Initiation visit 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. Completion of Investigator Site File	**Yes**	**No**	**Was not checked**
1.1 Is there an Investigator Site File available, including documents as required per local data monitoring plan? (if any missing, please comment)	☐	☐	☐
Comments:			

2. Number of clinical staff members 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	**Number of clinical staff members**
2.1. 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?	
2.2. What is the total number of clinical staff members on the delegation log?	

3. Blinding procedure for primary outcome assessment	**Yes**	**No**	**Was not checked**
3.1. Has the principal investigator demonstrated the local blinding procedure for assessment of hospital-free days (i.e., the primary outcome)?	☐	☐	☐
Comments:			

3. Blinding procedure for primary outcome assessment	Yes	No	Was not checked

Points for follow-up			
Date	**Follow-up**	**Respon-sibility**	**Com-pleted**

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.