

Recruitment will be OFFICIALLY PAUSED in the PriMUS Study, via submission of a non-substantial amendment. Relevant R&D offices and CRNs have been notified of this.

SAE Reporting

Patients who are already on the study may experience **unrelated SAEs due to being hospitalised**. If you become AWARE, or are MADE AWARE of an SAE (patient on the study hospitalised for whatever reason), then please report using the SAE Report Form or call the study manager to discuss this.

You may not be made aware of an SAE until after the SAE has resolved, this is absolutely okay, you just need to report it as soon as you are made aware of it.

The SAE Definition is ANY adverse event that:

- Results in death
- Is life-threatening*
- Required hospitalisation or prolongation of existing hospitalisation**
- Results in persistent or significant disability or incapacity
- Consists of a congenital anomaly or birth defect
- Other medically important condition***
- Visible haematuria (blood in urine)/Urethral bleeding requiring intervention

Note: The term 'life-threatening' in the definition of serious refers to an event in which the study participant was at risk of death at the time of the event or it is suspected that used or continued used of the product would result in the subjects death; it does not refer to an event which hypothetically might have caused death if it were more severe.

**** Note:** Hospitalisation is defined as an inpatient admission, regardless of the length of stay, even if the hospitalisation is a precautionary measure for continued observation. Pre-planned hospitalisation e.g. for pre-existing conditions which have not worsened, or elective procedures, does not constitute an SAE.

***** Note:** other events that may not result in death, are not life-threatening, or do not require hospitalisation, may be considered as an SAE when, based upon appropriate medical judgement, the event may jeopardise the participant and may require medical or surgical intervention to prevent one of the outcomes listed above.

Urodynamic Clinics Patients should now have been informed that ALL urodynamic clinics are postponed until further notice.

THE PRIMUS TEAM ARE WORKING REMOTELY BUT HAVE FULL ACCESS TO EMAILS. YOU CAN CONTACT US ON PRIMUS@CARDIFF.AC.UK.

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