SOP: Sponsor reporting adverse events

Version	Author(s)	Date	Changes	Approved by
1.0	Gorm Greisen Maria Skoog Anne Mette Plomgaard	29.05.12	Initial Version	Gorm Greisen

CONTENT

1.0 A report of a serious adverse reaction or serious device effect arrives by fax at the department of neonatology, Rigshospitalet (+45 3545 5025).

1.1 Secretary or nurse empties the fax machine

- **The fax must be handed to sponsor Professor Gorm Greisen within 24 hours.**

If sponsor is out of office

- The fax is handed to one of the PhD- students; Simon Hyttel-Sørensen or Anne Mette Plomgaard

If none of the above mentioned are available

- One of them must be contacted by phone:
  Gorm Greisen: +45 4046 0747
  Simon Hyttel-Sørensen: +45 2812 4036
  Anne Mette Plomgaard: +45 2858 8929

1.2 Sponsor receives the fax

Sponsor must

- make sure that the report is understandable and that the serious adverse reaction/serious device effect is correctly classified
- make sure that the investigators and relevant national competent authorities are informed - depending on the event reported – see 2.0 and 3.0

2.0 SUSAR or USADE

2.1 Who has to be informed?

- all investigators as soon as possible *(table 1)*

- all the national competent authorities that has given approval must be informed within 2 calendar days*(table 2)*

2.2 Sponsor reports the incidence to Copenhagen Trial Unit.

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    a. Sponsor agrees with the investigator concerning the classification of the event the report - Sponsor signs the report from the investigator.
    or
    b. Sponsor does not agree with the investigator – he fills in another eCRF for the incidence.

- Sponsor Calls Berit Grevstad at Copenhagen Trial Unit (CTU) +45 3545 7170 or +45 2874 5509 and informs her about the incidence

- Sponsor scans the adverse-event report received from the investigator (if disagreement in addition sponsors own eCRF concerning the incidence.)

- Sponsor sends the SAE-report and the scanned material to Berit Grevstad berit.grevstad@ctu.rh.dk

2.3 Copenhagen Trial Unit informs investigators and competent authorities

- *The SAE reporting form from EU is filled out.*
    http://ec.europa.eu/health/medical-devices/files/meddev/sae_reporting_form.xls
    The form is shown in Appendix A
    Remember when filling out the form: New/additional information must be highlighted
    Link to the guide “Clinical investigations: serious adverse event reporting under directives 90/385/EEC AND 93/42/EEC”
    http://ec.europa.eu/health/medical-devices/files/meddev/2_7_3_en.pdf

- **When the form has been filled out save the file, so additional information or new SUSAR/USADE can be reported continuously.**

- Berit Grevstad mails the SAE reporting form to the competent authorities and to all prime investigators.

2.4 What if Berit Grevstad is not available?

- Sponsor must contact Maria Skoog at telephone +45 3545 7165 or +46 730 327 001, email: M.Skoog@ctu.rh.dk, and she will inform the investigators and the competent authorities as described above.

Table 1
Investigators

Gerhard Pichler Phone: +0316 38580520 E-mail: pichler.gerhard@klinikum-graz.at	AT	Olivier Claris Phone: +33 (0) 427855283 E-mail: olivier.claris@chu-lyon.fr	FR
Gunnar Naulaers Phone: tel. +321843213 of +32 16 343211E-mail: gunnar.naulaers@uz.kuleuven.ac.be	BE	Gene Dempsey Phone: +353 21 492 0525 E-mail: g.dempsey@ucc.ie	IE
Cornelia Hagmann Phone: +41 44 255 53 98 E-mail: cornelia.hagmann@usz.ch	CH	Monica Fumagalli Phone: +39 02 55 032 951 E-mail: monica.fumagalli@mangiagalli.it	IT
Martin Wolf Phone: +41 44 255 5346 E-mail: martin.wolf@usz.ch	CH	Frank van Bel Phone: +31-88-7554545 E-mail: F.vanBel@umcutrecht.nl	NL
Claudia Roll Phone: +49 (0)2363-975 852 E-mail: c.roll@kinderklinik-datteln.de	DE	Lena Hellström-Westas Phone: +46 18 6114877, +46 73 3916330 E-mail: lena.westas@kbh.uu.se	SE
Adelina Pellicer Phone +34 917277416 e-mail: apellicer.hulp@salud.madrid.org	ES	Topun Austin Phone: E-mail: topun.austin@addenbrookes.nhs.uk	UK

Table 2
National competent authorities – Medical Device agencies

	Protocol No.	**Email address to the national competent authority**
AU	Number	inspektionen@ages.at
BE	?	
CH	Number	clinicaltrials.devices@swissmedic.ch
DE	?	
DK	LMST2012034729	med-udstyr@dkma.dk
ES	?	
FR	?	
IE	?	
IT	Not needed	
NL	Not needed	
SE	?	
UK	Not needed	

3.0 Device deficiencies, SAE-NI, ESAR or ESADE

Sponsor must

- Make sure that he agree with the classification and that the incidence is not a SUSAR/ESADE.

4.0 Quarterly rapport to Data Monitoring and Safety Committee

- Sponsor must make sure that quarterly reports with the required information about adverse events (see DSMC) are worked out. The process will be carried out by Berit Grevstad or Maria Skoog from the CTU.

5.0 Final report to the national competent authorities

- According to protocol the sponsor must report all SUSARs and USADE to the national competent authorities in all countries, where the trial has been approved, at the end of the trial (table 2).

MEDDEV 2.7/3 SAE Report Table v1			
EUDAMED - ID:			
Title of Clinical Investigation:			
CIP Number:			
Contact person (Name, Address, E-Mail, Telephone Number)		**Device type:**	
MS+NCA Reference Numbers for all participating Countries:		**Reference Member State:**	
No. of Patients enrolled to date (date of report):		**No. of Invest. Devices used to date**	
Date of Report:			

Status: **a,** m, u	**Date Sponsor received Report of SAE**	**Country**	**Study Center**	**Patient ID Code**	**Date of Procedure/ First Use**	**Date of Event Onset**	**Event: Organ System**	**Description of event**	**action/ treatment/patient outcome**	**Assessment of Relationship to Procedure:** Yes No Possibly	**Assessment of Relationship to Investigational Device:** Yes No Possibly	**Unanticipated SADE** yes/No	**Treatment Arm:** Investigational Device/ Control Group/ blinded/ n.a.	**Event Status:** Resolved/ Resolved with Sequelae/ Ongoing/Death

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