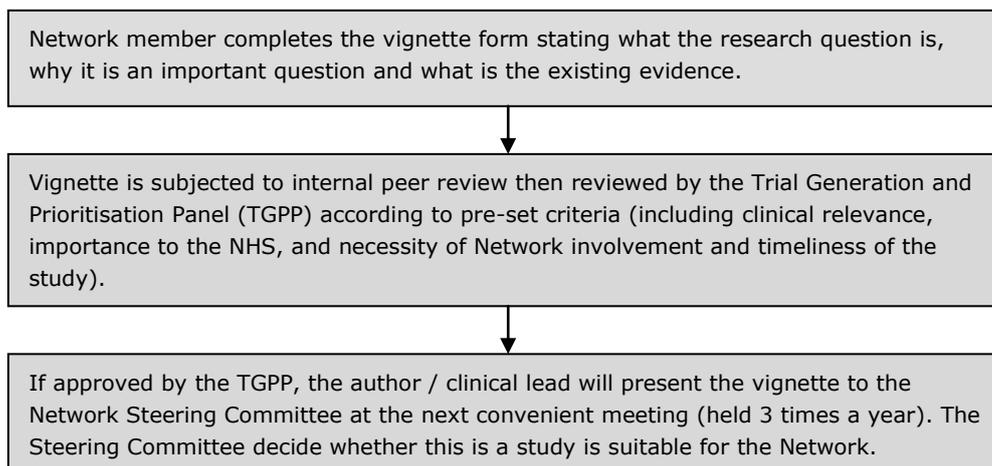# What is involved in being a Clinical Lead on a trial?

You may have a good idea for a clinical trial but are concerned that with an already busy clinical workload plus other commitments, you don't have time to lead a clinical trial. To help you make an informed decision, we have outlined below what is typically involved.

Firstly, the **vignette needs to be approved for development** through the Network, according to the following procedures:

> Network member completes the vignette form stating what the research question is, why it is an important question and what is the existing evidence.

> Vignette is subjected to internal peer review then reviewed by the Trial Generation and Prioritisation Panel (TGPP) according to pre-set criteria (including clinical relevance, importance to the NHS, and necessity of Network involvement and timeliness of the study).

> If approved by the TGPP, the author / clinical lead will present the vignette to the Network Steering Committee at the next convenient meeting (held 3 times a year). The Steering Committee decide whether this is a study is suitable for the Network.

If your vignette is approved you are usually expected to lead the study. You would work closely with your Trial Development Group (TDG) over the next 6-12 months to develop a grant proposal for submission to a funding body.

The co-ordinating centre can help identify statisticians, health economists etc. to form the TDG but **it is best to have a supportive team behind you at this stage**. Typically, the development work involves several meetings (some via teleconference) plus correspondence by email and telephone in between meetings. The UK DCTN senior trial manager will arrange the meetings, draft the grant application and do the trial costing, but your clinical expertise is vital at this stage and you will need to contribute to each of these tasks. If a pilot work or surveys are required, the Network staff can co-ordinate these activities along with input from you/ your team.

If the **funding bid is successful**, the co-ordinating centre will help with the **set up** (preparing protocols, gaining ethics and regulatory approvals etc.) As the Clinical Lead, you would contribute to the development of the protocol and study procedures, again usually through several meetings (some via teleconference) plus correspondence in between meetings with the trial manager and members of your study team.

Once the study is up and running, you would need to **provide clinical input** throughout the lifetime of the study and attend Trial Oversight Committee meetings. As Chief Investigator, you can delegate the day-to-day management of the study to the trial manager (and the Network co-ordinating centre) but you would retain overall responsibility. You would be **central to the final write up** of the study and any publications.

It takes up to 2-3 years from submitting a vignette to obtaining funding.