as a professional career in the academic community"
	"there is a significant problem with recognising the contribution a trial manager makes to the team"
	"I was once called a glorified administrator by an academic"
Fixed/short term contracts and funding	"Short term funding is the key barrier to career development"
	"Although I work in a large registered CTU, I do not feel that the training is given to support the move to the next level within the unit"
Lack of training and clear career pathway	"there is no guidance out there about what training would be best for career progression"
	"the role feels very much like a dead-end job with no official training or career pathway"
	"I would like to be able to send the staff on more external development opportunities, but it is difficult to see where that funding would come from"
Disparity between organisations	"Having worked on trials in different organisations and worked with colleagues who have also worked on trials in other trials units I think there are discrepancies across the country in terms of grading of trial manager and senior trial manager positions"
	"Huge disparity between organisations on how the role is treated and valued"
	"Lack of consistency between units - the name of roles is not consistent"
Lack of time and capacity to focus on career development	"Your whole time is taken up with the demanding work of keeping your trial running"
	"I think time and money are the biggest factors affecting career development"
	"There is lack of funding to provide time to develop outside the immediate delivery of the trial"

Discussion

Relevance to trial management professionals within the UK

Whilst there have been publications in the past that have highlighted the importance of career development for trial management professionals, to our knowledge this is the first published survey to demonstrate what is important to trial management professionals with respect to their own career development. The views of trial management professionals are important to consider by organisations involved in clinical trials when developing any initiatives to improve the

development, retention and remuneration of their staff. Our response rate was consistent with other surveys in organisational research (8). Though we recognise the response rate of 51.3% could lead to non-response bias, four hundred and twenty participants were included in the analyses and, other than a higher response from trial management professionals based in registered CTUs than overall, UKTMN members who responded to the survey were generally representative of UKTMN members. Participants had a range of experience, varying between less than one year to more than ten years and there was roughly an equal split between participants who had experienced a previous promotion to a more senior role and those who had not (53% v 46%) demonstrating the relevance of these survey results to trial managers based in the UK. There is clear disparity between organisations with respect to the job titles of trial management professionals, which could be a contributing factor to the development of a structured career pathway. The topic of career development is clearly important to trial management professionals, as demonstrated by almost all (401/420, 95.5%) participants rating career development as either 'very' or 'quite' important to them.

Opportunities for career development of trial management professionals

Our data has shown that attending relevant training courses is the most important opportunity for trial management professionals when they are considering career development. There were only minor differences in any sub-analyses when considering other associations such as length of time in a trial management role, their salary scale, whether they had previously been promoted/progressed or not or whether they were based in a registered CTU or not. This demonstrates a clear opportunity for Universities, NHS Trusts and CTUs and to ensure adequate investment in training for trial management professionals in order for them to manage clinical trials to the high quality required. Large funders such as NIHR are now offering many training opportunities through initiatives such as the NIHR Academy, although almost all are focussed on training for NHS health professionals (9), rather than operational staff who coordinate clinical trials located mostly in a university setting. Participants also rated helping with the design of trials highly (second most important opportunity for all participants, mean score overall 7.7/10), with trial management professionals who had been in their role for more than six years scoring this slightly higher than those in the role for <5 years. This is consistent with trial management professionals who are more highly paid also scoring the opportunity to assist with obtaining funding for trials highly (mean score 7.3/10). This could suggest that the desire to input into trial design and funding applications comes with more trial management experience, potentially having a deeper understanding on the importance of trial delivery and having seen design issues leading to difficulties with the conduct of the trial further along in the trial lifecycle. This is consistent with a recent commentary by Kelly et al (7) who suggests that lead investigators should invite senior operational staff to be co-applicants on trial grant applications to avoid such issues arising. Investigators and academic staff within CTUs should include experienced trial management professionals in the design stage of their trials as they can add value and make an important contribution. In addition this could facilitate the career development and job satisfaction of the experienced trial managers. Participants considered obtaining relevant qualifications applicable to trial management as important (all participants mean score 7.5/10, third most important opportunity) and this was seen as slightly more important for trial management professionals with less experience (<1-5 years) (mean score 7.8/10, second highest opportunity) and those based outside of registered CTUs (mean score 7.8/10, second highest opportunity). Whilst there are opportunities to obtain qualifications such as an MSc in clinical trials offered by various universities, the value of such qualifications is unclear since they do not link to a specific career pathway. In addition although employability following completion of the UCL Clinical Trials MSc has increased and led to promotion, (Helen Meadows personal communication) it can be difficult for trial managers to attend such courses due to some of the barriers already outlined

Barriers to career development

Lack of funding and fixed term contracts were clearly identified as barriers to career development, with 61% of all participants stating this was an issue and little difference in perception between trial management professionals with less or more experience. In an environment where funding for these types of roles is often project-based and for a time-limited period, this is difficult, and universities and NHS organisations should consider how trial managers may be given the same

opportunities as tenured staff. Participants also identified that they are given few opportunities to get involved in activities outside of the day-to-day running of their clinical trial and this perception was greater amongst trial management professionals with >6 years' experience. Investigators and Clinical Trials Units could consider how trial management professionals work together, possibly in teams (as is the case in many CTUs), to ensure adequate and appropriate cover for their clinical trials, whilst balancing the development needs of individuals to allow them opportunities to get involved in other activities outside of their trial (e.g. training, trial design, funding applications). It was no surprise to the authors that an unclear career pathway within an organisation was identified as a barrier to career development by nearly 60% of participants (slightly higher for trial management professionals with >6 years' experience); this reflects an area that the UKTMN has highlighted since its launch over twenty years ago. For trial managers based outside of CTUs, this is clearly a bigger barrier with almost three quarters of participants (74.8%) stating this was a barrier and, amongst this sub-group, this being the number one barrier identified. This is in line with 56% of participants also identifying that 'recognition of the role' is a barrier to career development and that, whilst most participants felt supported by their line manager (quite likely to be someone who works within clinical trials themselves), less support at a department and organisational level was identified. A structured career pathway, where trial management is recognised as a profession in its own right by employing organisations and funders, is a long-term vision of the UKTMN. In Universities, staff who are managing trials should be recognised for their input, in the same way that academic staff are. Our results show this is even more important if you are not based within a registered CTU and may not have this kind of support. As previously recognised, without a trial manager to manage the day-to-day activities of a clinical trial, even the best designed trial could fail (1).

Strengths and limitations

This is the first known study reporting what trial management professionals consider as important with respect to their career development. The results of the survey could help facilitate and shape the development of a standardised career pathway for trial management professionals within the UK. It is also hoped that employers, sponsors and funders give careful thought to a variety of opportunities that could exist for trial management professionals wishing to develop their own careers. By identifying perceived barriers to career development, the organisations involved in clinical trials within the UK can see where changes are required in order to recognise the contribution that trial management professionals make. In order to design and deliver high quality research, it is in the interest of the clinical trial community that consistency is introduced for trial management professionals. For example, funding bodies could consider providing funds for training within grants or bursaries for trial management professionals. We recognise that a limitation of this survey is that only members of the UKTMN were asked to complete this thus introducing an element of selection bias, however UKTMN members are geographically spread across the UK, come from a range of UK organisations and therefore are largely representative of trial management professionals in the UK. The response rate of 51.3% could have introduced some non-response bias, though every effort was made to increase the response rate, including sending several reminders directly to members, a social media presence and the incentive of a waived fee for the 2019 annual meeting upon completion of the survey, and respondents are representative of the UKTMN membership. A second limitation is that our survey did not prevent the possibility of duplicate entries from the same participant, although we acknowledged this in reminders, asking UKTMN members to only complete it if not done so previously. We consider the results of this survey as relevant to anyone working in clinical trials but also recognise this is a small step in the wider, national development of a structured pathway. Future research could focus on career development of trial management professionals from a multi-stakeholder and organisational perspective, since ultimately a career development pathway is a higher, strategic development that would require buy-in from many stakeholders across and beyond the clinical trials landscape.

Conclusion

Career development is considered important and highly relevant to trial management professionals. The opportunities and barriers to career development identified in the survey could help investigators, organisations, CTUs and funders facilitate

a structured career pathway in the future. Ensuring the development needs of trial management professionals are met is in the interest of all stakeholders involved in clinical trials, since without their skills and expertise, high-quality successful clinical trials will not be delivered effectively.

List Of Abbreviations

CTIMP – Clinical Trial of an investigational medicinal product

CTU – Clinical Trials Unit

MRC – Medical Research Council

NIHR – National Institute for Health Research

TMN – Trial Managers' Network (name prior to UKTMN)

UKTMN – UK Trial Managers' Network

Declarations

Ethics approval and consent to participate

Participant consent was assumed by completion and submission of the online survey.

Consent for publication

Not applicable

Availability of data and material

The datasets used and analysed during the current study are available from the corresponding author upon reasonable request.

Competing interests

All authors are voluntary members of the UK Trial Managers' Network Executive Group. There are no other competing interests.

Funding

No funding was received for this research. EJM is funded by the University of Nottingham.

Authors' contributions

EJM conceived the idea, drafted the survey questions, analysed the data and produced the first draft of the manuscript. NW built and coordinated the survey. All other authors contributed to the development and user-testing of the survey, results interpretation and read and approved the final manuscript.

Acknowledgments

We thank all UKTMN members who completed the survey and the trial management professionals who kindly user-tested the survey during the development stage.

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Figures

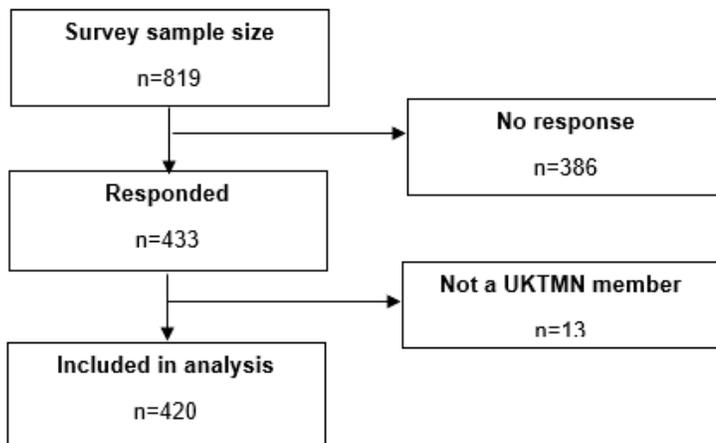


Figure 1

Flowchart

Supplementary Files

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