

SOP: Screening

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1.0 Introduction

All infants born more than 12 weeks before term, i.e., GA 27+6 or less, should be screened. If screening result is 'not eligible' the infant are given a 'Screening failure' Study-ID that will be used in the eCRF to fill out the 'Screening' form.

2.0 How do I give the child/children a 'Screening failure' study-ID?

- Find the 'Screening Failure List"
- Note the personal identification number of the child or the mother of the child in the first available box
- The child is given the study-id left to the Personal Identification Number

When creating the profile in the eCRF use the study-id.

2.1 What if it is twins?

Twins will be given two different 'Study-IDs' for screening purposes. This is different from the included twins (see SOP: Randomization)

3.0 How to fill the 'Screening' form of the eCRF for screening failures

- For in- or exclusion criteria not met please make a discrepancy note, i.e., press the little flag to the left of the text. The form cannot be 'marked as complete' if this is not done.
- Choose one or more of the possible reasons for the specific screening failure