Local data monitoring report

*Reviewed trial participant IDs (type below)**

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**Only participants that have reached 90 days after randomisation should be included in the report*

Protocol	SafeBoosC-IIIv trial			
Site				
Sponsor	Janus Christian Jakobsen, Copenhagen Trial Unit			
Investigator			**Date of visit**	
Participants	***Name (initials)***	***Role***	**Report date**	
	From site:			
	Local monitor person:			

1. Information on clinical records and signed consent	**Yes**	**No**	**Was not checked**
1.1. Is there a clinical record on each of the reviewed trial participants?	☐	☐	☐
1.2. Is participation in the trial documented in the clinical records of each reviewed trial participant?	☐	☐	☐
1.3. Are there relevant signed consent forms or, if 'opt-out' method is used, relevant documentation in clinical records for each of the reviewed trial participants?	☐	☐	☐
If any deviations, please comments:			

2. Source data verification	Yes	No	Was not checked
2.1 Is there agreement between the eCRF and clinical records regarding group allocation for each of the reviewed trial participants?	☐	☐	☐
2.2 Is there agreement between the eCRF and clinical records regarding gestational age more than 28 weeks for each of the reviewed trial participants?	☐	☐	☐
2.3 Is there agreement between the eCRF, clinical records and/or primary outcome log regarding mortality and hospital-free days for each of the reviewed trial participants?*	☐	☐	☐
If any deviations, please comment:			

*Please recall that participants should only be registered as "Dead" if the event occurred before 90 days of randomisation. If death occurs later, the participant should be registered as "Alive".

3. Delegation 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 log, and having received sufficient training to conduct their trial-related tasks?	
3.2. What is the total number of clinical staff members on the delegation log?	
Comments:	

4. Check of participant inclusion list	Yes	No	Was not checked
4.1 Is the participant inclusion list completed, i.e. date of randomisation, national identification number, and participant ID on all participants?	☐	☐	☐
4.2 Does the participant IDs on the participant inclusion list match the participant IDs registered in the eCRF?	☐	☐	☐

4. Check of participant inclusion list	**Yes**	**No**	**Was not checked**
If any deviations, please comment:			

5 Issues for follow-up from last visit	**Yes**	**No**
5.1. Were there any issues for follow-up at last monitoring visit?	☐	☐
5.2. If yes to '5.1', have the issues for follow-up been resolved?	☐	☐
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'.		

Next scheduled visit:	

Issues for follow-up		
Date	**Follow-up**	**To be performed by**

Signatures

This report has been prepared by:

Local monitor person _____ Date _____

As Principal Investigator I have reviewed the report and assumes responsibility to handle any follow-up until the next local data monitoring visit.

Principal Investigator _____ Date _____

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

Sponsor _____ Date _____

The signed report is archived in the Investigator Site File. A copy is sent to the Sponsor.