



Clonidine for Sedation of Paediatric Patients in the Intensive Care Unit



CloSed Project

Improving sedation of children in critical care

Welcome to the fourth Newsletter of CloSed, a 5-year project funded by the European Union, aimed to improve patients' treatment in the intensive care setting by studying clonidine.

CloSed will develop a **new formulation of clonidine** specifically designed for children and conduct a clinical trial in patients under the age of 18 with the aim to generate **safety and efficacy** data on clonidine in children, to support **Paediatric Use Marketing Authorisation (PUMA)** application and to develop **guidelines for sedation** of critically ill newborns and children in the Paediatric Intensive Care Unit (PICU). Throughout the project, the health outcome of children will be of utmost priority and all research activities will be conducted in accordance with European ethical requirements for studies involving the paediatric population.

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.



Events

Jan 20-21, 2016

Rotterdam

CloSed General Assembly Meeting in Rotterdam

The next General Assembly Meeting of the CloSed project will take place in **Rotterdam**, The Netherlands, in the period from **20th-21st January, 2016**. The meeting will be attended by the whole CloSed Consortium and is being organised by Erasmus Universitair Medisch Centrum Rotterdam (EMC) in collaboration with the CloSed Project Management Team.

Read More

Nov 18-20, 2015

Chester

CloSed Poster presentation at the PKUK 2015 Meeting in Chester

The CloSed project was presented to the **Pharmacokinetics PKUK 2015 Meeting**, an open forum for discussing all PKPD issues in drug development as well as clinical implications of PKPD studies. This year's meeting was held in Chester, UK, from **18th November to 20th November, 2015**.

Read More

Sep 16, 2015

Antwerp

CloSed at the 7th EuPFI Conference, Antwerp

On **September 16th, 2015**, CloSed was presented at the **7th Annual Conference of the European Paediatric Formulation Initiative (EuPFI)** on 'Formulating Better Medicines for Children'. The event was held in partnership with the APV (International Association of Pharmaceutical Technology) in Antwerp, Belgium, from **16th to 17th September, 2015**.

Read More

What's new?

Site initiation EMC Rotterdam

The first CloSed trial site "Erasmus MC – Sophia Children's Hospital" (EMC) in Rotterdam, The Netherlands was initiated on 2nd-3rd December, 2015. This site initiation visit (SIV) was attended by principle investigator Prof. Dick Tibboel and his team comprising highly motivated and experienced co-investigators and study nurses.

[Read More](#)

CloSed scientific leaflet

An information leaflet for scientific audiences has been released in English and will be disseminated in the context of conferences and scientific events, as well as the CloSed website and social network channels. The CloSed scientific leaflet is available for download in PDF format [here](#).

A layman's leaflet illustrating the CloSed project and clinical study to the general public has also been designed and will be soon published.

Regulatory submission, Investigational Medicinal Product (IMP) and patients enrolment

Another step forward has been made in the CloSed study after the Clinical Study Protocol finalization: the process of regulatory submission has been completed in The Netherlands and in Germany. The national Competent Authorities as well as the Ethics Committees

granted their positive opinion.

Recruiting sites in the Czech Republic, Italy and Sweden are currently preparing all documents necessary for submission.

[Read More](#)

Interview to Ms. Louise Rawcliffe from Therakind

The clinical study and the Marketing Authorisation Application (MAA) require specific regulatory prerequisites. For the CloSed project, these are managed by Therakind, the partner overseeing all regulatory activities related to the Paediatric Investigation Plan (PIP) and Paediatric Use Marketing Authorisation (PUMA) application. Therakind is also responsible for Study Management, Monitoring and Quality Assurance of the clinical study.

Following, an interview with Louise Rawcliffe (BSc, MBA) from Therakind who provides more in-depth information on the study progress.

[Read More](#)

Partners: Focus On



Recruiting Centre

Charles University Prague (CUNI) is one of the world's oldest universities and is dedicated to international co-operation with prestigious educational and research institutions.

With its 17 faculties at the University (14 in Prague, 2 in Hradec Králové and 1 in Plzeň), 3 institutes, 6 other centres of teaching, research, development and other creative activities, a centre providing information services, 5 facilities serving the whole University, and the Rectorate - which is the executive management body for the whole University, CUNI is also the largest and most renowned Czech university according to international rankings.

[Read More](#)

Partner's website



Bambino Gesù

OSPEDALE PEDIATRICO

Recruiting Centre

Bambino Gesù Children's Hospital & Scientific Institute (OPBG IRCCS) is the largest paediatric hospital in Italy and a reference center for children at a national and international level. It is part of the network of the Italian Healthcare System (SSN). It was founded in the second half of the 19th century (1869) and in 1985, Ospedale Pediatrico Bambino Gesù received recognition as an "Istituto di Ricovero e Cura a Carattere Scientifico" (IRCCS – Institute for Research, Hospitalization and Health Care).

[Read More](#)

Partner's website

Copyright © 2014 Closed Project, All rights reserved.

Our mailing address is:
closed@uk-erlangen.de

[unsubscribe from this list](#) [update subscription preferences](#)



Facebook



Website



This project has received funding from the European Union's Seventh Framework Programme for research, technological development and demonstration under grant agreement n.602453