Information sheet on the ESP2 study

What is the study about?

Setting up trial sites takes up time, effort and cost. Not all of this is worth it because not all of those sites will recruit as planned. What would help would be some way to predict whether a site would be a "good" site to have involved in the trial as far as recruitment is concerned.

The Estimating Site Performance–2 project (ESP2) project aims to test a tool that just might help. The project is led by trial managers based at the University of Aberdeen, UK and asks trial managers to make predictions about site recruitment after carefully considering eight 'red flags' for poor recruitment. These flags (e.g. lack of site staff engagement, or previous poor performance) were developed in the original ESP project, which was published in 2019 in Trials (https://trialsjournal.biomedcentral.com/articles/10.1186/s13063-019-3287-6).

Can I take part in the study?

You can take part if you are:

- A trial manager responsible for setting up trial recruitment sites and carrying out site initiation training with site staff. You may be undertaking this activity but have a different job title; you are eligible to take part on the basis of undertaking this activity.
- The trial(s) you would be making recruitment predictions for can be randomised or non-randomised and testing one or more interventions. We cannot accept predictions from cluster randomised trials.
- You can be based anywhere in the world; as can the recruitment site. You must be opening new recruitment sites.
- You are willing to make at least one prediction, although there is no limit to the number of predictions you can make.

What do I have to do if I want to take part?

- Register your details on the ESP study website (bit.ly/Recruitment_ESP2) and provide brief demographic information.
- Register brief details about the trial(s) you are working on the ESP2 study website.
- After you have completed site initiation training for a recruitment site, complete the ESP2 prediction form indicating whether you think the site will recruit to target, or not.
- Six and twelve months later, provide recruitment updates for the sites you have made predictions for.

We are aiming to reach 1000 predictions within a two year period.

What if I don't want to take part any more

You are free to withdraw from taking part in ESP2 at any point during the study. However, if you want to stop making predictions, we would be grateful if you could still provide follow-up recruitment data about the sites you have already made predictions for. If you are moving to a new post, the trial manager who takes over your trial may wish to register for the ESP2 study to to provide predictions and/or recruitment updates on sites that you made predictions for.

Will my taking part in the study be kept confidential?

Please be assured that all data collected within the study will be treated as confidential by the study team and will not be shared. The website has been developed by data management staff at CHaRT and complies with GDPR requirements. The University of Aberdeen is the data controller for this study and is responsible for looking after your information and using it properly. You can find more about this at www.abdn.ac.uk/privacy.

The study team will have access to the prediction and recruitment data; they will also have access to your details so that they can contact you about the study.

You will have a unique username and password for the study website and only be able to see your own predictions and recruitment data.

The statistical analysis is being conducted at the University of Aberdeen, and to maintain confidentiality, the person undertaking the analysis will only analyse completely anonymous data. In any publication resulting from this work, it will not be possible to identify individual trial managers, trials or trial recruitmentsites.

Electronic data will be kept for 3 years after publication on a secure server. Anonymised data will be available from the project team on reasonable request; it will not be possible to identify individual trials or trial managers from this data.

Your rights to access, change or move your information are limited because we need to retain data to ensure the reliability and accuracy of the research.

Who has reviewed the study?

ESP2 has been reviewed by the Ethics Review Board of the College of Life Sciences and Medicine of the University of Aberdeen.

Who is funding the study?

Web-development was funded by the University of Aberdeen Development Trust. Website maintenance was funded from the Health Research Board (Ireland) grant HRB-TMRN-2017-2. ESP2 incurs only minor costs in terms of trial manager time but this will be borne by the institutions for which the trial managers work. Funding for dissemination will either be sought from internal department funds or from external sources as necessary.

Authorship policy

Trial managers who contribute predictions and recruitment data to the ESP2 study will be appropriately acknowledged unless they request that their name is not included in the acknowledgements

For more information, please contact the ESP2 study team via esp2@abdn.ac.uk

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