CRED Compiling Successful Clinical Trial Applications

23-24 June 2021, London

DAY 1: Compiling Successful Clinical Trial applications

Chairperson: Shaila Choi, Seagen

Time	Session/ Activity	Presenter
09:00	**Registration and Coffee**	
09:30	**Welcome from TOPRA**	**Raluca Radu** TOPRA
09:35	**Introduction to the next 2 days**	**Shaila Choi** Seagen

09:45	**Overview of the EU CTA**
	• Initiation of clinical trials:
	  ○ What is in and what is out of the scope of the current legislation?
	  ○ Study start-up - what to do and what not to do.
	  ○ EU application form: Annex 1
	  ○ Paediatric CTs
	  ○ First in man studies
		Chris Parkinson
		GlaxoSmithKline

10:30	**Tea and Coffee**	

11:00	**IMPD dossier, R/B, Comparators, RSI**
	• The role of an IMPD in clinical trials
	• How does it fit into the CTA?
	  ○ Links to other CTA documents
	• Key sections
	  ○ Benefit: Risk assessment
	• Data requirements for different types of products
	  ○ Placebo; Comparators, etc.
		Stephen Thompson
		S Cubed

11:45	**The Voluntary Harmonisation Procedure/VHP+/Pilots** • Review process & timelines • Advantages and disadvantages • Key considerations for sponsors	**Pierre Omnes** Syneos Health
12:15	**Lunch**	
13:15	**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
14:15	**Tea & Coffee Break**	

14:45	**How to maintain your CTA: CTD/CTR maintenance**
	• Maintenance of the CTA:
	  ○ How to navigate the bumps and pitfalls;
	  ○ Amendments;
	  ○ Temporary halts;
		Chris Parkinson
		GlaxoSmithKline
		
		Stephen Thompson

Time	Session/ Activity	Presenter
	○ Safety reporting; ○ End of trial activities; ○ Reporting obligations; ○ Archiving/TMF maintenance ○ Clinical trial Transparency and Disclosure and maintenance of registries. ○ Transition considerations: CTD to CTR	S Cubed **Pierre Omnes** Syneos Health
17:00	**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
09:05	**Global Regulatory Lead: Product development & 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 Stephen Thompson – Global Development requires global data** **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
10:30	**Tea and Coffee break**	
11:00	**Case study (45 mins)** **Feedback (15mins)** • Considerations for Clinical Trial Applications • Amendment activities • How would you need to adapt your submission for the CTR	**Shaila Choi** Seagen
12:00	**Case Study presentations and wrap up**	**All**
12:15	**Lunch**	
13:15	**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 • TMF	**Bob Ibbotson** Lucis Consulting
14:00	**Tea and coffee break**	
14:30	**Agency's perspective on CTAs** • Hot Topics and Common Issues with CTAs • VHP & CTR	**Gunilla Andrew-Nielsen** Medical Products Agency (MPA) Sweden
15.45	**Closing summary of the day**	**Stephen Thompson** S Cubed
16:00	**Close of meeting**	