# CRED Compiling Successful Clinical Trial Applications
# 7-8 Febuary 2023, Brussels

**DAY 1: Compiling Successful Clinical Trial applications**

**Chairperson:** Shaila Choi, Seagen International GmbH

| Time | Session/ Activity | Presenter |
|---|---|---|
| **09:00** | **Registration and Coffee** | |
| **09:30** | **Welcome from TOPRA** | TOPRA |
| **09:35** | **Introduction to the next 2 days** | **Shaila Choi**<br>Seagen International GmbH |
| **09:45** | **Overview of the EU CTA**<br>• Initiation of clinical trials:<br>  ○ Study start-up - what to do and what not to do.<br>  ○ Paediatric CTs<br>  ○ First in man studies | **Chris Parkinson**<br>Independent |
| **10:30** | **Tea and Coffee** | |
| **10:45** | **IMPD dossier, R/B, Comparators, RSI**<br>• The role of an IMPD in clinical trials<br>• How does it fit into the CTA?<br>  ○ Links to other CTA documents<br>• Key sections<br>  ○ Benefit: Risk assessment<br>• Data requirements for different types of products<br>  ○ Placebo; Comparators, etc. | **Stephen Thompson**<br>S Cubed |
| **11:30** | **How to maintain your CTA: CTD maintenance**<br>• Maintenance of the CTA:<br>  ○ How to navigate the bumps and pitfalls;<br>  ○ Amendments;<br>  ○ Temporary halts;<br>  ○ Safety reporting;<br>  ○ End of trial activities;<br>  ○ Reporting obligations;<br>  ○ Archiving/TMF maintenance<br>  ○ Clinical trial Transparency and Disclosure and maintenance of registries. | **Chris Parkinson**<br>Independent<br><br>**Stephen Thompson**<br>S Cubed |
| **12:30** | **Lunch** | |
| **13:30** | **Clinical Trial Regulation 536/2014**<br>• Regulation 536/2014<br>• Portal and Database<br>• Maintenance; Modifications, Temp Halts, Safety reporting, EoT activities, reporting obligations, Archiving, Transparency & Disclosure<br>• Transition considerations: CTD to CTR<br>• Demo on CTIS | **Pierre Omnes**<br>Transperfect |
| **15:00** | **Tea and Coffee** | |
| **15:30** | **UK combined review process** | **Stephen Thompson**<br>S Cubed |
| **16:30** | **Close of meeting – Day 1** | |

**DAY 2: Global considerations for Clinical Trial Applications**

**Chairperson:** Stephen Thompson, S Cubed

| Time | Session/ Activity | Presenter |
|---|---|---|
| **09:15** | **Welcome and Introduction to the day** | **Stephen Thompson**<br>S Cubed |
| **09:20** | **GCP & inspections**<br>• GCP and what the RA professional involved in Clinical Trial Management needs to know<br>• Overview and types of GCP Inspections<br>• How the RA professional needs to prepare for an Inspection<br>• What to expect in the Inspection<br>• TMF | **Bob Ibbotson**<br>Shionogi BV |
| **10:15** | **Tea and Coffee break** | |
| **10:45** | **Case study (45 mins)**<br>**Feedback (15mins)**<br>• Considerations for Clinical Trial Applications<br>• Amendments/Modifications | **Shaila Choi**<br>Seagen International GmbH |
| **12:00** | **Lunch** | |
| **13:00** | **Global Regulatory Lead: Product development & Strategic considerations**<br>• Study design<br>• Choice and provision of comparators, populations, SOC<br>• Considerations for ATMPs and GMOs<br>• How regulatory interacts with clinical in clinical development<br>**Discussion led by Stephen Thompson – Global Development requires global data**<br>**Discussion led by Pierre Omnes– Post study treatment.**<br>What happens to patients following completion of the study? - Compassionate use/named patient supply. | **Sonia Rodrigues**<br>AstraZeneca |
| **14:30** | **Tea and coffee break** | |
| **15:00** | **Agency's perspective on CTAs**<br>• Hot Topics and Common Issues with CTAs<br>• CTR updates | **Nele Steens**<br>Federal Agency for Medicines and Health Products (FAMHP) |
| **16:00** | **Closing summary of the day** | **Stephen Thompson**<br>S Cubed |
| **16.30** | **Close the meeting** | |