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The Pediatric Clinical Research Unit (Petit-CRU) – Budget justification

For this study, the study team uses a special clinical research unit called Petit-CRU (<https://www.uzleuven.be/nl/petit-cru>).

Petit-CRU is a state-of-the-art unit for clinical and registry studies in children. The research team of Petit-CRU provides support in the development, start-up, planning, implementation, and follow-up of clinical and registry pediatric studies. Additionally, we offer support to researchers in both advising and practical aspects for academic and commercial studies, e.g. applications for Clinical Trial Center (CTC), Ethical Committee (EC), financial and legal regulation, and quality control.

Petit-CRU consists of a specialised, qualified, and GCP-certified research team. Nursing tasks are carried out by pediatric nurses who also have knowledge of the studies. This makes the conduct of the study much more efficient and easier for the study team (high quality & close follow-up).

To facilitate the planning and activities of the pediatric studies, Petit-CRU has a separate unit with several facilities: two research rooms, a room with three beds with own TV for therapy monitoring, and a laboratory including centrifuges and freezers (-20°C and -80°C) to process and store study samples.

In addition, Petit-CRU creates a safe and familiar environment for patients and parents allowing to build a trusting bond with our team. The patients are also monitored more closely by the physician and other disciplines. Game guidance, hospital school, physiotherapists, and psychologists are provided. To minimize pain during blood drawing, different methods are applied e.g. pain-numbing plasters, VR glasses, and nitrous oxide.

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The budget for Petit-CRU covers the following costs:

- The operational manager costs: follow-up of CTC/EC/budget/payments/...
- The study coordinator costs: actions in the flow chart, data entry, ...
- The nursing costs: monitoring of therapy, vital signs, blood collection, ...
- Administration (signatures, mails, meetings,...)
- SIV / Monitoring visits / Close-out visit

Kind regards



Prof. Dr. I. Hoffman