

A 3-Year Transformation of a Belgian Clinical Trial Pharmacy Team



Marie Coenen^{1,2}, Stefanie Goris^{1,2}, Thomas De Rijdt^{1,3} and Isabel Spriet^{1,3}
¹Pharmacy Department, University Hospitals Leuven, Leuven, Belgium
²Clinical trial team of the Pharmacy Department, University Hospitals Leuven, Leuven, Belgium
³Department of Pharmaceutical and Pharmacological Sciences, KU Leuven, Leuven, Belgium

WHAT WAS DONE?



Figure 1. Schematic overview of the 3-year transformation of the clinical trial team of the UHL pharmacy

WHY WAS IT DONE?

- **University Hospitals Leuven (UHL)**, a 1995-bed, tertiary care hospital, constitutes an **attractive setting for clinical trials** and a coveted partner for sponsors, due to its
 - **Close collaboration** between UHL's clinicians and scientists from Belgium's oldest academic institution KU Leuven;
 - **Patient availability**: specialization in a wide range of medical fields to treat complex pathologies;
 - **Infrastructure**: support of a Clinical Trial Center (CTC) experienced in scientific research, and review by a qualified, independent Ethics Committee (EC);
 - **Facility and training**: experienced and qualified research staff throughout the hospital;
- In recent years, both the number of clinical trials conducted at the UHL and the level of complexity of research design have increased in line with the **globally fast-growing research field**.
- Adopting the **changing research field** while ensuring the highest regulatory compliance was **challenging** for the **clinical trial team of the UHL pharmacy**.

WHAT WAS ACHIEVED?

- **Rapid growth** of pharmacy research activities was shown i.a. by an increase in the total number of active clinical trial protocols (table 1).
- Until 2019, **quantitative expansion was not followed by qualitative growth**, since staffing remained steady at 13 full-time equivalents (FTE) and the applied costs were outdated and not cost-effective.

Table 1. Results of the 4-year retrospective evaluation about research (activities) of the UHL pharmacy

	2017	2018	2019	2020
Active clinical trial protocols at the UHL pharmacy	964	1035	1128	1256
Applied prices for trial related pharmacy activities	Outdated	Outdated	Outdated	Updated
FTE at the clinical trial team of the UHL pharmacy	12,6	13	13	19

- To enable the transition towards qualitative growth, an **up-to-date pharmacy budget table** was developed based on the latest ABC-analysis and, along with an **estimate of future income**, approved by the hospital board in 2020.
- This allowed the following reinforcements:

- 19 FTE staff**
- + extra storage capacity for IMP**
- + research dedicated clean rooms**
- Implementation of the budget table using computerized support enabling automated billing**

HOW WAS IT DONE?

- 2016** • An 'Activity Based Costing' (ABC)-analysis was conducted by the Belgian Association of Hospital Pharmacists to determine the cost of various pharmacy activities within a clinical study.
- 2019** • The outcome of the analysis was **revised** to concur the fast-growing clinical research field.
- 2020** • To affirm the need to apply updated prices, a **retrospective evaluation** was performed documenting the number of clinical trial protocols, pharmacy staffing and applied prices over the past 4 years.
- The data were analyzed, conclusions were drawn and put into practice by presenting the **objectified unmet needs for reinforcement in resources** to the hospital board.
- 2022** • **Allocation of resources and reorganization of the flow** of conducting clinical trials in the UHL pharmacy.

WHAT IS NEXT?

- Continued increase of **digital quality** by automating accountability and compounding.
- Focusing on qualitative growth by advancing the role of clinical trial pharmacists into a specialized member of
 - the **hospital Research & Development team** (to participate in protocol development and consult on IMP management)
 - the **clinical pharmacy team** (for patient educating and monitoring of therapy).

