



**19-20 November 2019**

Crowne Plaza Hotel  
Heathrow, UK

A PSI Training Course

# ICH for Statisticians

presented by

Christine Fletcher (Amgen)

Kerry Gordon (IQVIA)

James Matcham (AZ)

Caroline Pothet (GSK)

This course will give an overview of ICH guidelines for all statisticians in the setting of drug development trials and drug approval in the pharmaceutical industry.

The course will describe key guidelines from regulatory bodies such as EMA, FDA, PDMA and CDE. The focus of the course will be on the content of ICH E9 (Statistical Principles for Clinical Trials) and ICH E10 (Choice of Control Group in Clinical Trials), ICH E6 (Good Clinical Practice) and E17 (Multi-Regional Clinical Trials) but other key regulatory guidance documents will also be highlighted. The course will also include workshops, a Q&A session and guidance on how to seek advice from regulators.

#### The following key topics will be included:

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| <ul style="list-style-type: none"><li>• <b>Introduction to the global regulatory environment</b></li><li>• <b>Overview of key ICH, FDA, CHMP, PMDA and CDE Documents</b></li><li>• <b>Detailed Review of ICH E9, E10, E6 and E17</b></li><li>• <b>Workshop: ICH guidelines</b></li></ul> | <ul style="list-style-type: none"><li>• <b>Workshop: Other regulatory guidance documents</b></li><li>• <b>Seeking scientific advice from Regulators</b></li><li>• <b>Q &amp; A Session</b></li></ul> |
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Course runs from: **10:00 – 17:00** (registration from **09:30**) on Day 1 and **09:00 – 16:00** on Day 2.

#### Registration

Please register online at [www.psiweb.org](http://www.psiweb.org) and click on Events; payment now available online.

**Registration costs (includes lunch and refreshments)**

***PSI are holding a limited number of hotel rooms until 18<sup>th</sup> October 2019 which will be allocated on a first come first served basis***

#### **Registration BEFORE 18th October 2019**

PSI Members: £595 plus VAT

Non-members: £690 plus VAT (includes PSI membership)

#### **Registration AFTER 18th October 2019**

PSI Members: £695 plus VAT

Non-members: £790 plus VAT (includes PSI membership)

PSI aims to be fully inclusive and endeavours to accommodate delegates with disabilities wherever possible. Please help us to help you by letting us know if you require additional facilities or have any special requirements.

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