Reporting of (serious) adverse events

Status	Genehmigt

Organisation	Departement Klinische Forschung
Kürzel	SOP EMINENT-ICH RCT 002

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Anmerkung

Das vorliegende Dokument ist eine Kopie aus der Applikation «Orca». Das Original, respektive die aktuell gültige Version ist unter orca.dkfbasel.ch verfügbar.

Inhaltsverzeichnis

1. Introduction

This SOP describes the process of reporting (serious) adverse events ((S)AE) and the respective timelines in the EMINENT-ICH RCT according to the law (KlinV). The process starts when a (S)AE is observed and ends if the reporting to the respective ethics committee has ben submitted.

Reporting of (S)AE is to be made **within 24 hours to the sponsor** and **within 15 days to the respective ethics committee**.

A SAE is defined as any untoward medical occurence that:

- Results in death or is life-threatening state,
- Requires in-patient hospitalisation or prolongation of existing hospitalisation,
- Results in persistent or significant disability or incapacity, or
- Causes a congenital anomaly or birth defect

2. Scope

Concerns all patients included in the EMINENT-ICH trial in all participating centres.

3. Terms and abbreviations

- (S)AE: Serious adverse event
- ASR: Annual safety report

4. Roles and responsibilities

Investigator

- Reports ((S)AE) to the sponsor of the trial and the study coordinator

Sponsor

- Reports ((S)AE) to the ethics committee
- Prepares annual safety report

5. Process

A (S)AE can occur either during hospitalization (Visits 1-4) or be reported on follow-up (Visits 5

and 6). In any case, the investigator will assess the seriousness of the event.

In case an event is not serious (see Introduction), the AE is noted in the CRF and the electronic patient file.

In case the event is serious, the investigator reports the SAE with the respective SAE file (SAE_EMINENT_ICH_Template_0323.docx[1]). He will judge whether the SAE was related to the intervention or not and whether the SAE was unexpected or not.

He will sign the file and report it to the sponsor within 24 hours after knowledge of the SAE. The investigator will further inform the study coordinator and send the original SAE file to the study coordinator.

The sponsor will report the SAE to the respective ethics committee 15 days via uploading a scan to BASEC. The SAE will be filed in the TMF (original version) and a copy will be filed in the electronic TMF.

In case the SAE occurs in a centre other than the main study centre, the local PI will report the SAE to the ethics committee in charge.

Exeptions from expedited reporting in the EMINENT-ICH trial are:

- Death
- Haemorrhagic transformation to an ischemic stroke
- Reccurent ICH
- Epileptic seizure
- Infection of any kind (i.e. surgical site infection, pneumonia, urinary tract infections etc.)
- Persistent focal neurological impairment

In case the SAE has not stopped/resolved, the patients will be followed-up and the investigator will file a final report when the SAE has stopped/resolved. This final report will be submitted as update to the existing SAE in BASEC.

The sponsor compiles all SAE that occured over a time period of one year for the ASR. The ASR will be uploaded to BASEC once per year.

1. https://orca.dkfbasel.ch/download/process/01b811f4-0c4a-11ee-9aee-0242ac120016

6. Process diagram

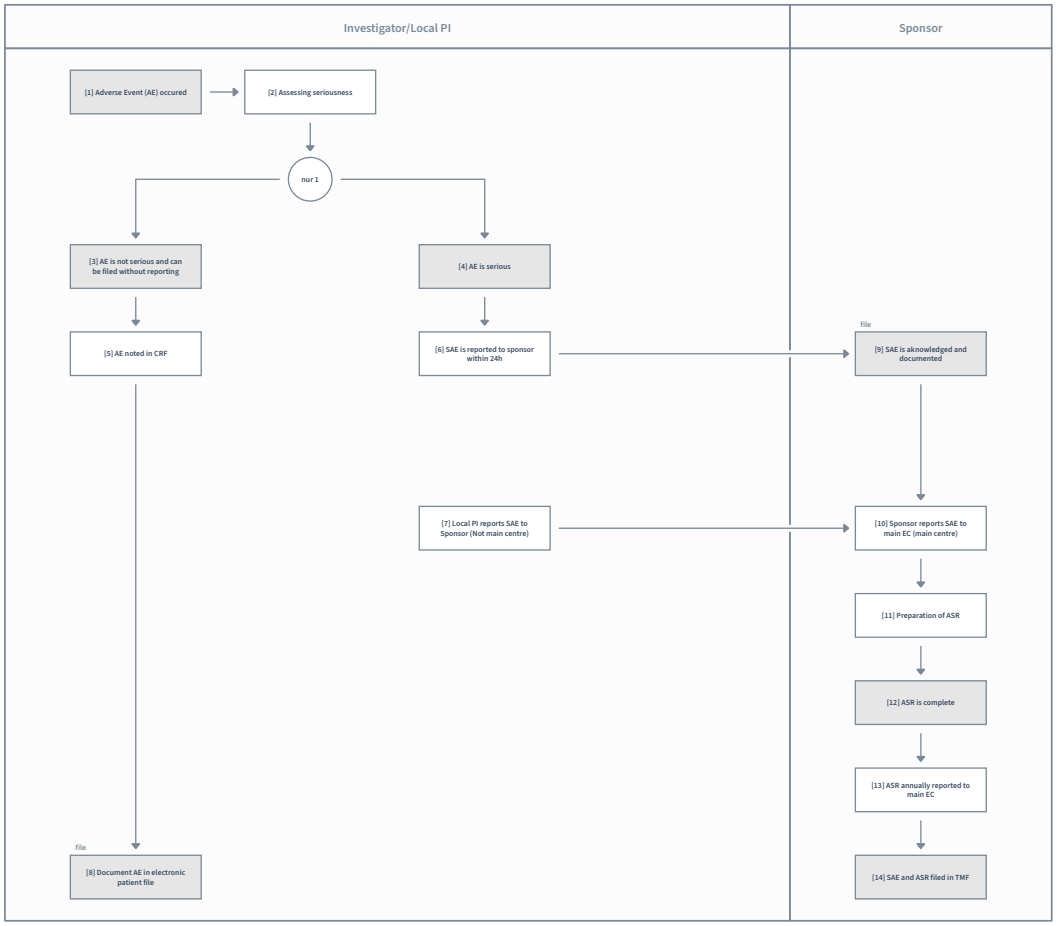

Diagramm 1

7. Metrics

Number and classification of (S)AEs in the EMINENT-ICH trial

8. Document filing

All (S)AE documents will be filed in the TMF together with the ASR. Additionally, a scan of every (S)AE will be filed in the electronic TMF.

9. References

SAE_EMINENT_ICH_Template_0323.docx[1]

1. https://orca.dkfbasel.ch/download/process/8194a5f1-c27b-11ed-800a-0242ac13000e

10. Details zu Diagramm 1

[1] Adverse Event (AE) occured

[2] Assessing seriousness

[3] AE is not serious and can be filed without reporting

[4] AE is serious

[5] AE noted in CRF

[6] SAE is reported to sponsor within 24h

[7] Local PI reports SAE to Sponsor (Not main centre)

[8] Document AE in electronic patient file

[9] SAE is aknowledged and documented

[10] Sponsor reports SAE to main EC (main centre)

[11] Preparation of ASR

[12] ASR is complete

[13] ASR annually reported to main EC

[14] SAE and ASR filed in TMF

Änderungsverzeichnis

Version	Beschreibung
Version: 2.3.0 (aktuell)	03.03.2023: Initial version of SOP regarding reporting of SAEs. Imported from TEMP V2.3.0 DKF