

# Optimization of sampling of injectable anticancer drug preparations and improvement of analytical control in a Centralized Preparation Unit







Thibaut Gelé, Mahamadou Tandia, Vanessa Thibault, Laurence Bonhomme-Faivre, Vincent Castagné  
AP-HP. Université Paris Saclay, Hôpital Paul-Brousse, PUJ, Unité de Préparation Centralisée des Médicaments Anticancéreux Injectables

## Background

Our unit prepares around 25.000 preparations a year whose less than 10.000 under a subcontract. Analytical control (AC) represents approximately 80% of the exhaustive control of our production. One of the main causes of nonconformities (NC) of AC results is the quality of sample and its representativeness of the controlled preparation.

The objective was to compare two sampling techniques in order to keep the most efficient method to guarantee a representative sample of the content of the final preparation.

## Sampling techniques

	Current technique (P1)	Tested technique (P2)
Sampling device	 BD Vacutainer® Luer Adapter	 BD Eclipse™ Safety Needle
Injection site		
Sampling site		

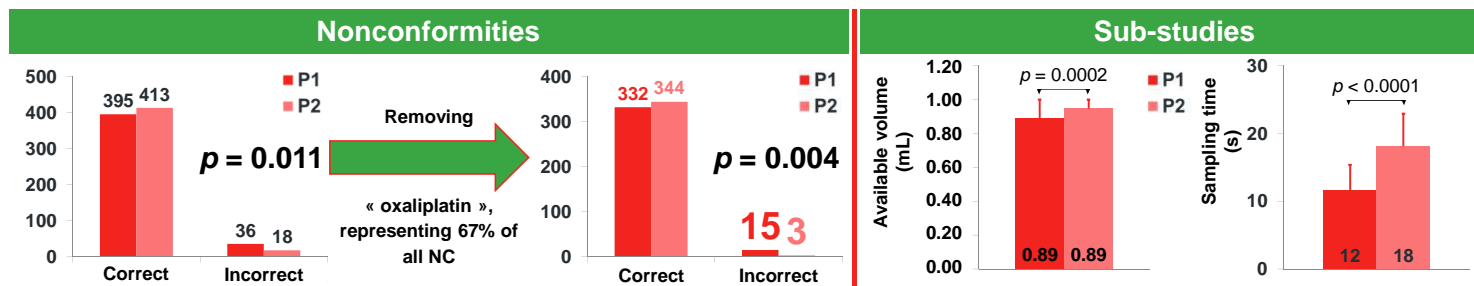
## Statistical analyses

- Comparison of the number of nonconformities  
*χ<sup>2</sup> test of homogeneity (α=5%)*
- Record of all sting injuries
- Two comparative sub-studies:  
*Paired-sample T-test (α=5%)*
  - Available volume (V) for QcPrep+® (n=100)
  - Time (T) it took to sample (n=50)

## Prospective observational study

- Period : 2019 January to February
- Samples taken from the same preparation
- Analytical control: UV absorption and RAMAN spectroscopies (QcPrep+®)
- Inclusion criteria:
  - Active ingredient (AI) can be controlled analytically
  - Final volume is ≥ 100 mL
  - Active ingredient which there is the most NC, based on a 2018 NC review (absolute value of relative error > 15%)

## Results



➤ No sting injuries were reported

## Conclusion

From 8% to 4% of NC (and from 4% to <1% removing « oxaliplatin »)

- Better representativeness of the controlled preparation by sampling from a different site of the injection site of the drug

## Change in unit practices

Adoption of the new sampling technique and enhancement of the security by the use of the One-Use Holder

