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

CURRENT STATUS: UNDER REVIEW

Eleanor Jane Mitchell
University of Nottingham School of Medicine
eleanor.mitchell@nottingham.ac.uk
ORCiD: https://orcid.org/0000-0002-6998-4533

Kirsteen Goodman
Glasgow Caledonian University

Suzanne Hartley
University of Leeds

Helen Hickey
University of Liverpool

Alison McDonald
University of Aberdeen

Helen Meadows
University College London

Shelley Rhodes
University of Exeter

Jodi Taylor
University of Bristol

Natalie Wakefield
University of Nottingham

Barbara Farrell
University of Oxford
SUBJECT AREAS
  Internal Medicine  Integrative & Complementary Medicine

KEYWORDS
  clinical trial, trial management, trial manager, career development, survey, UKTMN, project management
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 academic-led 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 an academic-led 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 UKTMN members. 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, whether they were currently based in a UK Clinical Research Collaboration (UKCRC) registered CTU and, for those employed within an academic-setting, whether they were employed on a professional/managerial or research contract.

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 (%) | Overall UKTMN member: n=819 (%) |
|----------------------------------------|-----------|---------------------------------|
| **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)| 464 (56)                        |
| No                                     | 103 (24.5)| 355 (43)                        |
| **Location of CTU**                    |           |                                 |
| n=317                                  |           |                                 |
| Region                          | Count (Percentage) |
|--------------------------------|--------------------|
| 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              | Count (Percentage) |
|--------------------------------|--------------------|
| Full-time                      | 313 (74.7)         |
| Part-time                      | 106 (25.3)         |
| Missing                        | 1 (0.2)            |

| Organisation type              | Count (Percentage) |
|--------------------------------|--------------------|
| University                     | 356 (84.8)         |
| NHS                            | 60 (14.3)          |
| Charity/Not for Profit         | 4 (0.1)            |

| NHS Grade/pathway              | Count (Percentage) |
|--------------------------------|--------------------|
| 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         | Count (Percentage) |
|--------------------------------|--------------------|
| 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 | Count (Percentage) |
|------------------------------------------|--------------------|
| <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           | Count (Percentage) |
|----------------------------------------|--------------------|
| 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     | Count (Percentage) |
|---------------------------------------|--------------------|
| 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                    | Count (Percentage) |
|--------------------------------------|--------------------|
| Trial manager                        | 176 (41.9)         |
| Senior trial manager/team lead       | 93 (22.1)          |
|                                      | 380 (46)           |
|                                      | 109 (13)           |
| Role                                      | Count | Percentage |
|-------------------------------------------|-------|------------|
| Trial coordinator                         | 77    | 18.3%      |
| Trial administrator/assistant             | 9     | 2.1%       |
| Other                                     | 65    | 15.5%      |
| Project Manager                           | 11    |            |
| Operations Manager                        | 11    |            |
| Research Assistant/Associate/Fellow       | 11    |            |
| Assistant/Associate Trial Manager         | 6     |            |
| Senior Trial Coordinator                  | 6     |            |
| Senior Research Fellow/Associate          | 4     |            |
| Programme Manager                         | 3     |            |
| Data Manager                              | 3     |            |
| Head of trial management                  | 2     |            |
| Assistant Professor of Clinical Trials    | 1     |            |
| Compliance Manager                        | 1     |            |
| Research Facilitator                      | 1     |            |
| Senior Research Manager                   | 1     |            |
| Senior Research Midwife                   | 1     |            |
| TMF Manager                               | 1     |            |
| Trial Director                            | 1     |            |
| Trial Management Director                 | 1     |            |

**Current salary range (full time equivalent)**

| Salary Range | Count | Percentage |
|--------------|-------|------------|
| <£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**

| Experience | Count | Percentage |
|------------|-------|------------|
| Yes        | 224   | 53.3%      |
| No         | 196   | 46.7%      |

**Reason for no experience of promotion/progression**

| Reason                           | Count | Percentage |
|----------------------------------|-------|------------|
| 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**

| Method                                      | Count | Percentage |
|---------------------------------------------|-------|------------|
| Via application to new/vacant position outside your organisation | 159  | 71%        |
| Via a promotional pathway in your organisation | 65   | 29%        |

**Importance of career development**

| Importance | Count | Percentage |
|------------|-------|------------|
| Very important | 276  | 65.7%      |
| Quite important | 125  | 29.8%      |
| Not very important | 18   | 4.3%       |
| Not important at all | 1    | 0.2%       |

* South East and South Central are counted together at time of UKTMN membership and therefore cannot be reported separately in this table – they are shown twice for transparency.

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. Surprisingly, of individuals based in an academic-setting (i.e. University), only a quarter were on a research-type contract, with the majority being employed on a professional/administrative/managerial contract. 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
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 almost all groups, 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

| Opportunities that are considered important - mean (SD) | All | Length of time in a trial management role | Sa |
|--------------------------------------------------------|-----|------------------------------------------|----|
|                                                        | n=420 | n=224 | n=196 | n=162 |
| To attend relevant training courses                    | 8.3 (1.8) | 8.4 (1.8) | 8.2 (1.9) | 8.4 (1.8) |
| To help in the design of trials                        | 7.7 (2.4) | 7.5 (2.5) | 8.0 (2.2) | 7.4 (2.6) |
| To undertake qualifications applicable to trial mgmt   | 7.5 (2.6) | 7.8 (2.5) | 7.2 (2.7) | 7.9 (2.5) |
| To contribute to academic writing and publication       | 7.3 (2.7) | 7.1 (2.7) | 7.5 (2.6) | 6.9 (2.8) |
| To join committees/ groups related to trials           | 7.0 (2.9) | 6.9 (2.5) | 7.2 (2.4) | 6.8 (2.6) |
| To assist with obtaining funding for trials             | 7.0 (2.5) | 6.6 (2.9) | 7.4 (2.8) | 6.5 (2.8) |
| To work on more complex trials                         | 6.5 (2.6) | 6.6 (2.5) | 6.4 (2.8) | 6.5 (2.5) |
| To work in a variety of clinical areas                 | 6.4 (2.7) | 6.6 (2.5) | 6.2 (2.8) | 6.9 (2.4) |
| To contribute to methodological studies/SWATs           | 6.1 (3.0) | 5.8 (2.9) | 6.5 (3.0) | 5.9 (3.0) |
| To present work at conferences                         | 6.1 (3.0) | 6.0 (2.9) | 6.1 (3.1) | 5.7 (3.1) |
| To work on trials outside the UK                       | 5.5 (3.2) | 5.4 (3.3) | 5.5 (3.2) | 5.7 (3.3) |
| To work on larger (sites and participants) trials      | 5.4 (2.9) | 5.7 (2.7) | 5.1 (3.0) | 5.7 (2.8) |

1 for salary scale, the 16 respondents who answered “prefer not to say” were not included in this analysis.
2 for Academic Grade/Pathway, only responses from respondents based in a University are included. Prof = “Professional/Administrative/Managerial/Academic-related”. Twenty respondents are not included since contract type was unknown.
### Top three professional development opportunities

| All respondents | Training | Trial design |
|-----------------|----------|--------------|

#### Length of time in a trial management role

| Length of time in a trial management role | Training | Qualifications |
|-------------------------------------------|----------|----------------|
| <1-5 years                                 | Training | Qualifications |
| 6->10 years                                | Training | Qualifications |

#### Salary scale

| Salary scale | Training | Qualifications |
|--------------|----------|----------------|
| <£35,000     | Training | Qualifications |
| >£35,000     | Training | Qualifications |

#### Previously promoted

| Previously promoted | Training | Trial design |
|---------------------|----------|--------------|
| Yes                 | Training | Trial design |
| No                  | Training | Qualifications |

#### Based in a registered Clinical Trials Unit

| Based in a registered Clinical Trials Unit | Training | Trial design |
|-------------------------------------------|----------|--------------|
| Yes                                       | Training | Trial design |
| No                                        | Training | Qualifications |

#### Academic Grade/Pathway

| Academic Grade/Pathway | Training | Trial design |
|------------------------|----------|--------------|
| Professional           | Training | Trial design |
| Research               | Academic writing | Training |

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
|                                | <1-5 years | 6->10 years |
|--------------------------------|------------|-------------|
| **Funding**                    | 256 (61.0%)| 132 (58.9%) |
| Few opportunities aside managing a trial(s) | 249 (59.3%)| 123 (54.9%) |
| Unclear career pathway in organisation | 247 (58.8%)| 122 (54.5%) |
| Recognition of role            | 237 (56.4%)| 106 (47.3%) |
| Lack of time                   | 223 (53.1%)| 114 (50.9%) |
| Training                       | 155 (37.0%)| 94 (42.0%)  |
| Geographical location          | 63 (15)    | 31 (13.8%)  |
| Size of organisation           | 54 (12.9%) | 32 (14.3%)  |
| No barriers perceived          | 10 (2.4%)  | 6 (2.7%)    |

|                                | n=420 (%)  | n=224 (%)  | n=196 (%)  |
|--------------------------------|------------|------------|------------|
| **M Yes**                      | 355,000    | 186,000    | 132,000    |
| Yes                            | 355,000    | 186,000    | 132,000    |
| No                             | 162,000    | 78,000     | 54,000     |

|                                | n=317 (%)  |
|--------------------------------|------------|
| **M Yes**                      | 186,000    |
| Yes                            | 186,000    |
| No                             | 131,000    |
for salary scale, the 16 respondents who answered “prefer not to say” were not included in this analysis.

2 for Academic Grade/Pathway, only responses from respondents based in a University are included. Prof = “Professional/Administrative/Managerial/Academic-related”. Twenty respondents are not included since contract type was unknown.

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
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 path”  
“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 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 sub-analyses when considering the associations of 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 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. Some differences were seen between trial management professionals employed on a research contract, rather than a professional/managerial contract. Unsurprisingly, those employed on a research contract considered the most important opportunity to be involved in academic writing (mean score 8.6/10). Attending conferences was also placed higher in those on a research contract compared to those on a professional/managerial contract (7.1/10 v 6/10). Both of these are consistent with common tasks an
academic researcher would be involved in, so understandably trial management professionals employed on a research contract would see merit in having opportunities to develop in these areas. 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. Within many universities, there are differences between promotional pathways for staff on research contracts and staff on professional/administrative contracts. Trial Management Professionals, employed on a research contract, could have the opportunity to apply for promotion via a standard promotions pathway for research staff. In order to achieve this promotion, they should be given opportunities to be involved in academic writing, publishing and applying for funding opportunities. However, those employed on a
professional/managerial contract often do not have the same opportunity and would require their position to be re-graded. 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; these may well differ depending upon the type of contract the individual is employed on. 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 UKTMN Executive Group. There are no other competing interests.

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

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.

References
1. Farrell B, Kenyon S, Shakur H. Managing clinical trials. Trials. 2010;11.
2. Campbell MK, Snowdon C, Francis D, Elbourne D, McDonald AM, Knight R, et al. Recruitment to randomised trials: strategies for trial enrolment and participation study. The STEPS study. Health Technol Assess. 2007;11(48).
3. Treweek S, Littleford R. Trial management-building the evidence base for decision-making. Trials. 2018;19.
4. Beaumont D, Arribas M, Frimley L, Balogun E, Roberts I, Shakur-Still H. Trial management: we need a cadre of high-class triallists to deliver the answers that patients need. Trials. 2019;20.
5. UK Trial Managers’ Network: www.tmn.ac.uk (accessed 1 July 2019).
6. Farrell B. Trial (management) and error. Lancet. 2019;393(10184):1935-6.
7. Kelly J, Hounsome B, Lambert G, Murphy C. Ensuring trial conduct is consistent with trial design: assumption is the enemy of quality. Trials. 2019;20(1):416.

8. Baruch Y, Holtom BC. Survey response rate levels and trends in organizational research. Human Relations. 2008;61(8):1139-60.

9. National Institute of Health Research: How to apply for career development support. https://www.nihr.ac.uk/researchers/apply-for-funding/how-to-apply-for-career-development-support/how-to-apply-for-career-development-support (accessed 1 July 2019).

Figures

Supplementary Files
This is a list of supplementary files associated with this preprint. Click to download.
Checklist.pdf
