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OPTIMIZING PHARMACEUTICAL MANAGEMENT OF CLINICAL TRIALS

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Introduction

The clinical trials pharmacists have an essential role in managing the pharmaceutical part of interventional studies (1).

Objective

Provision of a template for improving trials management for a growing number of studies without increasing personnel resources.

Methods

A retrospective study was conducted between 2016 and 2020 at the service of pharmacy of a University Hospital in Switzerland.

Results and discussion

In five years, the number of clinical trials (in progress) managed at the pharmacy **increased by almost 50%**.

Classification of clinical trials by sponsor and by domain

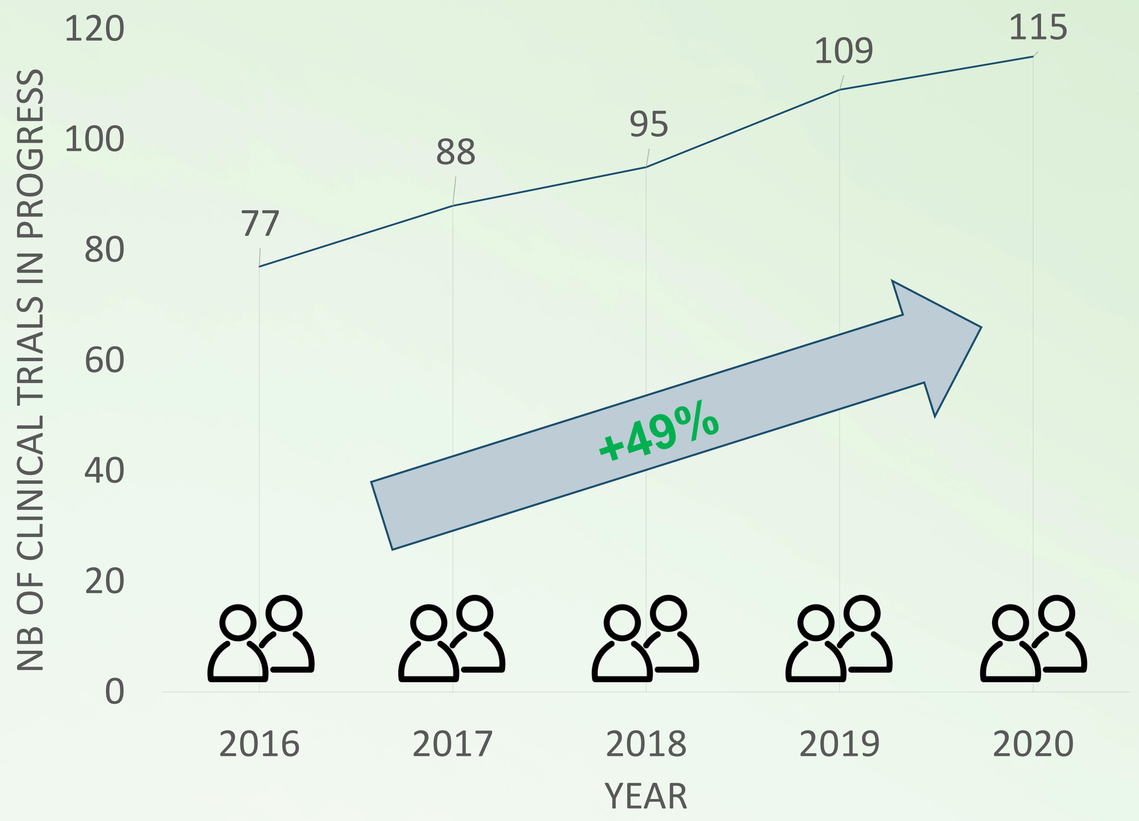
Between 01.2016 and 12.2020	Oncology	Other	Total
Industry n(%)	82 (63%)	19 (33%)	101 (54%)
Hospital/academic n(%)	48 (37%)	38 (67%)	86 (46%)
Total n(%)	130 (100%)	57 (100%)	187 (100%)

Duration of clinical trials

Duration of studies (years)	<1y	1-2y	3-4y	5-8y	9-10y	Total	Mean
Number of trials closed between 2016 and 2020	7	45	26	9	1	88	2.43 y (SD 1.77)
Number of trials in progress in 12.2020	36	34	19	9	1	99	
Total						187	

Conclusions

Substantial and improving changes could be made gradually in the routine practice of the clinical trials management by pharmacists to permit affording the yearly increase of the number of clinical trials whilst meeting tightened GxP requirements.



Considered and realized changes in routine tasks to **afford the higher workload** induced by the increased trials' number and to **still meet the tightened GxP requirements** :

- Electronic temperature monitoring
- Destruction of investigational medicinal products (IMP)
- Training of pharmacy technicians
- Internal standard operating procedures (SOP)
- Delegation to pharmacy technicians
- IMP reception modalities
- Management of used IMP
- Financial contracts with study sites
- Etc.

Improvement of the pharmaceutical and administrative management of clinical trials, without increasing personnel resources

Références

1. Die Rolle der Spitalapotheke in klinischen Studien. **Vera R. Mitter, Isabelle Sommer, Hélène Schaller, Stefanie Deuster, Jeannette Goette.** 12, 24. 03 2021, Schweizerische Ärztezeitung, Bd. 102, S. 427-429

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GSASA LUZERN KONGRESS CONGRÈS 2022