

## Paediatric Clinical Investigation Centre

### Cardiology

#### *PRESENTATION OF THE CLINICAL SPECIALISED UNITS*

Five paediatric cardiologists are involved in the unit that includes 13 beds, one catheterization room, and 3 ultrasound machines (with multiplan transesophageal echo). In 2004, there was 470 admissions, 4100 outpatient examinations, 6660 ultrasounds and 180 cardiac surgeries.

The unit contributes to different national multicentric trials, including follow-up of children with Senning or Mustard surgery for transposition of the great arteries (339 patients), and mean-term results of percutaneous closure of atrial septal defects (>250 patients). Intern protocols are set up to evaluate the long-term survival of corrected congenital cardiopathies (tetralogy of Fallot,...). Pharmacokinetics and/or safety-efficacy studies are also performed (Clodiprogel, Enalapril, Synagis). Finally, the unit sets up a data base for the 16.000 children followed or treated for congenital cardiopathy and for the antenatal diagnosis. Special protocols are designed for rare diseases (e.g., Marfan syndrome), aiming to better knowledge and improved care.

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### Endocrinology

#### *PRESENTATION OF THE CLINICAL SPECIALISED UNITS*

The patients have mainly pubertal disorders or growth retardation (dysmaturity, growth hormone deficiency, tumour, syndrome,...). Some of them are followed in collaboration with the Urology unit (sexual ambiguity) or the Neurology and Anatomico-pathology units (neonatal hyperinsulinism). Our joined expertises allow an optimal and unique management in Belgium. Moreover, the unit has a huge expertise in type 1 diabetes. The well-being of the patient is one of the top-priority in this chronic disease. A large cohort of children has cystic fibrosis and secondary diabetes. A special attention is also dedicated to the problem of obesity and its complications (metabolic syndrome, dyslipidemia, glucose intolerance, type 2 diabetes,...). Finally, the endocrinologic follow-up of patients with Prader-Willi syndrome or former cancer survivors was developed.

The two staff members are involved in the B.S.G.P.E. (Belgian Study Group for Paediatric Endocrinology). A dozen clinical trials was performed in the last 5 years. The main subjects were: treatments with growth hormone (indications, efficacy, follow-up,...), new insulins or insulin resistance syndrome, the endocrinologic and metabolic abnormalities related to obesity or short height. Some trials, currently performed, aim to improve the quality of life of all these patients.

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**Gastro-Enterology  
Nutrition & Hepatology**

### *PRESENTATION OF THE CLINICAL SPECIALISED UNITS*

Four staff members take care of the patients in this Unit of 13 beds. Almost 4000 outpatient examinations and 1000 technical tests (pHmetry and bilimetry, endoscopy, liver biopsy,...) are performed every year.

The hepatology section has an international expertise and recruits national and foreign patients in the field of paediatric liver diseases and transplantation. Many trials have been conducted in viral hepatitis B & C. Other studies are performed in autoimmune hepatitis, neonatal cholestasis, portal hypertension, and inborn errors of metabolism. The gastroenterology section follows a large group of patients with inflammatory bowel diseases (Crohn or ulcerative colitis), coeliac disease, food allergy and gastroesophageal reflux. Children are also referred for more acute illnesses, including diarrhoea, constipation or abdominal pain. The unit has the facility and expertise to perform endoscopies and other GI investigations.

Fourteen clinical trials were performed since 2000 (from phase II to testing before commercialisation).

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**General  
Paediatrics**

### *PRESENTATION OF THE CLINICAL SPECIALISED UNITS*

The general paediatrics unit counts 19 beds at St Luc and 18 in Mt Godinne. There are more than 2500 outpatient examinations every year. Besides general paediatrics, the unit has developed a recognised expertise in complex malformations and feeding disorders (e.g., Russel-Silver syndrome). A special attention is dedicated to allergy and infectious diseases.

Eight trials were performed in the last 5 years, mainly related to vaccination (phase II and III, vaccines against EBV, rotavirus, DTP, hepatitis A and B, pneumococcus,...) and including long-term follow-up. The children included, between 60 and 120 per study, are mainly healthy volunteers, from newborn to young adult. Depending of the protocol, the trials are proposed in schools, universities, child care centres or maternity unit. Listing of potential subjects is available.

The service follows also pediatric pneumology patients on both UCL St Luc and Mont Godinne sites.

## Paediatric Clinical Investigation Centre

### Hemato-Oncology

#### PRESENTATION OF THE CLINICAL SPECIALISED UNITS

The unit is the most important of the French-speaking Community in Belgium. About 70 new patients with cancer are seen every year, as well as a large number of children with haematologic (sickle cell disease) or immunity disorders. The staff includes 4 members and one non-resident specialist. In 2004, there were 4600 outpatient examinations and 2700 one-day hospitalisations, illustrating the critical mass of paediatric patients in the unit. There are 10 beds in the day-care centre, 2 sterile rooms for bone marrow transplantation and 14 beds for hospitalisation. About ten clinical trials were performed in the last 3 years (phase II and III, pharmacokinetics,...). Their aims were to permit the introduction of new treatments in Paediatrics (drugs and vaccines), to establish paediatric standards for drugs kinetics, and to define normal blood values in children. One asset of the unit is a huge experience in international protocols, in which most of the patients are included for their treatment.

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### Neonatology

#### PRESENTATION OF THE CLINICAL SPECIALISED UNITS

Between 250 and 300 newborns are admitted every year in the unit that counts 15 level III NICU beds and 5 level II beds. About 60 to 70 of them are babies with a birth weight below 1500g. In collaboration with the Obstetrical unit, the Neonatology is part of a Perinatal Intensive Care Unit for mothers and children. More than 50% of the 1700 deliveries/year are high risk pregnancies. The main reasons for admission are extremely low birth weight infant, congenital malformation (including special expertise in gastroschisis, omphalocele), congenital diaphragmatic hernia and twin-twin transfusion syndrome.

The four specialists in charge of the unit are members of the GBNI (Groupement Belge de Néonatalogie Intensive) which gathers the 17 Belgian Neonatology units. More than 5 national or international trials were performed in the last 5 years, including RSV infection prevention, prevention of cerebral haemorrhage, prevention of chronic lung disease and prevention of anaemia. A special attention was dedicated to the development of multidisciplinary long-term follow-up of the children and optimised reintegration of the patients and their family into the social life after long hospitalisations.

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### Neurology

#### *PRESENTATION OF THE CLINICAL SPECIALISED UNITS*

Five neurologists and several non-resident specialists take care of the children in the unit, with about 700 admissions per year, 300 video-EEG for complex epileptic syndromes and 5300 outpatient examinations. The main diseases are developmental disorders, epilepsy, acquisition problem at school, headaches, severe encephalopathy,... A particular attention is dedicated to the global treatment of children with motor disabilities, which is performed in collaboration with the units of Revalidation and Adult Neurology. Since 2 years, a close collaboration with the team "Interface Pédiatrique" was developed to allow home treatment of the patients with heavy diseases.

About 5 clinical investigations were performed in the last 5 years, mainly related to the problem of attention deficit hyperactivity disorder (ADHD). Another topic of interest is the follow-up of children with severe head trauma. Finally, within the Centre for Metabolic Disorders, patients with inborn errors of metabolism receive specific care. The molecular mechanisms of mental retardation and unexplained autistic syndromes are studied in collaboration with the laboratory of metabolic diseases.

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### Paediatric Emergency Unit

#### *PRESENTATION OF THE CLINICAL SPECIALISED UNITS*

The emergency department has a specific and separate paediatric facility, and all children are seen by experienced paediatricians. Protocols can also be conducted in this patient population.

## Paediatric Clinical Investigation Centre

### Paediatric Intensive Care

#### *PRESENTATION OF THE CLINICAL SPECIALISED UNITS*

There are 3 specialists and 10 beds in this unit, with more than 500 admissions every year. The patients, between 0 and 15 years old, have medical or surgical problems, mainly cardiac, respiratory, neurologic and digestive diseases. The expertise of the Cliniques Saint-Luc in acute hepatic failure and paediatric liver transplantation is recognised worldwide, particularly within the intensive care field. About 150 children are transferred from other hospitals, 20% of them for the multidisciplinary treatment of a cardiac malformation.

More than five clinical trials were performed since 2005 (multicentric studies on inhaled nitric oxide in newborns and cardiac patients, activated C protein, the need of blood transfusion in critically ill children,...). Moreover, the unit is involved in the protocols of other members of the PCIC (immunosuppression after liver transplant, different types of cardioplegic solutions during open heart surgery,...).

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### Anesthesia

#### *OTHER UNITS INVOLVED IN THE PCIC*

The department includes 19 staff members out of which 5 developed an expertise in paediatric anaesthesia. They are often involved in the care of infants and children followed in the clinical specialised units described above. Moreover, they participate to multicentric international trials devoted to special aspects of paediatric anaesthesia: for example, one trial to evaluate a new type of cuffed endotracheal tubes for children and one epidemiologic survey on the complications of locoregional anaesthesia in children were started in 2005.

### Center for Human Genetics

#### *OTHER UNITS INVOLVED IN THE PCIC*

The Centre for Human Genetics is dedicated to the diagnosis of hereditary diseases and genetics syndromes, antenatal diagnosis, drug pharmacogenetics and molecular biology techniques. The staff includes 4 medical doctors, 3 PhD and 35 technicians. There is a special interest in molecular karyotyping (CGH). The aim is to increase the diagnosis sensitivity of unexplained syndromes and to discover the genes involved.

### Dental Care

#### *OTHER UNITS INVOLVED IN THE PCIC*

The dental care department elaborates collaboration with each of the paediatric specialities, mainly for prevention, multidisciplinary outpatient examinations and individual patient care.

## Paediatric Clinical Investigation Centre

### Laboratory of analytical biochemistry

#### OTHER UNITS INVOLVED IN THE PCIC

The unit has a recognised expertise in the fields of xenobiotic analysis, pharmacokinetic and pharmacogenetic, metabolic disease, neonatal screening... Equipment includes immuno-analyzers, chromatographic and mass spectrometric instruments (HPLC, LC-MS/MS and GC-MS).

Quantitative measurements of several drugs were developed and published by the unit. Moreover, complete drug pharmacokinetic is performed routinely, including biodisponibility, clearance, distribution volume, metabolism,...

### Paediatric radiology unit

#### OTHER UNITS INVOLVED IN THE PCIC

The staff is composed by three senior paediatric radiologists. All the modern facilities and up-to-date equipments are available for imaging children from birth to adulthood. In 2005, 15470 X-rays, 7990 ultrasound studies, 1059 MRI and 778 CT scans were performed. All the fields of paediatric medical care are covered. Interventional radiology is also performed, essentially in urology, hepatology and transplantation.

### Pathology

#### OTHER UNITS INVOLVED IN THE PCIC

Pathologists are familiar with the analysis and the reporting of samples for clinical investigations, when necessary for the protocol.

### Pharmacy

#### OTHER UNITS INVOLVED IN THE PCIC

Two chemists and one assistant are allocated to clinical trials. After reading of the protocol, they organise the different steps of the study, including reception of the drugs with conformity control, appropriate storage of the products, delivery of the drugs based on specific prescription, preparation of the drug when necessary. An updated file allows accurate account of the product. The unit is involved in the monitoring inspection and audits.