**RAPS Euro Convergence 2023 Submission Template for Preconference Workshop**

**Proposal Title**

Be ready for EU CTR: strategy, systems and lessons learned

**Preferred Track**

* Preconference Workshop

**Preferred Topic**

* Pharmaceuticals

**Geographic Coverage**

* Europe

**Learning Level(s)**

* Applied: Content is appropriate for individuals who have strong knowledge of the topic(s) and/or demonstrated well-developed regulatory technical knowledge and skills. Regulatory Affairs Certification (RAC) is targeted to professionals at this level. Typical job titles at this level are manager/senior manager/reviewer.,
* Strategic: Content is intended for individuals who are well-versed in most/all concepts associated with the topic(s) and are involved in translating knowledge into effective plans and strategy. They work with other teams throughout the product lifecycle. Typical job titles at this level are director/vice president/executive director/CEO/experienced reviewer/section manager/division director.

**Instructional Format**

* Panel
* Case Studies
* Facilitated Q&A

**Description**

The European Union Clinical Trial Regulation (EU CTR) 536/2014 is the new set-up replacing the EU Clinical Trial Directive (EU CTD) 2001/20/EC and aims to simplify and harmonize procedures for the authorization, assessment, and supervision of clinical trials in the EU. The EU CTR was published on 16 April 2014, and implemented on 31 January 2022 with a 3-year transition period for ongoing trials.

The EU CTR allows sponsors to make one clinical trial application for all EU Member States (MS) intended to participate in a trial, via a centralized portal, the Clinical Trial Information System (CTIS).

Sponsors, Contract Research Organizations (CROs), Applicants and Authorities have been getting prepared for EU CTR, but adjustments had to be made while various stakeholder navigate the new requirements including processes, CTIS and MS Requests for Information.

This session discusses the strategic steps to be taken when implementing the EU CTR, the associated systems and tools required and CTIS alignment. We will discuss resources and training, including SOP updates and Job Aids. Creation of workstreams and cross departmental engagement is crucial, and communication is key. Document requirements and submission strategies will be evaluated, and lessons learned shared. There will be a space for the audience to share their own lessons learned, issues, and tactics for mitigation. In groups, there will be an exercise to produce one EU CTR implementation plan. In the afternoon, examples on how to prepare for the different steps, the taken strategies, lessons learned, and options will be presented.

Robust, proactive communication and planning with regards to the timely availability of submission ready documentation is significant. But making sure that the right systems and resources are available is fundamental. There will be time to discuss the bottle neck situations, countries requests, sensitive matters, and options.

Finally, the session will be open to a panel discussion giving experts and thought leaders the opportunity to express their opinions, challenge each other, and explore strategies.

**Learning Objectives**

*Upon completion, participants should be able to:*

* *Describe the specifications of EUCTR, background and current situation*
* *Propose a strategy on EUCTR application aligned with company needs, resources, goals, and objectives*
* *Apply lessons learned on the day to day of a Regulatory Affairs Lead as preparing for a EUCTR submission*
* *Name the principal challenges a company may face*

**Agenda Outline**

*7:00-8:00 am Registration and Continental Breakfast
8:00-8:30 am Welcome and Workshop Introduction
8:30-9:15 Background and Legislation
9:15-10:30 What does a company needs to evaluate upfront:*

* *Systems*
* *Resources*
* *SOPs and Job Aids*
* *Training*
* *Communication*
* *Cross departmental engagement*
* *Cross functional responsibilities*
* *Insource or Outsource?*

*10:30-11:00 Refreshment Break
11:00-12:00 Feedback and examples taken from the audience: their own experience
 Group Exercise
12:00-13:00 Lunch
13:00-14:30 Strategies and Lessons Learned:*

* *Systems and Tools*
* *SOPs revisions and updates*
* *Job Aids, Guides and Flow charts*
* *Liaison team*
* *Regulatory Affairs Leads (RALs)*
* *Hypercare RALs*
* *Regulatory Affairs Knowledge Center*
* *Cross Departmental workstream*
* *Steering Committee*
* *Cross functional Drop in Sessions*
* *Documents and Submission Strategy*
* *Member States specifications and “special” requests*
* *Redaction: Personal Protected Data (PPD) and Commercially Confidential Information (CCI)*

*14:30-15:00 Refreshment Break
15:00-15:45 pm Panel discussion
15:45-16:00 pm Review of the Day: Tying It All Together
16:00 pm Adjourn*