**777389 - c4c**

**conect4children (COllaborative Network for European Clinical Trials For Children)**

**Clinical Trials Supplies Advisory Service**

**Successful delivery of clinical trials depends on many factors, not the least of which is having an effective medicine supply chain. This aspect of clinical trial delivery is inherently complex and intertwined with regulatory and financial implications. As trial supply related decisions can significantly impact on study design, regulatory requirements, and study deliverability, it is imperative that specialist inputs are sought from the very start of the study planning process.**

**The c4c clinical trial supplies advisory service will be available, in confidence, to assist all investigators applying for the c4c call for multinational clinical studies in children and neonates. Mandy Wan, an experienced paediatric clinical trial pharmacist, will support investigators in developing feasible study proposals including providing assistance with selection of age appropriate formulations, blinding, placebo manufacturing and other medicines related aspects.**

**For further information, please email:** [**trial.applications@conect4children.org**](mailto:trial.applications@conect4children.org)

**Clinical Trials Supplies Advisory Service**

**Scope of Work**

The following scope describes the work that will be included as part of the c4c Clinical Trials Supplies Advisory Service.

**Aim**

The c4c Clinical Trials Supplies Advisory Service will be available to all investigators applying for the c4c call for multinational clinical studies in children and neonates (non-industry viability studies). The aim is to support investigators in identifying and developing feasible study proposals for clinical trial medications for these clinical trials.

**Timeline for requests**

1st September 2018 to November 15th 2018.

**Work to be performed**

* To provide specific advice to investigators in the following areas:
* Selection of age appropriate formulations
* Identifying potential manufacturers
* Sourcing of medicines
* Blinding
* Manufacturing plans
* Packaging & labelling
* Storage and distribution arrangements
* Logistics and management of clinical trial medications at investigator sites
* Medicines related regulatory requirements
* An initial report on clinical trial medications requirements with options appraisal and impact analysis will be provided to investigators within 2 weeks of initial discussion.
* Follow up meetings will be arranged as needed to ensure the supply plan for clinical trial medications remains robust as the study plan continues to be developed.
* The scope of work will be limited to the application stage and does not involve the set up and delivery of the funded clinical trials.