Importance of residual Investigational Medicinal Product count

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BACKGROUND
Good clinical Practice in clinical trials specify the role of the pharmacist. For each nominative dispensation, the pharmacist is responsible to the education of the patient on the treatment, residual Investigational Medicinal Product (IMP) count, and thus the evaluation of the compliance.

PURPOSE
The objective of this study is to assess the importance of pharmaceutical vigilance about IMPs.

MATERIALS AND METHODS
This prospective study has been realized during three months. For each nominative dispensation, a count of returned treatment (RT) by the patient from the previously dispensation was performed to assess compliance.

RESULTS
117 returned treatment analyzed

- 1 clinical trial not included = 43 RT
- 23 RT non conform = 48.9%
- Impossibility to evaluate compliance:
  - posology changes not notified to the pharmacy
  - unsuitable secondary packaging

Proportion of non conformity of Investigational Medicinal Product’s returns

- 80% conform
- 20% non conform

Time management of returned treatment [n=117]

- 13% 0-10 min
- 16% 10-60 min
- 17% 60 min-4h
- 35% 4h>9h
- 6% > 9h
- 13% Not reseigned

Average counting time = 12 minutes (5-30 min)

A returned IMP exact count was operated during the dispensation for 34% of RT.

In all cases, a global analysis of RT was performed before the dispensation.

CONCLUSIONS
This study points out the major role of the pharmacist in the education of the patient enrolled in clinical trials, about the return of all experimental medication and therapeutic schedule. It appeared very important to evaluate compliance during the act of dispensation, independently of the time consumed (12 min) in order to correct on time, possible errors of medication intake.

Keys words: Good clinical Practice, clinical trials, compliance