**Serious adverse events**

Any adverse event that results in death, is life-threatening, requires hospitalisation or prolongation of existing hospitalisation, results in persistent or significant disability or incapacity, or is a congenital anomaly or birth defect.

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

**Suspected unexpected serious adverse reaction**

Any suspected adverse reaction which is both serious and unexpected (the nature or severity of which is not consistent with Summary of Products Characteristics (SmPC) for Solu-Cortef).

If SAE is deemed related to the intervention, it will be considered a suspected unexpected serious adverse reaction (SUSAR).

* Contact the sponsor or coordinating investigator **without undue delay** ([covid-steroid@cric.nu](mailto:covid-steroid@cric.nu) or +45 3545 7237)
* Fill in the SUSAR report form ([#14a in the Site Master File](http://www.cric.nu/covid-steroid-susar-form/)) and e-mail it to sponsor ([covid-steroid@cric.nu](mailto: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](mailto:covid-steroid@cric.nu) or +45 3545 7237)
* Sponsor or coordinating investigator will contact unblinded primary trial personnel