

## Guidance Sheet 1:

### Screening and Eligibility



### Eligibility

Babies will be considered eligible for inclusion in the trial if:

- a) They were born at <30 (up to 29w <sup>+6d</sup>) weeks of gestation (including infants born as one of a multiple birth).
- b) Written informed consent has been obtained.
- c) Follow-up is likely to be feasible (i.e. routine outpatient appointments will be at the recruiting site, locality of baby's residence so follow up to one year corrected age is possible).
- d) Survival to one-year corrected age is anticipated.
- e) In addition to infants without an eventful course, the following groups are eligible for inclusion:

Infants diagnosed with bronchopulmonary dysplasia

Infants discharged home on oxygen

Infants who have had necrotising enterocolitis

Infants on oral or nasogastric tube feeding

Infants with treated patent ductus arteriosus

Infants with neurological disorders

Infants with resolved sepsis

This list is not exhaustive and others can be discussed with the PI in the first instance and trial team if necessary.

Babies will be **excluded** from participation in the trial if:

- a) Presence of major surgical, cardiac or congenital abnormalities (not including patent ductus arteriosus or patent foramen ovale).
- b) Contraindication of Bactek™ as specified in the Investigator's Brochure.
- c) Participation in other interventional trial that precludes participation in BALLOON.
- d) Primary immune deficiencies

Final eligibility can only be confirmed by a delegated individual, as recorded on the BALLOON Site Delegation Log.

### Co-enrolment

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Co-enrolment to other trials is permitted where agreed by the BALLOON Chief Investigator. Please contact BALLOON Trial Manager ([kotechasj@cardiff.ac.uk](mailto:kotechasj@cardiff.ac.uk)), who will contact the Chief Investigator.

### Screening

To ensure that potentially eligible babies are not missed, it is important that all NNU staff are familiar with BALLOON and can help with identification and recruitment. Try to identify parents of potential recruits as early as possible in the NNU.

Please ensure that the Screening Log is completed and records all infants born less than 30 weeks' gestation. This should be done at least once a week using the paper screening log. Please keep the log up to date by adding cases on a weekly basis. This should not include any personal identifiable information.