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

19th – 21st November 2024

Inter City Hotel, Katharina-Paulus-Straße 5, 10557 Berlin, Germany

Module Leader(s): **Katherine Bowen**
Date: Tuesday 19th November 2024

Time (CET)	Activity	Speaker
12.30	Registration	
13.00 – 13.30	Welcome & Introduction to Module	Katherine Bowen, Senior Director, Boyds
13.30 – 14.30	**Lecture 1: Introduction to global clinical development and role of regulatory** - Importance of global clinical development - Role of regulatory in defining clinical development - Introduction to legislative environment (key regions + ICH) - Intro to phases of development - Purpose of each phase - Totality of clinical plan and mapping to TPP/label Importance of guidance and precedent and what is where - Regulatory considerations for building a clinical development plan	Katherine Bowen, Senior Director, Boyds
14.30 – 15.30	**Lecture 2: Introduction to study designs** - Different study designs (parallel, randomized withdrawal, adaptive, single-arm etc) - When to use what - When less conventional designs are acceptable eg rare diseases, C&GT - Selection of endpoints and link to approval and claims	Harriet Gray Stephens, Medical Director, Boyds
15.30 – 16.00	**Refreshment Break**	
16.00 – 17.00	**Lecture 3: Clinical pharmacology** - Importance of clinical pharmacology in development - FIH studies - Dose determination - DDIs, QT etc.	Phil Barrington, Executive Medical Director, Transcrip

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Date: **Wednesday 20th November**

Time (CET)	Activity	Speaker
08.55 – 09.00	Module Lead's Introduction	Katherine Bowen, Senior Director, Boyds
09.00 – 10.00	**Lecture 4: Statistics** - ICHE9 - Importance of the statistical analysis plan - Basic stats principles - Stats and label claims - Questions regulatory should ask	Simon Cleall, Senior Director, Biostatistics, Biogen
10.00 – 11.00	**Lecture 5: Patient populations** - Diversity in clinical trials – FDA - Global representation and data requirements - Use of foreign data - Paediatrics - Orphan diseases - Other pops (renal, hepatic, elderly)	Sophie Laribiere Vice President, Head of Neuroscience Regulatory Affairs, Ipsen
11.00 – 11.30	**Refreshment Break**	
11.30 – 12.30	**Lecture 6: Operational elements of clinical trials** - Overview of clinical trial legislation and requirements - CTAs - INDs - ROW - Strategic considerations - Role of regulatory in successful clinical trial applications (protocol review; risk mitigation; high quality documents)	Emma Beausang, Consultant, Eriu Regulatory
12.30 – 13.30	**Lunch**	
13.30 – 14.30	**Lecture 7 : HTA/PRA** - Introduction to HTA, PRA - HTA assessment now - Future – including JCA - Impact for regulatory	Kevin Asher, Senior Associate Principal Decisive Consulting
14.30 – 15.30	**Lecture 8: Regulatory meetings during clinical development** - High-level overview of key points for interactions on clinical development - Options for speaking to regulators - Questions to ask - Designations (FTD, BTD, Prime etc) - How to build into a clinical regulatory strategy including divergent feedback!	Alex Yates, Vice President, Regulatory Affairs, BicycleTx

15.30 – 16.00	**Lecture 9: Building a clinical regulatory strategy** - How to combine all of the above into a clinical/reg plan - Importance of identifying risks and mitigations	Katherine Bowen, Senior Director, Boyds
16.00 – 16.30	**Refreshment Break**	
16.30 – 18.30	**Case Study and feedback**	Katherine Bowen, Senior Director, Boyds

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Date: Thursday 21st November 2024

08.25 – 08.30	Module Lead's Introduction	
08.30 – 09.30	**Lecture 10: Introduction to CTD and regulatory review** - Structure of a CTD - Importance of summaries and overviews - Storytelling and messaging - Differences between US and EU review - What does this mean for global development? - Building a global dossier	Thanos Konstantakopoulos, Global Regulatory Lead, GE Healthcare
09.30 – 10.15	**Lecture 11: CSRs** - ICHE3 structure and content - Appendices - Importance of the protocol/SAP/CSR correlation - Regulatory review of a CSR – what matters?	Sven Fritz, Director, Medical Writing, Pfizer
10.15 – 11.00	**Lecture 12: Summaries and overviews** - Requirements - How to structure - Messaging - Writing a good benefit risk - ISS and ISE for US and how to incorporate (or not) in EU	Sven Fritz, Director, Medical Writing, Pfizer
11.00 – 11.30	**Refreshment Break**	
11.30 – 12.30	**Lecture 13: Labelling** - Differences in global labelling - Building a global label - CCDS - Importance of dossier in supporting the label - Link to earlier TPP process	Jalpa Patel, Associate Director, Global Labelling, Alnylam
12.30 – 13.15	**Lunch**	
13.15 – 14.00	**Lecture 14: Common issues in clinical documents - Agency view** - What do regulators want to see - Likes - Dislikes - How to address	Dan O'Connor Director Regulatory and Early Access Policy, The Association of the British Pharmaceutical Industry

14.00 – 15.00	**Lecture 15: Risk management** - Introduction to RMPs and REMs - How to build an RMP - Link to overall strategy - Link to label	Marion Mueller Global Aggregate Reports and Risk Management, Novartis
15.00	**Summary, thank yous and Close**	Katherine Bowen, Senior Director, Boyds