

Paediatric Clinical Investigation Centre



PRESENTATION OF THE CLINICAL SPECIALISED UNITS

Cardiology

Endocrinology

Gastro-Enterology,
Hepatology and Nutrition

General
Paediatrics

Hemato-Oncology

Neonatology

Neurology

Pneumology

Emergency Unit

Intensive Care



OTHERS UNITS INVOLVED IN THE PCIC

Anaesthesia

Dental Care

Pathology

Radiology

Hospital Pharmacy

Toxicology
and Drug monitoring

Clinical Pharmacogenetics

Paediatric Research
Laboratory



The Paediatric Clinical Investigation Centre is an integrated platform thanks to the collaboration of different units, allowing to simplify several steps of clinical trials. The PCIC can organise and manage paediatric clinical protocols in every field of the Paediatrics, from phase II to IV, including epidemiological studies, with qualified staff and in strict accordance with GCP guidelines.

FOR MORE INFORMATION

Paediatric Research Institute
Paediatric Clinical Investigation Centre



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INTRODUCTION

The Paediatric Clinical Investigation Centre (PCIC) is part of the Paediatric Research Institute at the Cliniques Universitaires Saint-Luc, Université Catholique de Louvain. The Centre brings together the strengths of all paediatric subspecialties aiming to provide an efficient platform for high quality clinical investigations in accordance to ICH/GCP rules. The importance of the PCIC is highlighted by the European regulation which aims to promote a secure use of drugs in the paediatric population. The PCIC is not only conducting phase II & III paediatric drug trials, but also informative and epidemiological studies to create new information on diseases history. The PCIC also benefits from a fully equipped bench research laboratory and organises basic research targeting clinical problems, i.e. translational research.

THE DEPARTMENT OF PAEDIATRICS

Over the last years, the activity has constantly increased in both clinical practice and clinical trials. The Department conducted 4.700 admissions, 27.100 outpatient examinations and 3.500 one-day hospitalisations. The Department includes more than 90 beds distributed in the different units, and a one day clinic for semi-ambulatory care. Moreover, close collaborations are maintained with a network of general paediatricians: outpatient practices and paediatrics units of associated hospitals whom can participate in the trials. The department also includes the paediatric service from Cliniques UCL Mt Godinne.

THE PAEDIATRIC RESEARCH INSTITUTE (PRI)

The Paediatric Research Institute belongs to the Université Catholique de Louvain. Its aim is to develop and organise all research activities in the field of paediatrics. Beside the PCIC here described, the institute has a large bench research facility and is mainly active in the fields of transplantation, stem cell research and allergy. The new laboratory tower and manufactory processes follow strict GMP procedures.

THE EUROPEAN REGULATION

More than half of the drugs given to children have not been tested properly in paediatric clinical trials and have therefore not been approved for paediatric use. Clinicians are thus forced to use these drugs off label, without proper data on pharmacokinetics, efficacy and safety in this population. The European regulation on Medicinal Products for Paediatric Use will be implemented in 2007. The aim is to promote the optimal development of drugs for paediatric use and to allow both effective and safe treatments. The final goal is to improve the health of European children.

FACILITIES

Our personnel, including physicians, research nurses, pharmacists and technicians is highly qualified and has a long-lasting experience in trial organisation, protocol, data management and administrative follow-up. Trials are organised according to the Belgian law and the international quality standards. The PCIC has its own clinical and research facility. The material, which includes centrifuges, monitored refrigerators, -20° and -80°C freezers, fulfils all the quality and security requirements. The blood samples can be received, processed and stored 7 days/7 and 24h/24. Express shipments to the reference laboratories are well known procedures. The PCIC can recruit and take care of patients for clinical trials of every phase for drug trial. Depending of the design of the study, the patients are followed during hospitalisation, in the day-care centre, in the specialised outpatient clinics or within the network of associated paediatricians. The PCIC has already conducted many randomised control trials and is familiar with electronic CRF, collaboration with CRO, investigator meetings, audits,...