CRED Compiling Successful Clinical Trial Applications
25-26 February 2025, London and Online

DAY 1: Compiling Successful Clinical Trial applications

Chairperson: Shaila Choi, Azafaros Switzerland AG

Time	Session/ Activity	Presenter
09:00	**Registration and Coffee**	
09:15	**Welcome from TOPRA**	TOPRA
	Introduction to the next 2 days	**Shaila Choi** Azafaros Switzerland AG
	Introduction to Clinical trials & Essential Documents • ICH/GCP • IB, Protocol, IMPD • Risk:Benefit • Comparators • RSI	**Stephen Thompson** S Cubed
	Tea and Coffee	
	Overview of the EU-CTR • Initiation of clinical trials • Regulation 536/2014 • Portal and Database • Practical considerations • Experience	**Pierre-Frédéric Omnes** TransPerfect
	Lunch	
	Maintenance considerations • Maintenance; Modifications, Temp Halts, Safety reporting, EoT activities, reporting obligations, archiving, TMF • Transparency & Disclosure **Practical considerations**	**Pierre-Frédéric Omnes** Transperfect **Stephen Thompson** S Cubed
	Tea and Coffee	
	CTR Demo	**Pierre-Frédéric Omnes** Transperfect
17:30	**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
	GCP inspections • 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** Shionogi BV
	Tea and Coffee break	
	RoW CTs: • UK • FDA • SwissMedic • LATAM • APAC	**Stephen Thompson** S Cubed
	Lunch	
	Global Regulatory Lead: Product development & Strategic considerations • Study design • Choice and provision of comparators, populations, SOC • Considerations for study conduct • Scientific advice • How regulatory interacts with clinical in clinical development • Open label extension studies, Named patient supply, Early access programs, Compassionate use3	**Matthew Scullion** J&J Innovative Medicines
	Tea and coffee break	
	Agency's perspective on CTAs • Hot Topics and Common Issues with CTAs	**Kingyin Lee** MHRA
	Closing summary of the day	**Stephen Thompson** S Cubed
16.30	**Close the meeting**	