

SOP: 2 year follow up with ASQ

Version	Author(s)	Date	Changes	Approved by
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1.0 SafeBoosC and ASQ

According to the SafeBoosC protocol the child must be evaluated with an ASQ at 2 year follow up.

The Ages & Stages Questionnaire (ASQ) is a set of questionnaires developed for screening purposes. We use the total score as a quantitative measure of 'general' psychomotor development as the variable for comparing the two intervention groups. In order to obtain a normal distribution of the total scores, **we have chosen to use the 27 months ASQ for evaluation at corrected age of 24 months to minimize the ceiling effect.**

The ASQ can only be filled-in if the ASQ exists in a language the parents or some other member of the family understands. The ASQ is written in simple language (corresponding to 6th grade school reading level). This means that in general there is little problem with parents' misunderstanding of questions or 'tests'.

The SafeBoosC accepts ASQ second and third edition, but each centre must use only one version.

2 year follow up with Ages and Stages Questionnaire (ASQ)

2.0 ASQ at corrected age of 23 to 25 months

1. At corrected age of 23 months, send the ASQ 27 months to the child together with the invitation for the 2-year follow-up.
 - a. In addition to the questionnaire and the invitation to the 2-year follow up the envelope should contain
 - i. A letter stating the child has participated in the SafeBoosC trial and therefore is followed up with ASQ in addition to a neurodevelopmental test/standard procedure
 - ii. **A pre-stamped envelope for returning of the questionnaire and/or a request for handing in the filled-in ASQ at the time of the 2-year follow-up visit at the hospital.**
2. If the ASQ has not been returned at corrected age of 24 months or at the 2-year follow-up – send a reminder containing the same information as in "1". Repeat if necessary. The result of the questionnaire is valuable at any age. The statistical calculation will correct for age at filling-in.
3. Fill in the eCRF
4. If the ASQ is not sent to the parents please fill the eCRF anyway!

Keep the original ASQ records on site.

Appendix A: Information required in the eCRF

The ASQ 27 months was send to the parents: yes/no*

*If no – why not - Comment

The ASQ was returned by the parents: yes/no

ASQ edition: two/three

Date of ASQ filling-in: _____

Scores for the different domains:

Communication: _____points (limits 0-60)

Communication: _____items not filled-in (limits 0-6)

Gross motor: _____points (limits 0-60)

Gross motor: _____items not filled-in (limits 0-6)

Fine motor: _____points (limits 0-60)

Fine motor: _____items not filled-in (limits 0-6)

Problem solving: _____points (limits 0-60)

Problem solving: _____items not filled-in (limits 0-6)

Personal-social: _____points (limits 0-60)

Personal-social: _____items not filled-in (limits 0-6)

Total score: _____points (limits 0-300)

Total items not filled-in: _____ (limits 0-36)

Comments: