

## INTRODUCTION

- ❖ To **guarantee the quality of chemotherapy** preparations, several control techniques have been developed, such as analytical systems or video-assistance.
- ❖ At HEGP, 70% of preparations are controlled by analytical control (AC). In order to control the remaining 30%, a **reinforced visual control** traced during production has been introduced. Preparations in compliance (right product at the right dose +/-5%) are released for dispensing.

 **Feedback on visual inspection and assessment of factors influencing the performance of double visual inspection**

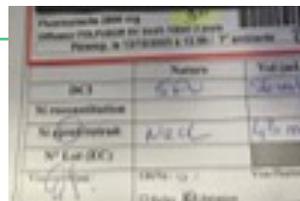
## MATERIAL AND METHODS

### Retrospective analysis

- January 2021 – December 2022 (24 month)
- Visual inspection of chemotherapies not controlled or not analytically controllable by a neutral person who collects: International Non-proprietary Name (INN), volume of drug substance introduced and, if reconstituted: volume and nature of solvent.
- Matching between Chimio<sup>®</sup> manufacturing sheet and data collected on an Excel<sup>®</sup> file by a member of the control laboratory.

### Data collection

- Preparation conformity: right product, right dose, reconstitution
- 2 types of molecules: clinical trials and non-clinical trials
- Operator visual control : devoted or not
- Criticality of preparation day: critical day if AC > 50% failure rate



### Data analysis

- Descriptive analysis: proportion of non-compliant preparations, clinical trial preparations, preparations requiring prior reconstitution, % of preparations lost.
- Identification of factors influencing visual control performance using multivariate logistic regression (Rstudio<sup>®</sup> software): criticality of the day, control operator, production difficulty (reconstitution or not), type of molecule, etc.

## RESULTS

### 1 – Descriptive analysis

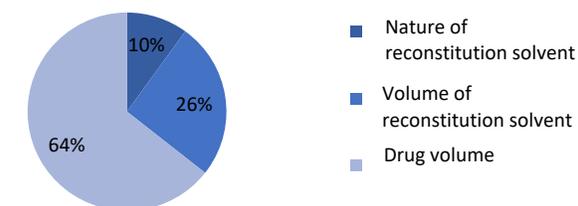
- ❖ 20,629 preparations checked by visual control of which :
  - ❖ **2477 (12%) clinical trial** preparations
  - ❖ **4479 (22%) preparations requiring prior reconstitution**
  - ❖ **3477 (17%) controlled by a devoted person** to visual control

- ❖ **133 (0.65%) preparations identified as non-compliant after conciliation, of which 102 (77%) required prior reconstitution.**

### Disposal of non-conformities



### Nature of non-conformities



### 2 – Multivariate logistic regression

Characteristic	OR <sup>1</sup>	95% CI <sup>1</sup>	p-value
Reconstitution * Day AC failure > 25%			
Yes * Not critically	4.31	1.83, 10.9	<b>0.001</b>
Type * Day AC failure > 25%			
Clinical trial * Not critically	3.45	1.14, 10.7	<b>0.028</b>

<sup>1</sup> OR = Odds Ratio, CI = Confidence Interval

2 factors influencing visual control performance were identified as increasing the risk of non-compliance:

- ❖ **control of preparations to be reconstituted**, on days when 25% of AC are failing to perform
- ❖ **control of clinical trials**, on days when 25% of AC are defective.

On days when 25% of the AC is missing, the visual control is carried out by a person not devoted to visual control.

## DISCUSSION - CONCLUSION

- ❖ The visual control is the minimum control required to guarantee the quality of chemotherapies in accordance with BPP.
- ❖ Implementation of a reinforced and traced visual control which enables preparations to be released after reconciliation between the data collected in Excel<sup>®</sup> and the manufacturing sheet.
- ❖ **Limiting points of the visual control:** reconstitution stage, persons carrying out the control and the type of product to be controlled.
- ❖ Revision of production unit organization: one person dedicated to VCD on critical days

**→ The reinforced and traced visual control is a reliable tool for securing the chemotherapy circuit and guaranteeing control of 100% of the preparations produced in our unit.**