CRED Compiling Successful Clinical Trial Applications

10-11 March 2026, London

DAY 1: Compiling Successful Clinical Trial applications

Chairperson: Shaila Choi, Azafaros Switzerland AG

Time	Session/ Activity	Presenter
08:30	**Registration and Coffee**	
08:45	**Welcome from TOPRA**	TOPRA
09:00	**Introduction to the next 2 days**	**Shaila Choi** Azafaros Switzerland AG
09:10	**Introduction to Clinical trials & Essential Documents** • ICH/GCP • IB, Protocol, IMPD • Risk:Benefit • Comparators • RSI	**Stephen Thompson** S Cubed
10:15	**Tea and Coffee**	
10:45	**Overview of the EU-CTR** • Initiation of clinical trials • Regulation 536/2014 • Portal and Database • Practical considerations • Experience	**Pierre-Frédéric Omnes** TransPerfect
12:00	**Lunch**	
13:00	**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
14:30	**Tea and Coffee**	
15:00	**CTR Demo**	**Pierre-Frédéric Omnes** Transperfect
16:00	**Agency's perspective on CTAs - EU** • Hot Topics and Common Issues with CTAs	**Claudia Riedel** BFARM
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
09:10	**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
10:00	**Tea and Coffee break**	
10:30	**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 use	**Matthew Scullion** J&J Innovative Medicines
12:00	**Lunch**	
13:00	**RoW CTs:** • FDA • SwissMedic • LATAM • APAC • UK	**Stephen Thompson** S Cubed
14:30	**Tea and coffee break**	
15:00	**Agency's perspective on CTAs - UK** • Hot Topics and Common Issues with CTAs	**Kingyin Lee** MHRA
16:15	**Closing summary of the day**	**Stephen Thompson** S Cubed
16.30	**Close the meeting**	