

GCP Report on monitoring at investigator site

*Reviewed trial subjects' study ID's (type below)**

**Only participants that have reached 36 weeks PMA should be included in the report*

Protocol	SafeBoosC III trial			
Site				
Sponsor	Gorm Greisen, Rigshospitalet			
Investigator			Date of visit	
Participants	<i>Name (initials)</i>	<i>Role</i>	Report date	
	From site:			
	GCP person:			

1. Information in clinical files/records and signed consent	Yes	No	Was not checked
1.1. Is there a clinical file/record on each of the reviewed trial subjects?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
1.2. Is participation in the trial documented in the clinical files of each reviewed trial subject?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
1.3. Is there a signed consent form (single or both parents as required by local regulations) with a date before the intervention (if deferred consent is used, the signature can be after the time of intervention) or if 'opt'out' method is used, documentation in clinical file of trial participation, that parents have been informed and their response, for each of the reviewed trial subjects?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

If any deviations, please comments:

2. Source data verification	Yes	No	Was not checked
2.1 Is there agreement between the clinical file and eCRF regarding group allocation, for each of the reviewed trial subjects?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2.2 Is there agreement between the clinical file and eCRF regarding gestational age lower than 28 weeks, for each of the reviewed trial subjects?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
2.3 Is there agreement between the clinical file and the eCRF regarding mortality, for each of the reviewed trial subjects?*	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
<i>If any deviations, please comment:</i>			

*Please recall that subjects should only be registered as “Dead” if the event occurred before 36 weeks of postmenstrual age. If death occurs later, the subject should be registered as “Alive”.

3. Delegation and training log	Number of clinical staff members
3.1. What is the number of clinical staff members that have signed for being informed on the trial, their tasks as written in the delegation and training log, and the web-based training and certification program?	
3.2. What is the total number of clinical staff members on the delegation and training log? Divide in nurses/neonatologists/radiologists	/ /
<i>Comments:</i>	

4. Check of patient inclusion list	Yes	No	Was not checked
4.1 Is the patient inclusion list completed, i.e. personal identifiers and study-ID on all patients?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
4.2 Does the study ID's on the patient inclusion list match the study-ID's registered in the eCRF?	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

4. Check of patient inclusion list	Yes	No	Was not checked
<i>If any deviations, please comment:</i>			

5 Issues for follow-up from last visit	Yes	No
5.1. Were there any issues for follow-up at last monitoring visit?	<input type="checkbox"/>	<input type="checkbox"/>
5.2. If yes to '5.1', have the issues for follow-up been resolved?	<input type="checkbox"/>	<input type="checkbox"/>
<i>If 'No' to 5.2, please specify below, which issues for follow-up that was not resolved and transfer them to this monitoring visits 'Issues for follow-up'.</i>		

Next scheduled visit:	
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Issues for follow-up		
Date	Follow-up	To be performed by

Signatures
This report has been prepared by:

GCP person _____
Date

As Principal investigator I have reviewed the report and assumes responsibility for any follow-up:

Investigator _____
Date

As Sponsor Investigator I have reviewed the report and assumes responsibility for any follow-up:

Sponsor Investigator, Gorm Greisen _____
Date

The signed report is archived in the investigators Trial Master File.