

COMPLEXITY OF CLINICAL TRIALS IN A PEDIATRIC HOSPITAL: IMPACT ON THE PHARMACY SERVICE

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BACKGROUND AND IMPORTANCE



Impact of European Regulation 1901/2006

Requires pharmaceutical companies to develop a pediatric investigation plan to ensure the authorization of medicines in pediatrics.

↑ N° of pediatric clinical trials (CTs)

↑ Involvement of the Pharmacy Service (PS) in managing investigational medicinal products

AIM AND OBJECTIVES

- Describe the **characteristics** of active CTs in the PS of a pediatric hospital
- Classify the **complexity** of active CTs using the scale developed by Calvin-Lamas et al.

MATERIAL AND METHODS

Retrospective, observacional study

Included all active CTs in the PS clinical trial unit, in March 2025

Clinical trials profile:

- Trial phase
- Department
- Blinding
- N° of drugs
- Use of interactive web response systems (IWRS)
- Storage
- Special conditioning
- Personnel involved
- Dispensing method

Complexity → Calvin-Lamas Complexity Scale:

Scoring system that classifies the complexity of CTs into three levels

Level 1 (Low, 6-10 pts)

Level 2 (Medium, 11-19 pts)

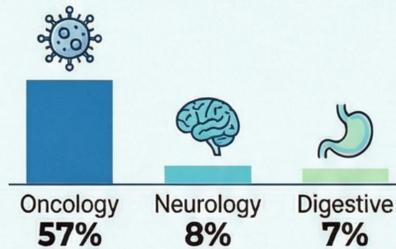
Level 3 (High, 20-33 pts)

RESULTS

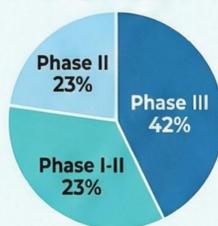
CLINICAL TRIALS PROFILE



83
Active Pediatric Clinical Trials



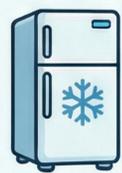
Trial Phases



51% are Open-Label Studies



55%
Involve 3+ Investigational Drugs
Managing multiple drugs increases complexity



49%
Require Refrigerated Storage:
Critical cold chain maintenance (5% need freezer)



76%
Use Interactive Web Response Systems (IWRS) for digital management



89% of trials require the pharmacy to dispense medication directly to the pediatric patient.

49%
Need Special Conditioning:
Specialized packaging required for medication integrity

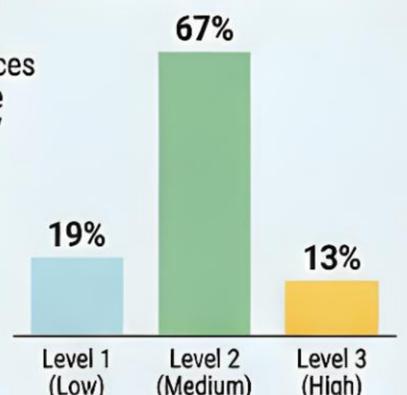
COMPLEXITY OF CLINICAL TRIALS FOLLOWING CALVING-LAMAS COMPLEXITY SCALE

Average Complexity Score: 14.9



67% of Trials are Medium Complexity (Level 2)

Mean score (SD 4.2) places the average trial in the "Medium Complexity" category.



CONCLUSION AND RELEVANCE

- ✓ The *Calvin-Lamas et al.* scale quantify the workload of the PS clinical trials unit, with particular impact on drug preparation, dispensing, and monitoring.
- ✓ Pediatric CTs demand highly individualized attention and rigorous dosage control.
- ✓ A validated pediatric-specific scale would be necessary to more robustly confirm the complexity of CTs in this population.

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