



Presents the

Pharmaceutical Medicine Specialty Training course

About the course Successfully launched in 2005, this course is designed for Pharmaceutical Physicians undertaking Pharmaceutical Medicine Specialty Training (PMST), wishing to gain a broad and solid understanding of the practical application of statistics and data management methods in clinical trials, and clinical studies more generally, in drug development. It is assumed that participants will have some basic knowledge of statistics as provided by the BraPP/ Cardiff University Postgraduate Course in Pharmaceutical Medicine Medical Statistics module or equivalent. Delegates wishing to receive PMST accreditation for attending this training must be enrolled on the PMST programme prior to attending the course.

Course Format The 2021 course will run as two 2½-day modules. Learning strategies will include presentations, case studies, group discussions and numerous workshop exercises to illustrate the practical application of statistical methodology. Formal assessment will be through a series of 4 assignments.

Course Topics Include Recap on some Fundamental Issues in Statistics - Adjusting the Analysis - Missing Data, Analysis Sets and Estimands - Multiplicity - Equivalence and Non-Inferiority - Observational Studies - Interim Analysis and DMCs - Adaptive Design - Data Quality - Survival Analysis - Meta Analysis and Network Meta Analysis - Bayesian Statistics - Statistical Issues in Regulatory Submissions - Quantitative Aspects of Health Economics - Statistics for Safety Evaluation

Course Outcomes On successful completion of the course, delegates will:

- Have acquired an understanding of the statistical principles that underpin a statistician’s approach to clinical drug development
- Be aware of statistical issues that could arise during the various stages of a clinical study and the impact they could have on the conclusions
- Have acquired knowledge of the data management process required to produce accurate and valid databases
- Have acquired knowledge of the quantitative thinking underlying a health economics evaluation
- Be able to critically review study reports and publications in terms of the statistical methodology used
- Be able to discuss and interpret results presented in study reports and publications which are based on statistical evaluation and assess the validity of the conclusions

Statistics and Data Management in Practice

One or both modules may run virtually depending on government restrictions

Dr Richard Kay,

Statistical Consultant, RK Statistics Ltd and Honorary Visiting Professor, University of Cardiff

and Guest Speakers including

Dr Simon Day, Clinical Trials Consulting and Training Ltd

Professor John Cairns, London School of Hygiene and Tropical Medicine

Jo Walker, Cambridge Clinical Solutions

Course Dates 2021

May 21st to 23rd, October 28th to 30th

Venue

Denham Grove
Tilehouse Lane
Denham
Uxbridge
UB9 5DU



REGISTRATION FORM

Statistics
and
Data Management
in Practice

Please return this form to:

Janet Kay, Course Administrator,
By Post:
RK Statistics Ltd, Brook House
Mesne Lane, BAKEWELL, DE45 1AL
Electronically:
Janet.kay@rkstatistics.com

Fee The course fee will be £2300 (£2760 inc. VAT at 20%). This includes refreshments, lunches (if the modules are run face-to-face) and full course lecture notes and training materials. The course is non-residential. Payment in full is required prior to the commencement of the course.

Bookings Course reservations can be made by completing a Registration Form (included in this brochure) and sending this to janet.kay@rkstatistics.com by email, or by post to Janet Kay, Course Administrator, RK Statistics Ltd, Brook House, Mesne Lane, BAKEWELL DE45 1AL. You will then be sent an invoice by RK Statistics Ltd. The number of spaces is limited and persons wishing to attend are advised to apply as soon as possible.

Cancellations If a delegate is unable to attend, substitutions may be made at any time without penalty. Regrettably, if no substitute delegate is available, cancellation charges may apply at 25% of the course fee if the cancellation is made between 8 and 4 weeks of the first day of the course, 50% between 4 and 2 weeks and 100% within 14 days if the place cannot otherwise be filled.

Venue The 2021 course will be held at:
Denham Grove Hotel, Denham, Buckinghamshire, UB9 5DU.
Further details regarding this specialist conference facility can be found at www.denhamgrove.com.

This course is non-residential. Should delegates wish to book accommodation at the course venue they should contact the hotel directly on +44(0) 844 980 2305 mentioning that they will be attending the course.

Course Timings For each module,
Day 1: 9.30am to 5pm
Day 2: 9am to 5pm
Day 3: 9am to 12.30pm

- Comments from delegates**
- Brilliant course, excellent presenters, learned a huge amount. Thanks
 - A difficult subject dissected into nicely digestible & retainable chunks
 - The course is excellent and I'd recommend it to those on PMST but also a wider industry group
 - Best course I have ever attended
 - Superb and highly relevant
 - I have thoroughly enjoyed the course. It is by far one of the best courses and relevant to my day to day practice
 - Well organised, well ordered (sequence of topics), workshops were most useful
 - I think the way Richard has structured this course is excellent. Starting from some basic principles and building on them throughout the week. The small exercises during or after lectures really help to solidify some concepts and provide some really good learning opportunities. Although still no pro, I feel much more confident about statistics after this week (Feedback from virtual course, 2020)

First name Surname

Job title

Company

Address for invoice

Telephone Email

Signature

Details of contact person if different from above

If you would like to play by credit card please tick

Mastercard/Visa (fee=2%)

AMEX (fee=2.5%)

Email address for invoice: