

Concerning Public consultation on the Guideline on Risk proportionate approaches in clinical trials

The recommendation from the GCP-inspectors at the Danish Medicines Agency is that this guideline should not be finalized before the new version of the ICH-GCP is final. It is important to get alignment between the two documents – especially on central monitoring.

Kind regards
Lene Grejs Petersen

Lene Grejs Petersen
Cand.pharm, Chefkonsulent
M.Sc.Pharm, Senior Adviser

Lægemiddelstyrelsen
Lægemidlers Godkendelse & Tilgængelighed
Kliniske forsøg
*Danish Medicines Agency
Medicines Licensing & Availability
Clinical Trials*
T +45 4488 9595
dkma@dkma.dk
www.lmst.dk



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