



SAEs and SUSAR

Report any serious adverse event (SAE) to sponsor or coordinating investigator **within 24 hours** (covid-steroid@cric.nu or +45 3545 7237)

If SAE is deemed related to the intervention (SUSAR)

Contact the sponsor or coordinating investigator **without undue delay** (covid-steroid@cric.nu or +45 3545 7237)

Fill in the SUSAR report form (#14a in the Site Master File) and e-mail it to sponsor (covid-steroid@cric.nu)



Unblinding of intervention for a participant

If deemed necessary by the treating clinician or the investigator for treatment or safety reasons (SUSAR)

Unblinding can be performed around the clock

Contact the sponsor or coordinating investigator (covid-steroid@cric.nu or +45 3545 7237)

Sponsor or coordinating investigator will contact unblinded primary trial personnel