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

19th – 21st November 2024

Berlin

Module Leader(s): **Katherine Bowen**

Date: Tuesday 19th November 2024

Time	Activity	Speaker
12.30	Registration	
13.00 – 13.30	Welcome & Introduction to Module	Katherine Bowen
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
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	TBC
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.	**TBC**

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Date: **Wednesday 20th November**

Time	Activity	Speaker
08.55 – 09.00	Module Lead's Introduction	Katherine Bowen
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 Cleal
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
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)	Thanos K
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	TBC
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 How to build into a clinical regulatory strategy including divergent feedback!	Alex Yates

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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
16.00 – 16.30	**Refreshment Break**	
16.30 – 18.00	**Case Study and feedback**	TBC

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Date: Thursday 21st November 2024

08.25 – 08.30	Module Lead's Introduction	
08.30 – 09.00	**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	Katherine Bowen
09.00 – 09.45	**Lecture 11: CSRs** ICHE3 structure and content Appendices Importance of the protocol/SAP/CSR correlation Regulatory review of a CSR – what matters?	Sven Fritz
09.45 – 10.30	**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
10.30 – 11.00	**Refreshment Break**	
11.00 – 12.00	**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
12.00 – 13.00	**Lunch**	
13.00 – 14.00	**Lecture 14: Risk management** Introduction to RMPs and REMs How to build an RMP Link to overall strategy Link to label	TBC
14.00 – 15.00	**Lecture 15: Common issues in clinical documents - Agency view** What do regulators want to see Likes Dislikes How to address	tbc
15.00	**Summary and Close**	Katherine Bowen