

A Practical Introduction to Contemporary Clinical Trials

Summary

Offering training to early-career researchers is vital to ensure that they gain the right experience to develop essential skills needed to plan and conduct a clinical trial. This course will provide researchers with an overview of the important elements to a trial and focus them towards key resources and published literature. The training will be suitable for more experienced researchers who are new to clinical trials research. Learning will be through online lectures and a weekly in-person small group tutorial with weekly tasks that accumulate in their development of a protocol on the researchers chosen research question.

The mixture of online material and face to face small group tutorials is designed to help researchers improve their fundamental understanding of clinical trials and then apply this to their own work. Our course is delivered over 10 weeks. This will include 8 learning weeks, 1-week break and 1 final presentation to senior academics. Within each learning week there is a collection of short videos that provide introductions to key topics and associated weekly tasks that are discussed within the weekly two-hour tutorials.

The tutorials will be led by experienced clinical trialists with additional contributions from the weekly lecture lead(s). Each week researchers will be asked to prepare by reviewing material for one module. Learning of the trial component will be consolidated by applying this to the development of their own proposed research at the face to face group sessions.

Why are we doing this course?

Designing, running, and evaluating clinical trials requires specialist knowledge across a team of people. Their complexity often means many early-career researchers don't get exposed to sufficient clinical trial design of modern methods or the practical considerations and the impact that these choices have on the quality of the research. The purpose of this training course is to provide researchers with the opportunity to access advice and support from experienced trialists and their peer-group through a bespoke programme of work. This will equip them with some fundamental knowledge to help them develop essential skills in clinical trials for progression.

The Imperial Clinical Trials Unit is frequently approached by researchers requesting our involvement in their study. There is a clear demand for researchers seeking experience from a clinical trials unit. However, for many early career researchers, this is typically not feasible to support due to the nature of their project or limiting factors such as budget or time constraints of staff members.

Although we wish to support everyone, it is clear that a better approach is required in order to provide a training programme that is both appealing and tailored to the needs of researchers. This training programme will offer a valuable opportunity to ensure new or early career researchers gain the necessary experience they need to progress, which in turn provides the trials unit with the next generation of investigators to collaborate with on future trials.

Who is it for?

The purpose of this series aims to support researchers who are either new to clinical trials or need more experience to move their career forwards. In particular, the training will target NHS clinicians looking to run their first clinical trial, as well as academic clinicians who have limited trials research experience. The 10-week training programme, including the bespoke peer support and face to face training, can also be offered to clinicians and scientists through fellowships.

Additionally, as this training will focus on the different aspects of designing and running trials, it is hoped the course will also be of interest to trial managers, operations managers and statisticians who are early on in their career.

What will they learn?

Attendees to the course will bring with them a research question (real or hypothetical). During the course they will learn all the key statistical and operational considerations which are needed to run a clinical trial effectively. They will develop a protocol over the 10 weeks based on their chosen research question.

Duration and format of the course?

The course will run over 10 weeks, during which candidates will have an overview of the inner workings of clinical trials and the important considerations. The online material will be structured as a collection of short videos that provide a summary of the key information related to the component covered.

The online format has been designed to ensure there are easily digestible chunks of information for learners. Videos will be the primary format to deliver key information on the topic(s). Attendees are expected to attend all 9 face to face tutorials held at ICTU Stadium house. Each face to face small group tutorial will run for 2 hours. This will be coordinated such that researchers will have the week to review the online material, then the opportunity to consolidate the topic and apply this to their own work clinical trial proposal (real or hypothetical) in discussion with tutors and support from their peers in the group.