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

1.6th 1.0th Mars 2022

 16^{th} - 18^{th} May 2022

Brussels Airport hotel

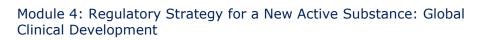
19.30



Dinner

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



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Date: Tue	sday 17 th	May	2022
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Date: Tuesday 17 ^t	-	Speaker
	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** Bob Clay Designs Highbury Regulatory Combined Phase studies (eg Phase I/II or Science Phase II/III trials) Phase 0 studies Early stopping rules Multi-arm studies Adaptive design Phase IV studies 14.15 - 15.00 **Lecture 8: Philosophies and Bob Clay Assessment Techniques of the** Highbury Regulatory **Regulatory Authorities** Science FDA vs EU vs others Consequences of review philosophy Regulatory developments - accelerated approvals, priority reviews, interaction with regulators, regulatory reform 15.00 - 15.30 **Refreshment Break** 15.30 - 17.00 **Case Study and feedback** 17.00 - 18.00 Chris Chinn **Lecture 9: Pharmacoeconomics** Studies Sanofi What needs to be done? How do we include measures of pharmacoeconomics in clinical trials? When do we do them? 19.00 Dinner



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Date: Wednesday 18th May 2022

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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	Agency Speaker
	An agency view of clinical documentation	
15.45		