

Sophie Dimonaco, Ruth Lowe, Alex Godwood, Gareth Thomas, Zelie Bailes,
Anastasiia Raievskaya, Hoi-Shen Radcliffe & Sophie Hodge

What is the ITIT Course?

The Introduction to Industry Training Course (ITIT) aims to give an overview of the pharmaceutical industry and the drug development process as a whole. The course is made up of six 2-day sessions covering a range of topics including Research, Toxicology, Data Management & CRO's, Clinical Trials, Reimbursement, and Marketing.

Where and when is it happening?

The course is run every year from October through to July. It's organised by a committee of PSI members (photo below) and each session is hosted by a different company within the industry. Host companies include both Pharma and CRO's and can change on a yearly basis.

In 2017/2018 five sessions have/are being held in the UK with one session in Sweden. We're aiming to host more mainland-Europe sessions in the 2018/2019 year with 3 being hosted by companies in the UK and 3 by companies in other easily accessible European countries.



ITIT Committee with the PSI chair (L-R): Zelie Bailes (GSK), Nigel Howitt (PSI Chair), Sophie Dimonaco (Roche), Gareth Thomas (Envigo), Hoi-Shen Radcliffe (Amgen), Sophie Hodge (Iqvia), Anastasiia Raievskaya (Veramed), Ruth Lowe (PPD), Alex Godwood (Heptares, ITIT chair)

Who can sign up?

Anyone! We offer 25 places each year and the course is primarily aimed at new starters with 1-3 years of experience in the industry.

Is it a statistical course?

Although the course is aimed at Statisticians and Programmers, the content of the sessions is not statistical but aims to give an insight into the drug development process of how compounds are discovered, the journey from discovery to clinical trials, to regulatory approvals and beyond.

What do the sessions involve?

You can expect most sessions to give a basic understanding of the topic through presentations from subject matter experts within the host company, as well as lab tours (research and toxicology) and workshops for hands-on experience of the tasks undertaken at that point in the drug development process.



How much does it cost and what's included?

PSI member: £1050+VAT

Non-PSI member: £1145+VAT

Included in the course fees: attendance at all 6 sessions, bed+breakfast for one night per session, two lunches and one evening meal per session. Entertainment is also included for a number of sessions and previously these have included bowling, casino nights, murder mystery and quizzes.

Not included in the course fees: travel to and from the sessions, additional drinks or amenities.

How can I apply?

Applications for the 2018/19 year are open until 30th June 2018 – apply soon to avoid disappointment but make sure to check with your manager first. Application forms available from the [PSI website](#).

For further information contact:

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What will I learn?

Session 1 - Research

The different functions within pre-clinical research are discussed in detail, including areas such as target identification, high throughput screening, candidate selection, translational science and personalised healthcare. Participants are usually able to take a biology or chemistry laboratory tour. A workshop is usually held where participants are able to consider the statistical issues that are pertinent to pre-clinical research, such as in-vivo study design.

Session 2 - Toxicology

This session explains what toxicology is and why it is needed in research and development of new compounds. There are several areas within toxicology, such as genetic and reproductive toxicology. Other topics covered include carcinogenicity, pharmacology and statistical approaches in toxicology studies. The session will usually include a workshop where participants are presented with toxicology issues to resolve.

Session 3 - Data Management & CRO's

The DM part of the session covers database structure and design, CRF design, procedures for entering data, data validation, data quality and data transfer. There is usually a workshop as part of the session where participants are involved in discussing an example of a typical data management issue, such as designing CRFs or a data validation process. The CRO part of the session gives an overview of the role of a CRO, the history of CRO's, interactions between pharma companies and CRO's, the concept of customers, and the typical processes involved for a CRO when bidding for work. A workshop involving construction of a bid for a contract is usually included.

Session 4 - Clinical Trials

This session focuses on the overall clinical development plan, with a focus on phases I-III trials. Key documents, roles and activities are described including trial protocols (incl. sample size estimation), statistical analysis plans, clinical study reports as well as the trial set-up process, monitoring and good clinical practice. Other topics covered can include conducting analysis, statistical programming and CDISC, operations, safety, regulatory affairs and medical writing. A workshop is normally included which can involve for example, participating in a DMC, study management team in crisis or CDP planning.

Session 5 - Reimbursement

This session gives an overview of the process and modelling aspects of economic evaluation of medicines. The presentations explain the methods and measures used in economic evaluation and the participants usually have an opportunity to do a critical assessment of an economic evaluation. The use of meta-analysis and systematic reviews and their use in evaluations are also discussed with an exercise to review a published systematic review.

Session 6 - Marketing

The marketing session is intended to give an overview of what happens to a drug after regulatory approval, and reimbursement and its subsequent launch. It covers the role of market research, how analysis of the market can improve the chances of a successful product launch and how the sales function works. Other topics include regulatory issues relating to promotion of drugs, increasing generic market and responses to changes in the government financing of the NHS. The session will usually include a workshop during which delegates are encouraged to propose a marketing plan for a hypothetical drug.

