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Clonidine for Sedation  
of Paediatric Patients  
in the Intensive Care Unit



Newsletter #1

## CloSed Project

### Improving sedation of children in critical care

CloSed is a 5-year project funded under the Seventh Framework Programme (FP7) with an international Consortium comprising 10 European partners and coordinated by the University Hospital of Erlangen.

The project aims to study clonidine, which is currently used off-label as sedative in paediatric intensive care units (PICU) and to conduct a **multicentre clinical trial in children until the age of 18**.

Indeed, children (until the age of 18) in critical care, admitted to the intensive care unit and in need of sedation, are often treated with drugs that are not specifically approved for them. Thus, **age-appropriate formulations and data on efficacy and safety are required for this drug**. CloSed project is expected to fill this gap, since it is aimed to develop and test a parenteral age-appropriate formulation of clonidine, specifically for the treatment of neonate, paediatric and adolescent patients. Once it will be demonstrated its efficacy and safety, the project results will be used to obtain a Paediatric Use Marketing Authorisation (PUMA).

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## Project Consortium

The project Consortium comprises 10 European partners: one not-for-profit organisation, five clinical centres, one SME, two universities and one patient organisation, all focused on developing appropriate medicines for children.



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## Events

**Dec 2-3, 2013**

**Erlangen**

### **Project Kick-off Meeting**

The new European project CloSed was officially kicked off in Erlangen, Germany. The meeting was an occasion for the project clinicians to discuss and share their experience in sedation in PICU, local practices, the use of different medications and dose regimens

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**May 22-23, 2014**

**Paris**

### **CloSed Scientific Meeting**

The meeting focused on the development and finalisation of the clinical trial protocol, while other important issues, such as the finalisation of some deliverables, the upcoming Patient Advisory Board Meeting and Study Management were also discussed.

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**Jun 1, 2014**

**Milan**

### **Patient Advisory Board Meeting**

Organised by Vereniging Samenwerkende Ouder, the first PAB meeting focused on the identification of issues that may arise from a patient/child's perspective on CloSed and to develop a plan to address them accordingly.

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## Partners: Focus On

**Universitätsklinikum  
Erlangen**



### Project Management Office

University Hospital Erlangen (UKER) is the coordinator of the CloSed project and thus responsible for the conduction of the project from the administrative and the scientific point of view. It is the academic research and teaching hospital of the Friedrich-Alexander University Erlangen-Nuremberg (FAU) and the Department of Paediatrics and Adolescent Medicine is leading these activities. The Project Management Office (PMO) assists the Coordinator in the day-by-day project management and supports the Steering Board.

[Partner's website](#)



### Dissemination Leader

The Gianni Benzi Foundation (FGB) is a registered not-for-profit scientific research organisation founded in 2007. Its mission is to contribute to the advancement of pharmacological research in the fields of neuropathies, rare diseases, paediatric drugs, regulatory sciences and doping. In the CloSed project FGB is responsible for the training and dissemination activities and contributes to regulatory activities and project management.

[Partner's website](#)

## What's new

### Writing the protocol

Over the next few months the CloSed Project team will be focusing on the finalisation of the study Protocol. In the Paris meeting on May 22nd all key components of the Protocol synopsis were discussed and finalised and the foundations for the first draft of the Protocol were laid out. This is now underway and is planned to be ready for the first round of review by the Protocol review team in early July. The final version is likely to be ready by early September.

The next steps to be taken in the set up of the study are:

- The stability testing of the study drugs
- Design of blinding and the randomisation
- Shipment process of the study drugs

**2015: First patient in the CloSed study!**

**...Project website available!**

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