



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

### 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	
	<b>Introduction to the next 2 days</b>	<b>Shaila Choi</b> Azafaros Switzerland AG
	<b>Introduction to Clinical trials &amp; Essential Documents</b> <ul style="list-style-type: none"> <li>• ICH/GCP</li> <li>• IB, Protocol, IMPD</li> <li>• Risk:Benefit</li> <li>• Comparators</li> <li>• RSI</li> </ul>	<b>Stephen Thompson</b> S Cubed
	<b>Tea and Coffee</b>	
	<b>Overview of the EU-CTR</b> <ul style="list-style-type: none"> <li>• Initiation of clinical trials</li> <li>• Regulation 536/2014</li> <li>• Portal and Database</li> <li>• Practical considerations</li> <li>• Experience</li> </ul>	<b>Pierre-Frédéric Omnes</b> TransPerfect
	<b>Lunch</b>	
	<b>Maintenance considerations</b> <ul style="list-style-type: none"> <li>• Maintenance; Modifications, Temp Halts, Safety reporting, EoT activities, reporting obligations, archiving, TMF</li> <li>• Transparency &amp; Disclosure</li> </ul>	<b>Pierre-Frédéric Omnes</b> Transperfect
	<b>Case study/Practical considerations</b>	<b>Stephen Thompson</b> S Cubed
	<b>Tea and Coffee</b>	
	<b>CTR Demo</b>	<b>Pierre-Frédéric Omnes</b> 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	<b>Welcome and Introduction to the day</b>	<b>Stephen Thompson</b> S Cubed
	<b>GCP inspections</b> <ul style="list-style-type: none"> <li>• Overview and types of GCP Inspections</li> <li>• How the RA professional needs to prepare for an Inspection</li> <li>• What to expect in the Inspection</li> <li>• TMF</li> </ul>	<b>Bob Ibbotson</b> Shionogi BV
	<b>Tea and Coffee break</b>	
	<b>RoW CTs:</b> <ul style="list-style-type: none"> <li>• UK</li> <li>• FDA</li> <li>• SwissMedic</li> <li>• LATAM</li> <li>• APAC</li> </ul>	<b>Stephen Thompson</b> S Cubed
	<b>Lunch</b>	
	<b>Global Regulatory Lead: Product development &amp; Strategic considerations</b> <ul style="list-style-type: none"> <li>• Study design</li> <li>• Choice and provision of comparators, populations, SOC</li> <li>• Considerations for ATMPs and GMOs</li> <li>• Considerations for Phase 1 studies</li> <li>• Scientific advice</li> <li>• How regulatory interacts with clinical in clinical development</li> <li>• Open label extension studies, Named patient supply, Early access programs, Compassionate use</li> </ul>	<b>Matthew Scullion</b> J&J Innovative Medicines
	<b>Tea and coffee break</b>	
	<b>Agency's perspective on CTAs</b> <ul style="list-style-type: none"> <li>• Hot Topics and Common Issues with CTAs</li> </ul>	<b>TBC</b>
	<b>Closing summary of the day</b>	<b>Stephen Thompson</b> S Cubed
16.30	<b>Close the meeting</b>	