CRED Compiling Successful Clinical Trial Applications

19-20 June 2019, London

DAY 1: Compiling Successful Clinical Trial applications

Chairperson: Shaila Choi, Independent Consultant

Time	Session / Activity	Presenter
09:00	**Registration and Coffee**	
	Welcome from TOPRA	**Samantha Alsbury** TOPRA
	Introduction to the next 2 days	**Shaila Choi** Independent Consultant
	Overview of the EU CTA • Initiation of clinical trials: o What is in and what is out of the scope of the current legislation? o Study start-up - what to do and what not to do. o EU application form: Annex 1 o Paediatric CTs o First in man studies	**Chris Parkinson** GlaxoSmithKline
	Tea and Coffee	
	IMPD dossier, R/B, Comparators, RSI • The role of an IMPD in clinical trials • How does it fit into the CTA? o Links to other CTA documents • Key sections o Benefit: Risk assessment • Data requirements for different types of products o Placebo; Comparators, etc.	**Stephen Thompson** S Cubed
	Lunch	
	How to maintain your CTA • Maintenance of the CTA: o How to navigate the bumps and pitfalls; o Amendments; o Temporary halts; o Safety reporting; o End of trial activities; o Reporting obligations; o Clinical trial Transparency and Disclosure and maintenance of registries.	**Chris Parkinson** GlaxoSmithKline **Stephen Thompson** S Cubed
	Tea and Coffee break	
	Regulatory considerations for conducting clinical trials in Markets ex EU • Overview of Emerging Markets: Why Emerging Markets? Trends & Challenges, Risks & Mitigations and use of data • Overview of Japan: Clinical development and bridging strategies for Japan, CTN process: requirements and timelines, Managing PMDA consultations, Orphan Drug designation and Sakigake designation • Overview of US CT's: Key Processes, Strategic considerations • Considerations for China	**Jo Hulbert** PRA Health

Time	Session / Activity	Presenter
	Discussion led by Stephen Thompson – Global Development requires global data	
	GCP & inspections • GCP and what the RA professional involved in Clinical Trial Management needs to know • Overview and types of GCP Inspections • How the RA professional needs to prepare for an Inspection • What to expect in the Inspection	**Bob Ibbotson** S-Cubed
17:15	**Close of meeting – Day 1**	

DAY 2: Global considerations for Clinical Trial Applications.
Chairperson: Stephen Thompson, S Cubed

Time	Session / Activity	Presenter
09:00	**Welcome and Introduction to the day**	**Stephen Thompson** S Cubed
	Clinical Development: Operational considerations for clinical study conduct • Strategic considerations • Study design • Choice and provision of comparators, populations, SOC • Considerations for Genetically Modified Organisms • How clinical interacts with regulatory in clinical development **Discussion led by Pierre Omnes– Post study treatment;** • What happens to patients following completion of the study? Compassionate use/named patient supply.	**Matt Scullion** Janssen
	The Voluntary Harmonisation Procedure • Review process & timelines • Advantages and disadvantages • Key considerations for sponsors	**Pierre Omnes** Syneos Health
	Tea and Coffee break	
	The evolving landscape: the new Clinical Trial Regulation 536/2014: How will the new regulation influence the conduct of clinical studies in the EU? • The Evolving Regulatory Environment • Regulation 536/2014 • Portal and Database • Timelines for implementation • Readiness activities • Considerations	**Pierre Omnes** Syneos Health
	Lunch	
	Case study (45 mins) **Feedback (15mins)** • Considerations for Clinical Trial Applications • Amendment activities	**Shaila Choi** Independent Consultant
	Case Study presentations and wrap up	**All**
	Tea and coffee break	
	Agency's perspective on CTAs • Hot Topics and Common Issues with CTAs • VHP & CTR	**Gunilla Andrew-Nielsen** Medical Products Agency (MPA) Sweden
	Closing summary of the day	**Stephen Thompson** S Cubed
17:00	**Close of meeting**	