

Executive summary

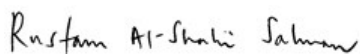
This document describes the need for mentoring, coaching or peer support for chief investigators (CIs) of clinical trials.

The mentorship needs of CIs are met by a variety of schemes (e.g. those provided by the Academy of Medical Sciences, professional associations, the National Health Service [NHS], or higher education institutions).

However, coaching and peer support schemes specific to the knowledge and capabilities required for clinical trials are scarce.

Building on a survey of Directors of Clinical Trials Units (CTUs) in the UKCRC Network of Registered CTUs, and informed by my pilot of a coaching scheme for new (i.e. first-time) CIs of clinical trials in the Edinburgh CTU (ECTU) 2020-2024, this document is a blueprint for both coaching new CIs of clinical trials as well as peer support for any CIs of clinical trials who are employed by The University of Edinburgh and/or NHS Lothian.

I am very grateful to colleagues who provided feedback on the document and to the [ECTU Clinical Advisory Group](#) for being willing to coach colleagues embarking on their journey as a chief investigator of a clinical trial.



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The need for mentoring, coaching and peer support for chief investigators

Who are chief investigators?

The term 'clinician-trialist' was coined by David Sackett to identify a specific group of health professionals who also have skills in the design, execution, analysis, interpretation or implementation of clinical trials.¹ His Clinician-Trialist Rounds in the journal *Clinical Trials* recognised the need for specific support for clinician-trialists, who were implicitly doctors. Nowadays, there is a greater diversity of 'chief investigators'* (CIs) of clinical trials, who can be any healthcare professional (who for Clinical Trials of Investigational Medicinal Products [CTIMPs] must be an authorised health professional [i.e. doctor, dentist, nurse, or pharmacist][†]). CIs have challenging and extensive responsibilities in the leadership of clinical trials,[‡] without a formal requirement for education, training or experience in collaborating with specialists in the design and delivery of clinical trials, some of whom are not encountered in healthcare settings.

Why do chief investigators need coaching, mentors, and peer support?

The clinical trial pathway is extremely complex, includes many different professionals, and is highly regulated (including a legal framework in which a Sponsor delegates responsibilities to a CI). Despite the availability of training resources relevant to clinical trials, their unique challenges may be unfamiliar and overwhelming to people who have not been a CI of a clinical trial or worked with a Clinical Trials Unit (CTU), despite being experienced healthcare professionals with leadership roles. Consequently, new (i.e. first-time) CIs of clinical trials may benefit from mentorship, coaching, and peer support that are distinct, but partially overlapping activities:

What is mentoring?

Mentoring is a developmental dialogue between two people who meet as equals. It is a process of ongoing support and development, which can empower the mentee to tackle issues and problems that they identify.

What is coaching?

Coaching unlocks someone's potential to maximise their performance, helping them learn, rather than teaching them.

What is peer support?

Peer support is a process in which people who share similar environments/experiences or are facing similar challenges come together as equals to give and receive assistance based on the knowledge gained from shared experience.

Mentoring and coaching are easily confused; although they are distinct, there is overlap. Mentoring is a longer-term confidential activity that involves a trusted mentor facilitating a mentee to reflect using approaches such as Egan's framework (explore their current situation,

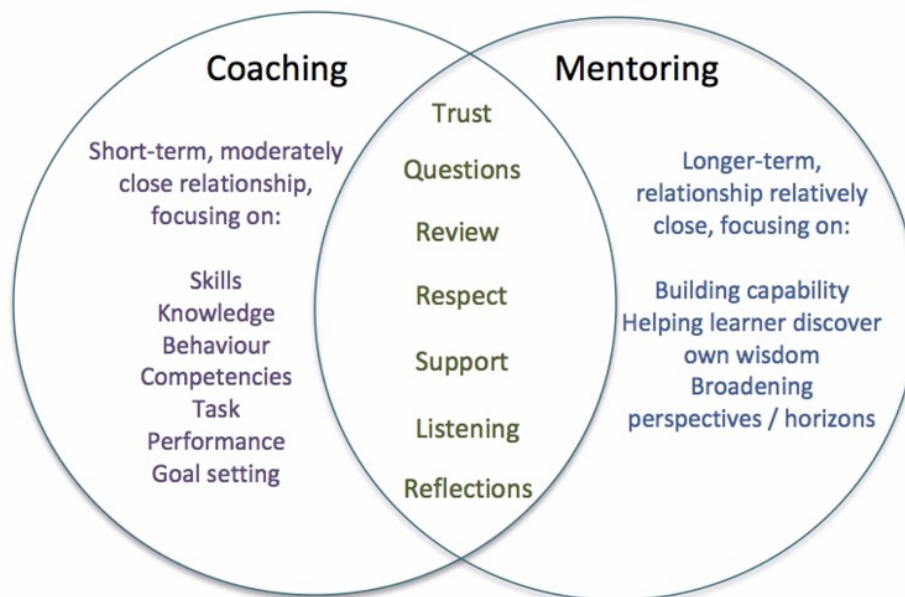
* "The chief investigator is the overall lead researcher for a research project... In addition to their responsibilities if they are members of a research team, chief investigators are responsible for the overall conduct of a research project." <https://www.hra.nhs.uk/planning-and-improving-research/research-planning/roles-and-responsibilities/#chief>

[†] <https://www.hra.nhs.uk/planning-and-improving-research/research-planning/roles-and-responsibilities/mhra-and-hra-position-who-can-act-chief-investigator/>

[‡] <https://www.hra.nhs.uk/planning-and-improving-research/policies-standards-legislation/uk-policy-framework-health-social-care-research/uk-policy-framework-health-and-social-care-research/#chiefinvestigators>

their preferred scenario, and actions to meet their goals having obtained a new understanding). Coaching is a shorter-term relationship focusing on a more experienced coach conveying skills, competencies, knowledge, and behaviours to a less experienced colleague. Although coaching and mentoring are distinct, several attributes of these professional relationships (trust, questions, review, respect, support, listening, and reflections) are common to both mentoring and coaching:

What are coaching & mentoring?



Do chief investigators benefit from mentorship, peer support, or coaching?

For clinical academics in general, whether they are primarily employed by the NHS or a higher education institution, mentoring is perceived as an important part of academic medicine. The evidence to support this has improved since a systematic review found that the evidence to support this perception was not strong in 2006.² A systematic review of the meaning and characteristics of mentoring in academic medicine, which included nine studies published before 2009, found that successful mentoring requires **commitment** and **interpersonal skills** of the mentor and mentee, and a **facilitating environment** at academic medicine's institutions.³ Another systematic review of mentoring programmes for academic clinicians conducted until May 2011 identified various successful attributes (e.g. **mentees choosing their own mentors, protected time, adequate resources, and written agreements**).⁴ Unfortunately, recent systematic reviews of gender-specific issues have not found robust evidence that it reduces gender inequalities,⁵ possibly because there seem to be gender inequalities in access to mentoring (women perceived mentorship to be more valuable to their career development yet were more likely to report having no mentor).⁶

There are few studies of coaching⁷ and peer support in academic medicine. Peer support can be used in conjunction with coaching or mentoring; peer-coaching has been acceptable and feasible

for inpatient physicians,⁸ and peer-mentoring has been associated with academic productivity and advancement.⁹

The key elements that seem to have determined the success of such programmes for clinical academics are:

- People
 - Commitment from mentor, mentee, and their institutions
 - Mentees choosing their own mentors
 - Interpersonal skills of mentors
 - Protected time
- Organisation
 - Adequate resources
 - Attention to inequalities
 - Written agreements to define expectations of mentor and mentee
 - Clear programme structure
- Design
 - Resources
 - Plans/checklists
 - Milestones with timelines
 - Flexible timing and modality of delivery
- Evaluation with metrics

For CIs specifically, Marvie Sibanda (an MSc in Clinical Trials student at The University of Edinburgh) conducted a systematic review up to 18 November 2021, which did not identify any specific mentoring, coaching, or peer support programmes for CIs. However David Sackett initiated a series of 28 'Clinician-Trialist Rounds' in 2010,¹ which drew on experience to offer advice about generic issues for CIs like time management,^{1,10} priority setting,¹¹ grant funding,^{12,13} and saying no,¹⁴⁻¹⁶ as well as issues specific to clinical trial design and conduct.¹⁷⁻²⁴ Six articles dealt with the need for mentoring,²⁵ the structure and function of effective mentoring,^{26,27} the attributes of an effective mentor,²⁸ and the problems that can arise between mentor and mentee.^{29,30} One article dealt with apprenticeships for CIs in training.³¹ Two articles covered graduate courses in clinical trials.^{32,33}

What mentorship, peer support, or coaching opportunities are available for chief investigators of clinical trials in the UK?

UK

The Academy of Medical Sciences

This flagship one-to-one mentoring [programme](#) has run for 20 years for any post-doctoral academic clinician in training, who selects a mentor outside their institution using online mentoring profiles.

Funding agencies

Some funding agencies (e.g. the National Institute for Health and Care Research [NIHR] and Cancer Research UK [CRUK]) have created dedicated fellowships or opportunities for joint lead applicants

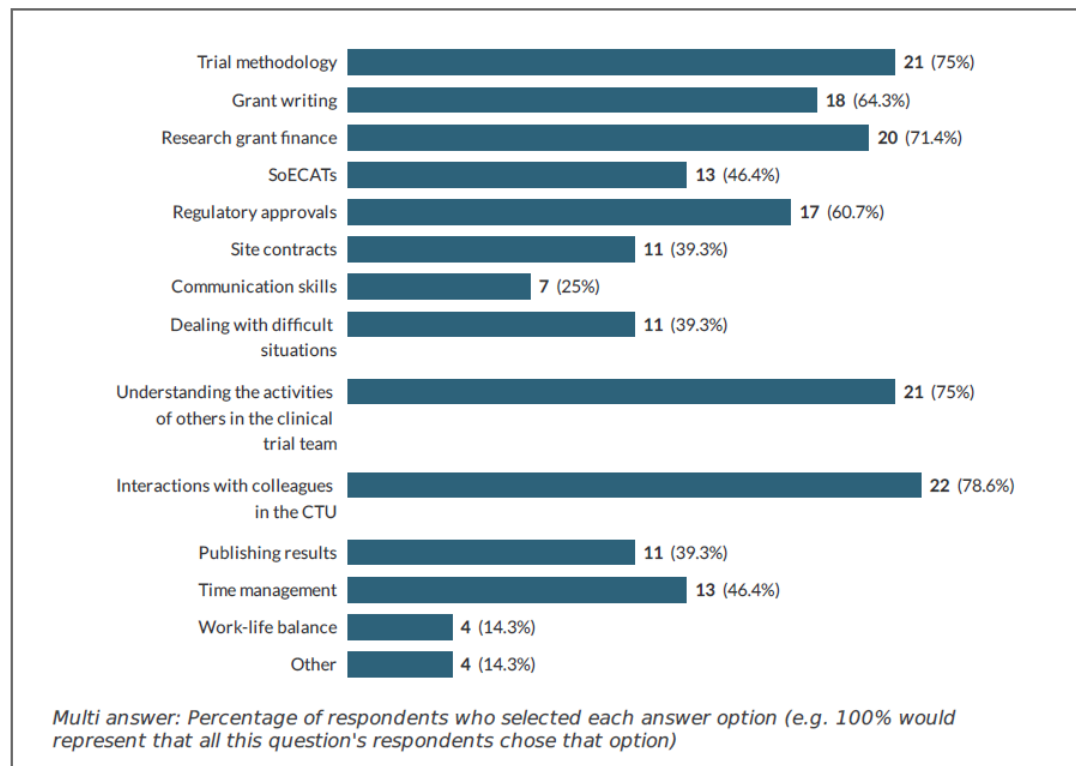
Coaching and peer support for ECTU's chief investigators of clinical trials

in clinical trial funding applications. CRUK offers a [Clinical Trial Fellowship Award](#), which is designed to support clinicians with a demonstrable interest in clinical trials and who would benefit from further training within the setting of a CTU in order to gain clinical trial experience, with the ultimate objective of leading high impact, practice changing cancer clinical trials in the future as a CI. The CRUK clinical trial fellowship requires a joint lead applicant, a mentor, and a main supervisor (who might take the role of a coach). The [NIHR Fellowship programme](#) offers four fellowships (the first and the third may focus on clinical trials): Predoctoral-level opportunities, Doctoral-level opportunities, Postdoctoral-level opportunities, and Professorships and Senior Investigators. Furthermore, the NIHR funding streams for clinical trials permit the addition of a joint lead applicant, which enables a new CI to be supported by a more experienced clinician trialist as a mentor or coach.

Survey of the UKCRC CTU network

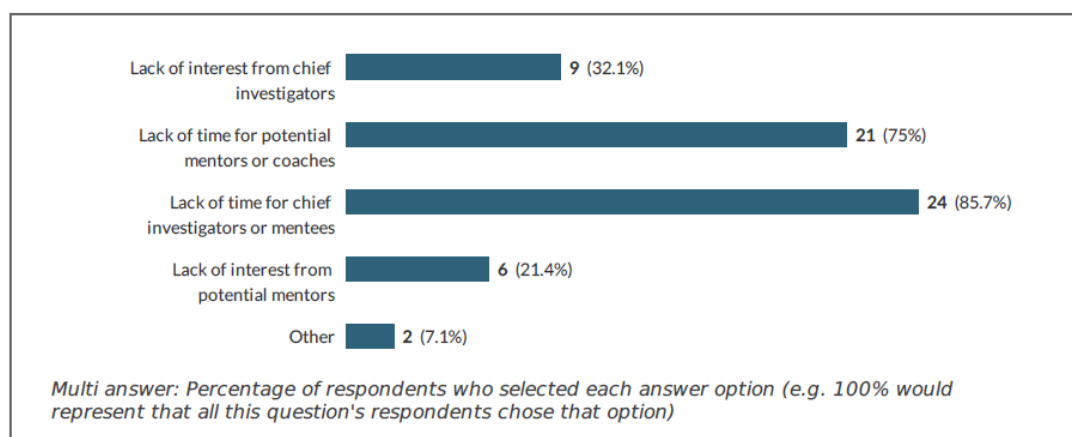
CTUs may also provide support for CIs, so I surveyed the Directors of all 52 CTUs in the UKCRC registered Network on 15 March 2022. 28 (54%) responded. Only four (14%) CTUs reported having mentorship programmes, all of which were optional (ECTU, Southampton, Birmingham, and Brighton & Sussex); two offered mentoring, one used a Clinical Trial Management module, one delivered coaching, and none organised peer support. One of the CTUs apparently used on-site training in addition to mentoring. However, none of these programmes had been evaluated to determine their efficacy. 17 (68%) of the CTUs without CI development programmes would be interested in setting up such a scheme. Key observations by the CTUs about the needs of CIs and barriers to setting up development programmes are illustrated in the histograms below:

In general, what do chief investigators of clinical trials need to be mentored to do better?



Coaching and peer support for ECTU's chief investigators of clinical trials

Have you experienced, or do you anticipate, any challenges with a coaching, mentoring, or peer support programme for chief investigators?



Edinburgh

Post-doctoral academic clinicians are encouraged to join the Academy of Medical Sciences mentoring programme. NHS Lothian provides a Peer Mentoring Programme to support medical staff to thrive in their work (<https://www.med.scot.nhs.uk/wellbeing/peer-mentoring>), and targets support four groups (Foundation Level Programme, Speciality and Associate Specialists, Doctors in Speciality Training, and Consultants in their first five years). However, coaching or peer support programmes do not appear to be available.

Edinburgh Clinical Trials Unit (ECTU)

Overview

ECTU was founded in 2006 to encompass the infrastructure for running multicentre clinical trials already in Edinburgh and to build on that capacity. ECTU worked closely with the Health Services Research Unit (HSRU), which ran independently from 2010 to 2016, providing support to a wide range of health services research projects. In 2016, ECTU and HSRU merged but maintained the functions previously delivered by both. ECTU has full registration within the UKCRC CTU network, a track record in delivering clinical trials, a large portfolio of clinical trials run simultaneously, and works under a quality framework in accordance with the International Conference on Harmonisation (ICH) Good Clinical Practice (GCP). ECTU has had a clinical director working alongside the Director since February 2020.

Clinical trials strategy

Providing mentorship is objective 3.6 of The University of Edinburgh's clinical trials strategy (www.ed.ac.uk/usher/edinburgh-clinical-trials/clinical-trials-strategy). ECTU recommends mentorship for new CIs of clinical trials from the point of application development through to the dissemination of results. After writing The University of Edinburgh's clinical trials strategy in 2020, ECTU's clinical director (Rustam Al-Shahi Salman) offered to coach Edinburgh-based new CIs of clinical trials.

Pilot phase of a coaching programme for new chief investigators of clinical trials in ECTU

The ECTU clinical director's coaching model from 2020 was to become involved during development of the funding application, having been alerted by the ECTU Research Development and Trial Planning Team, so that a coach could guide the new CI from the outset. This normally resulted in the coach's inclusion as a co-applicant on the funding application(s). Coaching has continued through the process of application development, trial design, application submission, application review, trial delivery (start-up, set-up, recruitment, follow-up, and analysis), and trial dissemination. Over three years, the ECTU clinical director coached new CIs of four clinical trials, two of which were funded by the Chief Scientist Office of the Scottish Government (PANACHE [chief investigator Luca Lancerotto] and TARGET-Type 2 [chief investigator Andrew Chapman]), one was funded by NIHR EME (INTACT-2 [chief investigator David Griffith]), and one was invited for resubmission by the British Heart Foundation. These were not the only new CIs of clinical trial proposals during that time because Involvement of ECTU's clinical director was not initially regarded as necessary if a new CI already had an experienced CI of clinical trials 'in-house' in their own department who was involved as a funding co-applicant and agreed to take responsibility for coaching. However, ECTU's experience over three years has indicated that these in-house coaches did not always adequately address the following priorities identified in the survey of UKCRC CTUs (see Survey of the UKCRC CTU network on page 6) for CIs' interactions with CTUs: interactions with CTU colleagues, understanding activities of others in the clinical trial team, and trial methodology. This was discussed at the inaugural meeting of the ECTU Clinical Advisory Group (CAG) in May 2023, who agreed that a coach for new CIs should be advised by the ECTU Research Development and Trial Planning Team, and that this coaching was within ECTU CAG's Terms of Reference, given their understanding and familiarity with interactions with colleagues in ECTU, and the low burden that would arise for them (based on current experience, approximately one new CI per year between 10 ECTU CAG members).

Coaching for new chief investigators of clinical trials in Edinburgh

The lessons learned from generic mentorship schemes for academic clinicians, David Sackett's advice in his Clinician-Trialist Rounds, and experience in the pilot phase of a new CI coaching programme in ECTU have informed this coaching scheme for new CIs of clinical trials in Edinburgh.

Aim

This coaching scheme is intended to unlock new CIs' potential to maximise their performance in collaborating with ECTU and to help them learn about the effective development, design, delivery, and dissemination of clinical trials.

Eligibility of new CIs

People are eligible for this coaching scheme if they are:

1. A new CI of a clinical trial (i.e. they haven't been a CI of a clinical trial before), and
2. They are employed by The University of Edinburgh or NHS Lothian, and
3. They are seeking to obtain, or have obtained funding for this clinical trial, and

4. They will conduct the clinical trial in collaboration with ECTU, either fully (i.e. ECTU provides all of the main components of the trial), or partially (i.e. some of the components of the trial are provided by some of the teams in ECTU), and
5. They wish to be coached by an experienced member of the ECTU CAG.

Eligibility of coaches

Coaches are eligible to support new CIs in this coaching scheme if they are:

1. A member of the ECTU CAG, and
2. They have first-hand experience of working with ECTU to deliver clinical trials (see ECTU guidance for CIs in the CI section of the ECTU website), and
3. They are not already based in the same research group / department as the new CI, and
4. They have the time available to fulfil their responsibilities as a coach (see below).

Identification and initiation

- Usually, the ECTU Research Development and Trial Planning Team will identify a new CI when they seek support from ECTU for a funding application for a clinical trial. The ECTU Research Development and Trial Planning Team will direct the new CI to the new CI coaching scheme page of the ECTU website.
- The ECTU Research Development and Trial Planning Team will advise the ECTU clinical director about the identification of a new CI at the weekly ECTU Portfolio Management meeting, or by email.
- If ECTU agrees to support the new CI's funding application and the new CI accepts the offer of a coach, the Research Development and Trial Planning Team will tell the new CI to contact the ECTU clinical director, who will meet the new CI.
- The new CI will be given the opportunity to identify potential coaches from the ECTU CAG and express their order of preference (if any). The ECTU clinical director should ensure that due consideration is given to inequalities, diversity, and inclusion.
- The ECTU clinical director will approach the potential coach(es) in the new CI's order of preference. Once a coach is identified, the ECTU clinical director then introduces the coach and the new CI by email.
- The coach sets up the first meeting with the new CI, and discusses and agrees the frequency of future meetings.
- Thereafter, the new CI takes the lead in organising meetings.
- The coach should be engaged:
 - during bid development for the clinical trial,
 - included as a co-applicant (in recognition of their time commitment to coaching and other contributions during the trial),
 - invited to the Trial Planning Team meetings during the start-up phase (retaining awareness from agendas and minutes may be sufficient to monitor progress), and
 - invited to the Trial Management Group meetings for awareness of trial progress and any issues that arise (retaining awareness from agendas and minutes may be sufficient to monitor progress).

Roles and responsibilities of the people involved

Commitment to the coaching relationship is required from the new CI and the coach at the outset. The institutions involved have already made a commitment via their representatives on the [Clinical Trials Oversight Group](#) (CTOG).

New chief investigator

- Agree to uphold the recommendations in this document.
- Ensure that adequate protected time is available for coaching.
- Identify and discuss their preferred coach(es) from the ECTU CAG with the ECTU clinical director, raising any issues that are relevant to equality, diversity and inclusion.
- Read ECTU guidance for CIs in the CI section of the ECTU website.
- Identify their clinical trial-specific development needs.
- Organise, agree format (virtual/face-to-face), attend, and document meetings with the coach.
- Cancel meetings with adequate notice.
- Defer to the ECTU clinical director, Director, or Chief Operating Officer if required.

Coach

- Agree to uphold the recommendations in this document.
- Ensure that adequate protected time is available for coaching.
- Embody the suitable personal attributes and behaviours that characterise an effective mentor/coach²⁸ and that are expected by The University of Edinburgh and NHS Lothian.
- Attend to equality, diversity and inclusion throughout.
- Agree format (virtual/face-to-face) and attend meetings with the new CI.
- Cancel meetings with adequate notice.
- Read the agendas and minutes of the new chief investigator's meetings with the Trial Planning Team and Trial Management Group, attending where necessary, to retain awareness of trial progress and any issues.
- Help the new CI to identify their needs, which may include:
 - Clinical trial-specific knowledge, such as:
 - Edinburgh's clinical trials strategy and ECTU's portfolio prioritisation strategy
 - how to interact effectively with ECTU team members
 - understanding the roles of others in the clinical trial team
 - trial design and methodology, including an embedded study-within-a-trial (SWAT)
 - grant development, grant writing, responses to peer reviewers, resubmission after rejection, checkpoint reviews, negotiations, and extensions
 - patient and public involvement and engagement (PPIE)
 - grant finance including SoECAT
 - budget oversight
 - protocol development
 - oversight committees
 - trial set-up including Sponsor risk assessment and regulatory approvals
 - contracts
 - recruitment
 - retention
 - analysis

- reporting
 - dissemination
- Generic issues, which are outside the specific remit of a coach but need intervention with institutional support, such as:
 - communication skills
 - expected behaviours
 - time management
 - project management
 - leadership of a clinical trial with a CTU
- Signpost the new CI to training resources and ECTU team leads who can deal with any clinical trial-specific needs.
- Defer to the ECTU clinical director, Director, or Chief Operating Officer if required.

Suggested structure of a coaching session

Structure underpins time-effective coaching, and the following recommended structure may be helpful²⁷ for a coaching session between the coach and new CI, although flexibility and adaptation to the specific needs of the new CI should be encouraged:

- Greet and check in
- Confirm that the new CI will take minutes focussed on key decisions/actions
- Celebrate any good news
- Identify any urgent issues for the top of the agenda
- Set an agenda
- Review any items pending from the last session
- Assess the time available for the session
- Prioritise the agenda items and get started
- Summarise actions (using the SMART approach) and clarify responsibilities
- Set the date of the next meeting
- The new CI emails minutes immediately after the meeting

Frequency of coaching sessions

In general, meetings may occur as often as weekly for an hour in the early stages of bid development, trial start-up, and trial set-up phases of the project. Meeting frequency is expected to drop during and after these phases. However, flexibility is to be encouraged to accommodate the needs of the new CI, so impromptu / ad hoc check-ins may be required, and adapt to the time that both new CI and coach have available.

The coaching relationship is expected to last the duration of a clinical trial and adapt itself to the major milestones of a clinical trial:

- Application development, internal peer review, costing, and submission timeline
- Start-up planning
- Set-up and regulatory approvals
- Recruitment
- Follow-up
- Analysis
- Dissemination

What if problems occur?

The problem that is most likely to arise is a lack of time for either the coach, the new CI, or both. This was the main challenge identified by the respondents to a survey of UKCRC CTUs. Hopefully, this would manifest as a cancellation with warning, but a no-show might happen, and advice on how to handle this is available.³⁰ Failure to complete tasks and meetings grinding to a halt can be prevented and resolved.³⁰ Abuses of power are concerning, and should be escalated.²⁹ Although the coaches who are drawn from the ECTU CAG are chosen for their collaborative nature, unanticipated difficulties due to interpersonal differences with the new CI may arise. The coach may leave Edinburgh, in which case the ECTU clinical director will confirm the need for a successor with the new CI and identify a successor in the same way that the preceding coach was identified, as described above. If any of these problems are identified by either party, they should try to resolve the issue, but if it cannot be resolved they can raise this with the ECTU clinical director who will seek to resolve the problem with mutual consent and only escalate within the College of Medicine and Veterinary Medicine if this fails.

Peer support for chief investigators of clinical trials in Edinburgh

There are various ways in which peer support can allow new and experienced CIs of clinical trials in Edinburgh to come together as equals to give and receive assistance based on the knowledge gained from shared experience:

- There is an e-mail distribution list (ectu-ci@mlist.is.ed.ac.uk) for all Edinburgh-based CIs of clinical trials currently active in ECTU, which is used to disseminate useful information, ask the community questions, or convene meetings to discuss issues that affect them all. Responsibility for keeping it up-to-date lies with ECTU.
- There is an additional e-mail distribution list (ectu-ci-community@mlist.is.ed.ac.uk) that includes CIs of closed clinical trials that were run by ECTU, as well as people identified by ECTU CAG and others in Edinburgh who might be new CIs of clinical trials in the future.
- There is an MS Teams group for all Edinburgh-based ECTU CIs (<https://teams.microsoft.com/l/team/19%3a0a72e37deb944efe8953cd26b98f6c7c%40thead.tacv2/conversations?groupId=af4a7531-757f-4c8f-94da-c8e9802f03eb&tenantId=2e9f06b0-1669-4589-8789-10a06934dc61>), that is managed by an ECTU Research Coordinator and the ECTU clinical director.
- Face-to-face meetings are likely to be most valuable, especially to new CIs who don't already know the CI community.

There are plans for further events to foster peer support in the future:

- Regular face-to-face, hybrid, and online meetings of CIs of clinical trials in Edinburgh.
- Regular meetings to celebrate the successes of those delivering clinical trials in Edinburgh.
- Newsletter items to celebrate the successes of the clinical trials pathway (e.g. grants and publications, sourced from reports that are summarised two-monthly for CTOG meetings), funding opportunities etc.
- Networking events.

Requirements and allocated resources

The Academy of Medical Sciences recognises that there are three key components to a good mentoring scheme, which also apply to coaching and peer support:

- (1) Infrastructure and resources (including communications channels and materials)
- (2) Leadership and commitment (including a committed organisation, senior leader advocate, and a protected budget)
- (3) People and support (including clear ownership, dedicated staff, and support for both parties in the relationship)

In Edinburgh, a Research Administrator (now Research Coordinator) has been appointed in ECTU to support the ECTU Director, clinical director, and chief operating officer. An ECTU Clinical Advisory Group has been appointed, including 10 experienced chief investigators. These resources are a first step towards underpinning support for coaching and peer support for chief investigators.

Evaluation

This coaching scheme will be evaluated every year, using a short questionnaire to assess satisfaction, successes, challenges, and comments from coaches and the new CIs. The evaluation will be provided for the ECTU CAG, Director, clinical director, and chief operating officer.

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