

# PROFILE AND COMPLEXITY LEVEL OF CLINICAL TRIALS IN THE PHARMACY SERVICE

Gázquez Pérez R<sup>1</sup>, Alcalá Soto Á<sup>1</sup>, Puvecino Moreno C<sup>1</sup>, Jiménez Pichardo L<sup>2</sup>, Varas Pérez A<sup>1</sup>, Sánchez-Matamoros Piazza V<sup>1</sup>, Sierra Sánchez JF<sup>1</sup>, Gómez Germá P<sup>1</sup>, Mora Herrera C<sup>1</sup>, Gómez de Travededo y Calvo MT<sup>1</sup>.

<sup>1</sup>Hospital Universitario Jerez de la Frontera (Pharmacy Service)

<sup>2</sup>Hospital San Juan Grande, Jerez de la Frontera (Pharmacy Service)

## BACKGROUND

Pharmacists are involved in critical steps for the performance of clinical trials (CT), such as the reception, dispensing and storage of samples.

## PURPOSE

To describe the profile and analyse the complexity level of clinical trials.

## MATERIAL AND METHODS

Descriptive and observational study

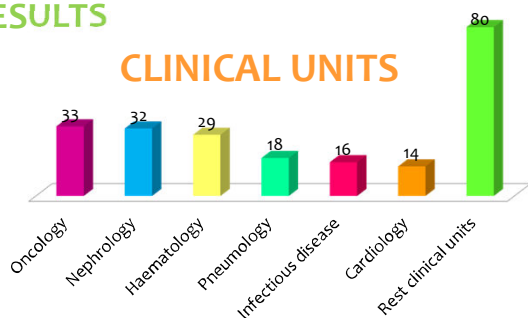
### Calvin Lamas Classification

Low Complexity = 6-10 points  
Moderate Complexity = 11-19 points  
High Complexity = 20-33 points

1. Blinding
2. Number samples/clinical trial
3. Type of dispensation
4. Professionals involved
5. Use of interactive system (IVRS/IWRS)
6. Pharmacy preparation
7. Storage conditions
8. Need for additional conditioning material

## RESULTS

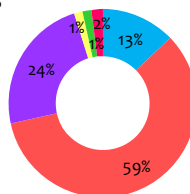
### CLINICAL UNITS



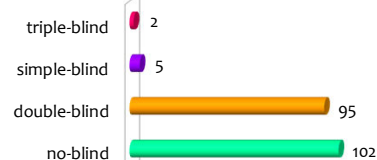
### STUDY DESIGN

Phases

- II
- III
- IV
- I-II
- II-III
- III-IV



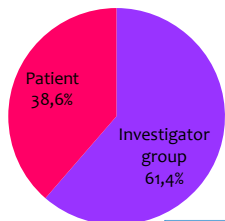
### Masking



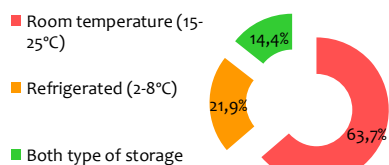
## SAMPLES

2 samples/CT (0 - 11)

### Type of dispensation



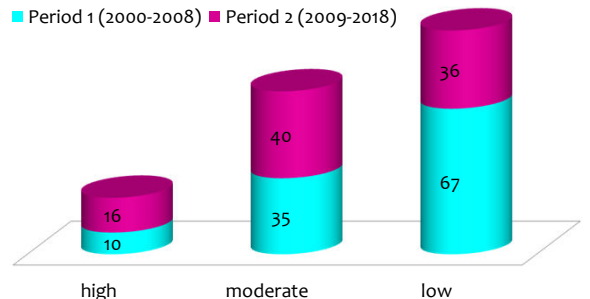
### Storage Conditions



Preparation under aseptic conditions = 20,6%

## COMPLEXITY

■ Period 1 (2000-2008) ■ Period 2 (2009-2018)



## CONCLUSIONS

The most frequent CT was phase III, no-blind, randomised and controlled. Oncology, haematology and nephrology units performed almost half of the CT during the study period. Period 2 was characterised for having a higher number of high complexity CT.

