Monitoring Plan, SafeBoosC Phase II Trial

The following is defined as the minimum required level of monitoring at each site:

Initiation Visit

An initiation visit must take place at each site before inclusion of the first trial participant. At this visit the Investigator Site File should be checked for all required documents. Forms intended for registration of trial participants and serious adverse events (as specified in the protocol) should be available. Procedures regarding storage of biological samples must be discussed. Available resources, facilities and equipment as well as training of trial personnel have to be evaluated.

On-site Monitoring

On-site monitoring visits have to be performed at each site. The first visit should take place after enrollment of the first trial participant in order to ensure, that trial procedures are correctly understood and followed at the site.
The following visits should be planned according to the inclusion rate at each center:

Data, for **all children** included in the trial, must be verified according to the source data:

- Signed informed consent form
- Study number and patient indentifiers on patient inclusion list
- Start of intervention before 3 hours of age
- Gestational age
- Whether child is dead or alive at time of discharge from hospital
- Date of death/discharge from hospital

Data, for the **first 2 children** included in the trial and for **approximately every 5th child** hereafter, must be verified according to the source data:

- Registration, reporting and follow-up (according to protocol and local legislation) of severe adverse reactions, including burn marks
- Discharge diagnoses for NEC, ROP and BPD
- Timely performed aEEG and cUS according to the SOP
- Storage, handling and labeling of blood samples

In case of an unacceptable number of mistakes at a certain site the monitoring plan should be adapted accordingly in order to increase the quality control, and hereby the quality of the data.

Close-out visit

A close-out visit has to take place at each site. At this visit, it should be checked that the Investigator Site File is complete and ready for archiving and that relevant authorities has been notified timely and correctly about the completion of the trial.

Monitoring reports will be made after each visit and sent to the principal Investigator in each country. Sponsor will receive a copy.