

## How To Design A Successful Clinical Trial

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Understand the critical and central role that Clinical Trial Design plays in the success of a clinical trial.

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### What Is The Course About?

This course reveals the importance of clinical trial design for the success of the trial, including the key role of statistical design in achieving the dual aims of treating patients and gaining additional information to increase understanding of the disease.

The objectives of this course are:

- To understand the key elements of clinical trial design and how they interact
  - To understand how protocol design, statistical design and CRF design combine to provide the platform for the clinical trial
  - To understand the importance of a clearly defined protocol and a well-designed CRF that enables data to be captured easily, accurately and clearly
  - To understand how statistical design influences the design of the trial and how advanced statistical computing techniques can be used to extract valuable information from trial data
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### The Trainer

Nina Downes

Nina has more than 30 years experience in the industry and has extensive operational and strategic experience in all aspects of clinical research having worked in different functions in many CRO and pharmaceutical companies, ranging from niche to global in size.

Among the positions that Nina has held are Head of Clinical Operations, Clinical Programme Director and Group Project Director, and she is currently using this experience to help companies create and implement clinical strategies to support global regulatory submissions. This involves strategic understanding of what the drug needs to achieve and the knowledge to design studies that fit the programme objective, as well as the ability to form and lead high-performing teams who can achieve the study goals.

Nina is a true clinical expert, and uses skills first learnt as a qualified teacher to bring training to life and share her experiences for other people to benefit.

#### **Course Fee: £599 +vat**

If you book on the course more than 9 weeks in advance, a 10% discount will be applied.

Location: The Regency Hotel, 100 Queens Gate, South Kensington, London, SW7 5AG

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# Programme

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### Introduction & Objectives

#### The Importance of Good Clinical Trial Design

- Why do we need good clinical trial design?
- How to plan good clinical trial design

#### The Ideal Team To Ensure Good Clinical Trial Design

- What elements involve design decisions to be made?
- Who should be involved/consulted during making them?
- The essential team roles

#### Defining The Key Elements That Lead To Good Protocol Design (Part 1)

- Aims & Objectives
- Choice of Design

#### Defining The Key Elements That Lead To Good Protocol Design (Part 2)

- Endpoints
- Choice of Comparator

#### The Role and Design of the CRF

- Who uses the CRF?
- Aspects of Design

#### Integrating the Study Documents

- Which documents need to be integrated?
- Where are they integrated?

#### Hints & Tips To Avoid Common Mistakes