Overview
A perennial question within drug development is whether the same drug dose can be given across all sub-groups within a disease population. Is it enough to target the typical patient? A problem arises with this approach as the typical patient is difficult to define. In cardiovascular disease the patient population is skewed towards individuals over 45 years of age. Conversely asthma is common across all ages. At both ends of the age spectrum physiological processes such as hepatic and renal function differ to those of a healthy adult. An understanding of how these physiological changes affect the pharmacokinetics of a drug will aid the selection of the right dose for the right patients at the right time.

Course Objectives:
To provide participants with the knowledge and understanding that will allow them to design and interpret the PK from studies in special populations.

What will participants gain?
Following the course, attendees will have an understanding of how key pharmacokinetic parameters are affected by the physiological changes brought about during ageing and disease. Additionally they will have an overview of the design elements required in clinical studies of new medicines/formulations to allow the estimation of PK parameters in special populations

How will participants learn?
Participants will learn through a mixture of formal lectures and learning in action workshops. The learning in action sessions are designed to complement and reinforce the formal teaching through individual and group exercises.

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Who will benefit?
Participants should have a basic knowledge of pharmacokinetic concepts. The course would benefit individuals that have to design PK studies and either interpret or review the subsequent data generated. For example, clinical scientists, project pharmacokineticists, project directors, statisticians and clinicians.

Course Programme

Course will commence with registration from 8.45am, course proper at 9.00am and will finish at 5.00pm.

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<tr>
<th>Time</th>
<th>Topic</th>
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<tbody>
<tr>
<td>9.00</td>
<td>Introduction</td>
</tr>
<tr>
<td>9.15</td>
<td>Influence of renal and hepatic impairment on Clearance and Volume</td>
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<tr>
<td>10.00</td>
<td>Workshop: case studies</td>
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<td>10.30</td>
<td>Tea/coffee</td>
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<tr>
<td>11.00</td>
<td>PK Design considerations in hepatic/renal impairment studies</td>
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<tr>
<td>11.45</td>
<td>Workshop: case studies</td>
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<tr>
<td>12.30</td>
<td>Lunch</td>
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<td>1.30</td>
<td>Clearance and Volume in children</td>
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<td>2.30</td>
<td>Workshop: case studies</td>
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<td>3.00</td>
<td>Tea/coffee</td>
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<tr>
<td>3.15</td>
<td>PK Design considerations in paediatric studies</td>
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<td>4.00</td>
<td>Workshop: case studies</td>
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<td>4.45</td>
<td>Concluding remarks</td>
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<td>5.00</td>
<td>Close</td>
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Venue

DoubleTree Hilton Islington (Formerly Jurys Inn Hotel) 60 Pentonville Road, Islington London N1 9LA Website: www.doubletree3.hilton.com

Course fee includes all course materials, refreshments, and lunch, accommodation is not included.

Accommodation and travel directions are available on our website www.pharma-training-courses.com
Course Speakers:

Dr Graham Blakey
Graham is a pharmacist with expertise in pharmacokinetics (PK) and clinical pharmacology. His career started in hospital pharmacy. Following a PhD from the University of Manchester he joined AstraZeneca, where he worked as a pharmacokineticist gaining extensive experience with many global project teams developing new medicines in Europe, Japan and North America.

At AstraZeneca he was a principal scientist where he played a leading role in developing the drug interaction strategy within the clinical function. Latterly he has worked as an independent consultant through consult2deliver limited (formerly GBPK Consulting Ltd.), a company he co-owns. In this role he has provided PK and clinical pharmacology support to large pharmaceutical companies, smaller biotech companies and CROs.

Graham has a particular interest in teaching the wonders of PK to non-specialists. He has run workshops for the European Medical Writers Association and has lectured on the Experimental Therapeutics MSc course run by the University of Oxford.

In addition, to running bespoke in-house courses for healthcare companies. Graham holds a BSc (Hons) degree in Pharmacy and is a member of the Royal Pharmaceutical Society. He has an MSc in Clinical Pharmacology from the University of Glasgow and a PhD from the University of Manchester.

Hussain Mulla BSc (Hons) MSc PhD
Hussain Mulla is a graduate of Pharmacy from the University of Portsmouth (1992), and Clinical Pharmacy from the University of Derby (1996). He was awarded a PhD in Clinical Pharmacokinetics from De Montfort University in Leicester (2003).

He was a senior clinical pharmacist in adult and paediatric intensive care (1996 to 2003) at Glenfield Hospital in Leicester. Following completion of his doctorate (2003), he took a position at AstraZeneca in the Department of Experimental Medicine and Clinical Pharmacology. In 2006 Hussain returned to Glenfield Hospital, Leicester as a senior research pharmacist in paediatric clinical pharmacology.

His research interests span applications of population pharmacokinetic/pharmacodynamic modelling, formulation development, safety and tolerability of excipients and microanalytical methodologies for facilitating paediatric pharmacokinetic/pharmacodynamic studies.

Hussain has been the recipient (principle investigator) of an NIHR RfPB grant to investigate the bioavailability of unlicensed formulations, as well as industry funded and investigator led PK studies and is currently a collaborator in an MRC funded European project (ESNEE) to investigate the kinetics of excipients in formulation administered to neonates.

In 2009, Hussain joined Nova Laboratories (part-time) as a clinical adviser for paediatric product development.
REGISTRATION DETAILS:
Pharmacokinetics in Special Populations — 7 November 2014, London

7 November 2014, London

Fee: 1 day course £610.00 (+ VAT if applicable, see VAT rules)

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• 20% for 3 courses or 3 delegates or any combination thereof
• 30% for 4 or more courses or 4 or more delegates or any combination thereof

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Phone: ++44 2071937703 Email: info@pharma-training-courses.com

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