

3 DAY MASTERCLASS

CLINICAL TRIALS

New York, 22-24 Feb 2017

Also available:

London, 14-16 Jun 2017

London, 23-25 Oct 2017

COURSE AGENDA

Who should attend?

The 3 Day Masterclass in Clinical Trials is designed to provide insight into new business opportunities in the field of clinical trials and the development process of new healthcare interventions.

The course will provide insight into complex cross-disciplinary integrated health within the process of diffusion of new medical interventions, from pharmaceuticals, medical devices, diagnostics, surgical interventions to dietary supplements.

This 3 Day Masterclass in Clinical Trials and Medicine Development is designed for people who want to understand the whole of the drug development process, from chemistry to post marketing responsibilities. It is suitable for new graduates with a bioscience degree or people already working in the pharmaceutical industry who need to enhance their knowledge of the of the drug development process.

In just 3 days, you will...

- Learn how new drugs are discovered
- Learn about the new and developing technologies
- Understand what data is needed before clinical trials can start
- Become familiar with the regulatory and ethics processes
- See what is needed for a target product profile
- Evaluate the four phases of clinical trials
- See how planning and logistical issues are critical to the successful running of trials
- Learn how to write protocol
- See the challenges of data management and statistics
- Appreciate the importance of planning to collect and analyse safety data
- Learn by experience and carry out a simulated clinical trial Biotech companies
Consultancy Firms

COURSE SCHEDULE

Day 1: The Basics of Clinical Trials

- Big Picture Introduction
- Speed Networking

How are new medicines discovered?

- Ethnographic origins
- Classical chemistry
- Recombinant proteins
- Mono clonal antibodies
- Gene therapy
- Stem cell therapy

Non clinical data needed to support clinical trials

- Pharmacology
- Non clinical safety (toxicology)
- Pharmacy and formulation
- How this data informs drug candidate selection

Simulated case study – selecting a molecule

Getting permission to do a clinical trial

- Regulations in the EU and USA
- The structure of the agencies and how they work
- What is the process in Europe and the USA?
- Ethics approval
- What you need to provide to the ethics committee
- How ethics committees work

International Conference on Harmonisation

- Who are the players
- What is the process
- Aligning EU, USA and Japan

- GCP and clinical trials

Target Product Profile

- What to put in
- How to construct it
- Kill points

Simulated case study

- What indications are you going to develop?
- Develop a TPP

Day 2: The Analysis of Clinical Trials

The phases of clinical trials

- Phase 1 issues
- Phase 2 – when to start
- Phase 3 – how big
- Phase 4 – what more can you learn

Simulated case study: Review phase 1 data and plan for phase 2

How to write a phase 2 protocol

- Objective of the study
- Justification for the study
- End points
- Inclusion criteria
- Exclusion criteria
- Statistical considerations

Simulated case study – write a phase 2 protocol

Management issues in clinical trials

- Project planning
- Clinical trial supplies
- Recruiting centres
- Subject recruitment

- Budgeting

Day 3: Management of Clinical Trials

Safety considerations and the risk management plan

- How to build safety into a clinical trial
- Definition of serious and unexpected
- Reporting responsibilities

Data and how to manage it

- Setting up data sets
- Producing graphs and tables
- Organising the data

Simulated case study - receive and analyse data from clinical trial

Simulated case study - prepare feedback on simulation

Group presentations on data from clinical trial

How to write up a study and publish

- Wrap

MEET YOUR TRAINER

Carl Naraynassamy's clinical research career includes work for Aventis, Kendle Inc and GlaxoWellcome. His professional association work includes the Association of Clinical Research Professionals & the Academy of Pharmaceutical Physicians and Investigators. His academic work includes Hibernia College, Dublin and The London School of Tropical Medicine, London University.



PRICING

THE EARLIER YOU BOOK, THE MORE YOU SAVE...

Before 2 Dec 2016	Before 13 Jan 2017	Before 3 Feb 2017	After 3 Feb 2017
USD \$3,510 Save USD \$780	USD \$3,900 Save USD \$390	USD \$4,095 Save USD \$195	USD \$4,290

INHOUSE TRAINING

Need to get your whole team up to speed? We can come to you. For groups of six or more, our trainers will design a bespoke programme to meet your business needs, including a lesson pack with examples, models, user-driven content, custom case studies – everything you need to keep learning on your own time.

In-house training is the most cost-effective and convenient option for teams, so get in touch today and let us customise your training experience.

For further information please refer to: <http://www.terrapiinntesting.com/in-house-training>

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