THE PARTNERS IN NEMO

Universities / Institutes

University College London with the Institute of Child Health and the Institute for Women's Health *(UK)*, University College Cork *(Ireland)*, Institut National de la Santé et de la Recherche Médicale *(France)*, Hospital District of Helsinki and Uusimaa *(Finland)*, University of Leeds *(UK)*, Uppsala Universitet *(Sweden)*, Universitair Medisch Centrum Utrecht *(Netherlands)*, Assistance Publique – Hôpitaux de Paris *(France)*, Duke University *(USA)*, Karolinska Institutet *(Sweden)*, Great Ormond Street Hospital For Children NHS Trust *(UK)*, Erasmus Universitair Medisch Centrum Rotterdam *(Netherlands)*

SME's

GABO:milliarium mbH & Co. KG *(Germany)*, Only For Children Pharmaceuticals *(France)*, ClinInfo S.A. *(France)*

Photographs posed by models.

THE KEY CONTACTS IN NEMO

Coordinator

University College London, Dr Ronit Pressler

Co-coordinator

University College Cork, Dr Geraldine Boylan

Sponsors of the clinical study

Only For Children Pharmaceuticals (O4CP),
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Project Office

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SEVENTH FRAMEWORK PROGRAMME

NEMO is a Collaborative Project funded by the European Commission under the 7th Framework Programme

NEMO

Treatment of **NE**onatal seizures with **M**edication **O**ff-patent: evaluation of efficacy and safety of bumetanide

BACKGROUND

Seizures or fits which occur in newborn babies shortly after birth (neonatal seizures) are the focus of the **NEMO** project. Seizures are more frequent during the neonatal period than during any other time in life. The most common cause of neonatal seizures is brain injury, secondary to a lack of oxygen or blood which occurs around the time of delivery. We call this hypoxic-ischaemic encephalopathy (HIE). HIE is a major cause of death and long term disability worldwide. Neonatal seizures can be difficult to control using current available antiepileptic drugs (AED). We hope that better seizure control will improve the neurological outcome of babies with HIE.

Better treatments for neonatal seizures, particularly in babies with HIE, have been identified as a high priority for research by several international expert groups including the European Medicines Agency (EMA).

WHAT IS NEMO?

NEMO stands for **"Treatment of NEonatal seizures with Medication Off-patent: evaluation of efficacy and safety of bumetanide"**.
NEMO is a Collaborative Project funded by the European Commission under the 7th Framework Programme and will be **the largest multicenter European study of neonatal seizures and their treatment**.

The **NEMO** consortium consists of 15 participating institutions and partners based in Europe and in the USA. It comprises renowned researchers, each one with a strong scientific and/or clinical background in the field of neonatology, neurophysiology, pharmacology, neurobiology or epileptology. Excellent research standards – including the latest scientific and technological advances – will be the basis for **NEMO**.

AIM OF NEMO

The aim of **NEMO** is to develop an effective antiepileptic drug regimen suitable for the treatment of neonatal seizures. An age-dependent ion pump in immature brain cells is thought to be responsible for the vulnerability which babies have to seizures. It is also the reason why drugs which work in adults do not work well in babies. The **NEMO** clinical study will evaluate bumetanide, which specifically blocks this age-dependent mechanism. It has been safely used in babies as a diuretic for many years. Bumetanide is included in the EMA's revised priority list for studies into off-patent paediatric medicinal products, but it cannot be tested as an AED in older children or adults as this mechanism ceases to be effective during the first few months of life.

This will be the first time that an antiepileptic drug specifically aimed at this age-group will be evaluated in a European-wide multicentre study using EEG monitoring.

KEY DATA FOR NEMO

Start date:	1st October 2009
Project duration:	5 years
EC contribution:	5.800.000 Euro
Website of the project:	www.nemo-europe.com
Website of the clinical study:	www.nemo-study.com