TASC

Tayside Medical Sciences Centre

STOP-COVID19

Superiority Trial Of Protease inhibition in COVID-19

Pharmacovigilance

TASC website:
http://www.ahspartnership.org.uk/tasc/

NHS Tayside

University of Dundee

SERIOUS ADVERSE EVENT
ICH GCP 1.50 DEFINITION

Any untoward medical occurrence that at any dose:

- results in death
- is life-threatening
- requires inpatient hospitalisation or prolongation of existing hospitalisation
- results in persistent or significant disability/incapacity
- is a congenital anomaly/birth defect.

SAFETY REPORTING
ICH GCP 4.11.1

All serious adverse events (SAEs) should be reported immediately to the sponsor except for those SAEs that the protocol or other document (e.g., Investigator's Brochure) identifies as not needing immediate reporting. The immediate reports should be followed promptly by detailed, written reports. The immediate and follow-up reports should identify subjects by unique code numbers assigned to the trial subjects rather than by the subjects' names, personal identification numbers, and/or addresses.

SERIOUS ADVERSE EVENT

- Read approved protocol section 9:Pharmacovigilance
- Recording and reporting of SAEs, SARs AND SUSARs protocol section 9.3.
- All SAEs must be reported to sponsor within 24 hours of the investigators knowledge of the event.
- The TASC SOP11 “Identifying, Recording and Reporting Adverse Events for CTIMPs” can be found on the website by following this link; https://www.ahspartnership.org.uk/tasc/for-researchers/sops/safety-and-pharmacovigilance

SERIOUS ADVERSE EVENT REPORTING

- Please use the latest SAE form available from the TASC website: https://www.ahspartnership.org.uk/tasc/for-researchers/sops/safety-and-pharmacovigilance
- Download and save the file. Do not fill the form while opened in the browser.
- Causality, severity and expectedness on the form must be completed by a medically qualified professional (CI or PI, delegated doctor listed on the delegation log) who must also sign the form.
- Send the completed SAE form via email to Tay.pharmacovigilance@nhs.scot

SAE REPORTING GUIDE

- All SAEs must be reported to sponsor within 24 hours of the investigators knowledge of the event.
- Print and file the signed report in the ISF.
- There is a guidance document available to assist with the completion of the SAE form and subsequent follow up reporting.

PREGNANCY REPORTING

- Approved protocol section 9.7: Pregnancy Reporting
- Pregnancy on a clinical trial must be recorded and reported to the Sponsor (Pharmacovigilance monitor).
- The pregnancy forms are available on the TASC website SOP 11 associated documents https://www.ahspartnership.org.uk/tasc/for-researchers/sops/safety-and-pharmacovigilance
- Pregnancy notification form must be completed and reported via email to: Tay.pharmacovigilance@nhs.scot
- It is desirable to follow up the pregnancy but the mother's consent must be obtained. A follow up form should be completed and sent via email to: Tay.pharmacovigilance@nhs.scot