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01_What is the role of the National Study Team in the Associate PI Scheme?

The National Study Teams are instrumental in driving the success of the Associate PI Scheme, and your support is greatly valued in this endeavour. As part of the scheme, when a study enrols, we request the designation of an ***'Associate PI Study Contact'.*** This individual will assume a more prominent role in handling Associate PI Scheme affairs pertaining to their specific study. It is important to note that this role can be fulfilled by various positions, including but not limited to a Sponsor Representative, Trial Manager, Study Coordinator, or even the Chief Investigator.

While we acknowledge that the ***'Associate PI Study Contact'*** is being requested to take on supplementary responsibilities as part of the Scheme, we want to emphasise that these additional tasks are minimal. It is our hope that the potential benefits that the Associate PI Scheme can offer to the participating trials are duly recognised and outweigh any extra duties involved.

The benefits that Study Teams can expect from participating in the Associate PI Scheme are as follows:

- Enhanced support for study delivery at the site.
- Provision of an additional dedicated point of contact for the study at the site.
- Added assistance for Local PIs through the designation of a delegated 'second'.
- Improved data completeness and accuracy.
- Facilitation of additional recruitment.

By engaging in the Associate PI Scheme, the Study Team contributes to the development of future Principal Investigators, thus making an essential investment in the future of clinical research.

Below are the primary responsibilities that the ***'Associate PI Study Contact'*** should undertake within your study team. Many of these activities should not be excessively time-consuming and should align with much of the existing workload. While some tasks are new, they are designed to ultimately benefit the study.

To aid in the completion of these Associate PI Scheme-specific tasks, resources have been provided for your convenience.

Study approvals for the Scheme:

To initiate the registration of a study for the Associate PI Scheme, it is imperative a member of the Study Team (Sponsor representative, Study Coordinator, Chief Investigator etc) complete and submit the designated Associate PI Scheme Study Application Form.

Should you have any inquiries, please do not hesitate to contact us at associatepischeme@nihr.ac.uk.

The application is then reviewed against the Associate PI Scheme Study Eligibility Criteria by a member of the Associate PI Scheme team. The eligibility criteria include:

- The study is NIHR-portfolio adopted.
- The study has at least six months of recruitment activity left.
- The study would provide an Associate PI the opportunity to:
    - Facilitate patient-level consent.
    - Get involved with a local research team, interacting with multiple members to deliver the study.
    - Learn more about a patient pathway that will require coordination/multiple interactions/FU time points/liaison between different departments to deliver.

If the study meets the eligibility criteria, the Associate PI Scheme team will seek approval from:

- The CI of the study (unless they are the person who filled out the form)
- The Managing Organisation Signatory (a representative of the Sponsor).

This is to ensure that both parties are happy for the study to join the Scheme and are willing to provide the support needed to the Associate PI Scheme team and the Associate PIs for their study.

Engaging Study Sites and Local PIs:

Upon successful registration of a study onto the Associate PI Scheme, proactive engagement from the Study Team becomes crucial. It is imperative that all study sites and Local PIs are promptly informed of the study's involvement in the Scheme so that the local PIs and sites can initiate communication with potential Associate PI Trainees at each site.

This engagement is a pivotal aspect contributing to the overall success of the Associate PI Scheme within your study.

You can find more guidance about engaging your study sites and local PIs in document 03_How can I engage our study sites and PIs with the Associate PI Scheme?

We have also created some promotional materials you can use to engage your study sites and Local PIs. These can be found in document 00_Promotional Materials for National study Teams.

Kindly note that individuals interested in joining the scheme as an Associate PI must complete and submit an application form specifically designed for the Associate PI Scheme Trainee Application. - Associate PI Scheme Trainee Application Form

Interacting with Associate PIs

The ***'Associate PI Study Contact'*** will serve as the primary liaison within the Study Team for interactions with the Associate PI Scheme. They are expected to be aware of their Associate PIs and occasionally engage with them during their tenure in the Associate PI Scheme.

Once an Associate PI completes their successful registration, they should initiate contact with the Study Team. However, we also encourage Study Teams to proactively introduce themselves to their Associate PIs.

During their 6-month tenure, Associate PI Trainees must fulfil the mandatory items on the Associate PI checklist, including tasks related to data management such as overseeing the delegation log, among others. Therefore, it is anticipated that the Study Team could provide support to Associate PIs in comprehending the data management aspects of running the trial, and enlighten them further about the managing organisation's role in a study.

Our aim is to foster a working relationship between Associate PIs, the Study Team, and the local research delivery team. This collaboration aims to ensure a clear understanding of responsibilities and interactions among all stakeholders involved.

Monitoring your Associate PIs are

We've developed a dedicated dashboard in QlikSense for National Study Teams. This dashboard enables them to access data regarding all Associate PIs involved in their study or studies, along with information on their respective working sites.

To find out more about accessing this dashboard, please refer to document 04_How can I find out who the Associate PIs are for my study?

Signing Associate PI Checklists

Please refer to document 02_What are my responsibilities in regards to signing an Associate PIs Checklist?

Associate PI Champions

We strongly encourage you to designate an Associate PI Champion within your managing organisation. The primary objective of this role is to promote awareness of the Associate PI Scheme within the managing organisation, facilitating its dissemination and uptake.

The Associate PI Champion will serve as a local information source, providing expertise and support to managing organisation staff and the study's Chief Investigator (CI) regarding the managing organisation's role in the Associate PI Scheme.

For further details about the Associate PI Champion role and guidance on recruiting one, please refer to document: 08_Identifying an Associate PI Champion and the Associate PI Scheme Champion Role Description.

Paused/suspended Studies

Please inform us if a study is paused or suspended, so we can reach out to the affected Associate PIs. Kindly notify us by emailing associatepischeme@nihr.ac.uk. Upon receiving this information, we will promptly contact the study team to seek clarification.

Once we are aware of a study being paused or suspended, we will contact the Associate PIs to discuss their individual circumstances and provide guidance on the necessary steps to continue their tenure on the Associate PI Scheme.