



## Paediatric Clinical Research Infrastructure Network

### Procedures for the setup of neonatal trials

#### Feasibility assessment of neonatal studies and selection of investigator sites/ study centres: Points to consider

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<b>Description</b>	This tool lists examples of points to consider for the feasibility assessment and selection of neonatal centres
<b>Key words</b>	Neonatal trial, Protocol development, Guidance document, Tool, Feasibility

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**Disclaimer:** Sponsors and researchers unfamiliar with clinical trials in neonates and/or neonatology are advised to seek expert advice due the complexity of neonatology.

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## Introduction

The feasibility assessment of clinical trials takes into consideration the epidemiology of the neonatal disease, the details of the protocol and trial procedures, amongst others. It may further consider the particularities of trial centres and local/ regional issues (e.g. ethics approval process, informed consent).

### **Feasibility assessment and selection of neonatal centres: Points to consider**

Research experience, past trial performance, as well as technical aspects such as local access to investigations adapted to the neonatal population (e.g. Magnet Resonance Imaging), neonatal pharmacy expertise, local availability of the study medication and local routine clinical practice and follow up practices may be included in the feasibility assessment of individual clinical trial centres.<sup>1,2-3</sup>

In addition the availability of dedicated research physicians and nurses as well as the potential of concurrent other neonatal trials should be included in the assessment because they may compete for patients and/or research resources.<sup>1,4</sup>

Multicentre, multi-country neonatal trials should examine the impact of the potential delay in ethics approval and possible differences in the informed consent process for each participating centre and/or country.<sup>2,5</sup> International ethics review boards may help reducing the time to study start.<sup>2</sup>

For parents providing informed consent at a time of considerable stress can be very challenging.<sup>5,6</sup> Parent associations may provide valuable advice on how to provide support within the local cultural context.<sup>7,8</sup> [Table 1](#) provide points to consider in the feasibility assessment and selection of neonatal centres.

### **Competing interests**

All authors consider not having any competing interests for this tool. BA has worked for GlaxoSmithKline between October 2006 and September 2009 and holds company shares. Between October 2009 and May 2015 she has worked for Novartis.



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**Table 1. Feasibility assessment and selection of neonatal centers: Points to consider\***

Feasibility assessment item	Possible sources of information	Points to consider for neonatal clinical trials
- Research experience and past trial performance	- Investigator	- Specific questions in the investigator survey and publicly available information (Clinical trial registries, publications) will be informative
- Local access to population specific investigations	- Investigator - Local radiology department - Local laboratory	- Local written Standard Operating Procedures will be informative
- Local pharmacy expertise - Local availability of study medication and population specific formulation	- Investigator - Pharmacist	- Can provide valuable advice on neonatal formulation issues
- Local clinical practice and follow-up routine	- Investigator	- Study procedures and follow-up should be consistent with local practices in order to avoid protocol violations and to reduce the risk of trial failure
- Concurrent other neonatal studies	- Investigator	- May compete for patients and/or research resources
- Ethics and regulatory approval processes	- Regulatory experts	- Not all reviewers in ethics boards and regulatory authorities may have access to experienced neonatal/ paediatric researchers - Detailed information on the current lack of neonatal data, the evidence for the estimated benefit-risk balance and risk management may be helpful in reducing the number of questions from reviewers
	- Investigators	- May have experience in how to anticipate and manage potential delays in the approval process
	- International Ethics Review Boards	- May help reducing the time to study start
- Informed consent	- Parent associations - Investigators - Nurses and other health care professionals	- Will have valuable advice on how to support parents in the decision making process and study procedures which may not be acceptable to parents

\* Not exhaustive