Module 4: Regulatory Strategy for a New Active Substance: Global Clinical Development

16th - 18th May 2022

Brussels Airport hotel

Module Leader(s): **Nicole Herijgers and Liesbeth Hoff**

Date: Monday 16th May 2022

Time	Activity	Speaker
15.30	Registration	
16.00 – 16.10	Welcome & Introduction to Module	Module Leader Nicole Herjigers Janssen Biologics Liesbeth Hoff AM-Pharma
16.10 – 17.00	**Lecture 1: Strategy for a Global Development** What is global? Costs: development, healthcare, pharmaceuticals Territories used in development Design of a CT program Product profile Into full development	Ian Braithwaite Tiscali
17.00 – 18.00	**Lecture 2: The Clinical Trial Programme** Setting the clinical strategy Target product profiles Selection of clinical endpoints and comparators Impact on the product label Issues in Global Development	Ewoud-Jan Hoogdalem ICON
18.00	New Student Tutorial	Dr Laura Brown Course Director
19.30	**Dinner**	

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Time	Activity	Speaker
08.25 – 08.30	Chairpersons Introduction	
08.30 – 09.30	**Lecture 3: Overview of Requirements for Clinical Trials** Phases of clinical development **Toxicology package requirements for each phase of development** Standard Trial designs Brief overview of CTA procedures (include experiences of VHP) Impact of proposed changes to EU Clinical trial directive Data requirements for clinical study start-up Quality Assurance systems in clinical trials Ethics committee approvals Import/export and Labelling of experimental substances	Liesbeth Hoff AM-Pharma
09.30 – 10.15	**Lecture 4: Ethnic Factors and Clinical Strategies for Non-ICH Markets** Defining the strategy Understanding the data requirements Analysing and presenting the data	Michelle Ortiz Gilead
10.15 – 10.45	**Refreshment Break**	
10.45 – 11.45	**Lecture 5: The Statistical Input** Designing and analysing clinical trials Regulatory requirements Key principles - bias / precision / multiplicity Maximising reliability of conclusions How many patients do we need? Statistical input to protocol	Thomas Zwingers CROS-NT
11.45 – 12.30	**Lecture 6 : Paediatrics and other Special Populations** The need for paediatric medicines Paediatric regulations and incentive systems Design and issues in paediatric clinical development Geriatric Studies Other special populations (renal/hepatic studies, drug:drug interaction studies)	Amy Cheung
12.30 – 13.30	**Lunch**	

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13.30 – 14.15	**Lecture 7: Unconventional Study Designs** Combined Phase studies (eg Phase I/II or Phase II/III trials) Phase 0 studies Early stopping rules Multi-arm studies Adaptive design Phase IV studies	Bob Clay Highbury Regulatory Science
14.15 – 15.00	**Lecture 8: Philosophies and Assessment Techniques of the Regulatory Authorities** FDA vs EU vs others Consequences of review philosophy Regulatory developments - accelerated approvals, priority reviews, interaction with regulators, regulatory reform	Bob Clay Highbury Regulatory Science
15.00 – 15.30	**Refreshment Break**	
15.30 – 17.00	**Case Study and feedback**	
17.00 – 18.00	**Lecture 9: Pharmacoeconomics Studies** What needs to be done? How do we include measures of pharmacoeconomics in clinical trials? When do we do them?	Chris Chinn Sanofi
19.00	**Dinner**	

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Date: Wednesday 18th May 2022

08.25 – 08.30	Chairperson's Introduction	
08.30 – 09.15	**Lecture 10: Clinical Study Reports – Strategic Importance** Purpose The ICH guideline Use of in international dossiers Study reports for special situations Planning and preparation	Julia Forjanic Klapproth Trilogy
09.15 – 10.00	**Lecture 11: Clinical Summary Documentation** When are the clinical summary documents needed? Content and style Assessment of benefits and risks Regional considerations Success and Failure Updates	Nicole Herijgers Janssen Biologics
10.00 – 10.30	**Refreshment Break**	
10.30 – 11.15	**Lecture 12: Pharmacovigilance Strategies** Trends in Pharmacovigilance legislation Impact of new EU Pharmacovigilance legislation PSURs and PBRERs (include moving from DSURs to PSURs and PBRERs) Risk Management Systems Monitoring effectiveness of Risk Management Strategies	Lambert Creuwels Lundbeck
11.15 – 13.00	Case Study and presentations	
13.00 – 14.00	**Lunch**	
14.00 – 14.45	**Lecture 13: Pharmacogenetics/Pharmacogenomics** Strategic value of Pharmacogenomics Better and safer drugs Disease screening Impact on drug discovery and approval Barriers to pharmacogenomics progress	Jeroen Aerssens JNJ
14.45 – 15.45	**Lecture 14: Common Faults in Clinical Registration Packages** **An agency view of clinical documentation**	Agency Speaker
15.45	**Close of Module**	