

## SAEs in the EMINENT-ICH Trial

**The following SAEs must be reported if they occur within 180 ± 30 days after intervention**

- Death of the patient
- Epileptic seizure requiring medical therapy to control
- Serious, life-threatening infection
- Any other untoward medical occurrence that
  - Results in death
  - Results in-patient hospitalization or prolonged hospitalization
  - Results in significant, persistent disability

**The following SAEs must be reported if they occur within 30 days after intervention**

- Ischemic transformation of a haemorrhagic stroke in the affected vascular territory as confirmed by CT/MRI
- Recurrent ICH into the same hematoma cavity confirmed by CT/MRI

### Which events qualify as SAE?

- An SAE is any untoward medical occurrence that:
  - Results in-patient hospitalization or prolonged hospitalization
  - Results in significant, persistent disability
  - Results in death
- It can be classified as not related, unlikely related, possibly related, probably related or definitely related.

### What do I have to assess?

- Any of the events defined as potential SAEs in the EMINENT-ICH trial. Please assess, whether the SAE is related to the **intervention** (possibly, probably, definitely) or not (not related, unlikely).

### How do I report SAEs?

- Over secuTrial. Log in, chose the patient concerned (patient overview) and open his/her eCRF. Select “Serious Adverse Event” and then “new adverse Event”. Enter all requested data in detail and hit “save + close entry”. Your local PI will receive a link for confirmation & e-signature. The form is directly forwarded to the sponsor.

- **Please report the SAE within 24 hours to the Sponsor**

### Who do I contact if I have questions?

- Please contact the EMINENT-ICH core team ([eminent-ich@usb.ch](mailto:eminent-ich@usb.ch))