

# Evolution of Pharmacists' Participation as Principal Investigators in Registered Clinical Trials: A Longitudinal Study from 2004 to 2024

J.M. ESPINA LOZANO<sup>1</sup>, H. RODRÍGUEZ RAMALLO<sup>1</sup>, N. BÁEZ GUTIÉRREZ<sup>1</sup>, A. RODRÍGUEZ-PEREZ<sup>2</sup>, Á. MORALES GARCÍA<sup>3</sup>.

<sup>1</sup>HOSPITAL UNIVERSITARIO NUESTRA SEÑORA DE VALME, PHARMACY, SEVILLA, SPAIN, <sup>2</sup>HOSPITAL UNIVERSITARIO VIRGEN DEL ROCÍO, PHARMACY, SEVILLA, SPAIN,

<sup>3</sup>HOSPITAL UNIVERSITARIO JERÉZ, PHARMACY, JERÉZ, SPAIN.

## Aim

To evaluate the participation of pharmacists as principal investigators (PIs) in clinical trials (CTs) registered in ClinicalTrials.gov and analyze its evolution from 2004 to 2024.

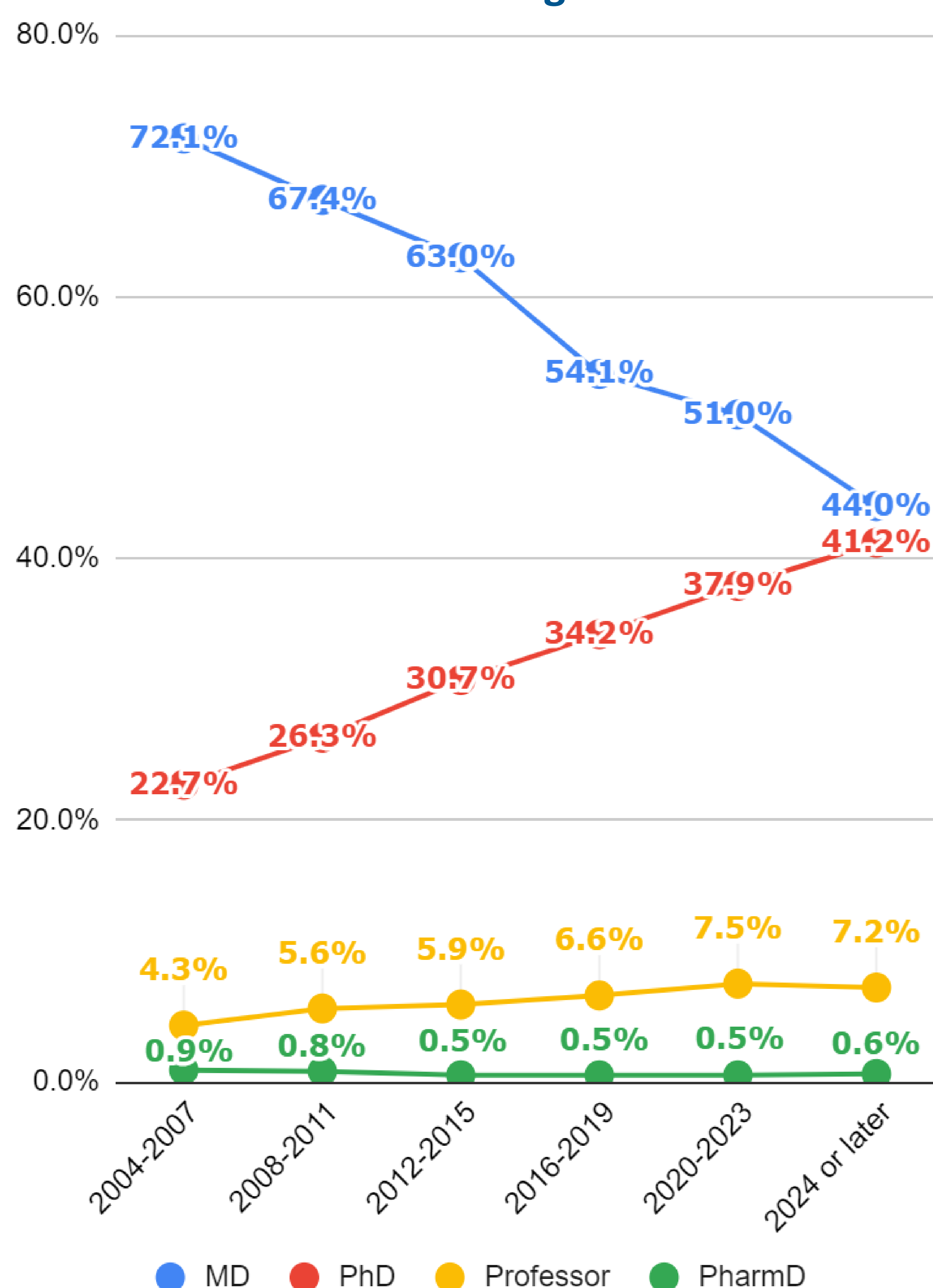
## Methods

- Study Design: Retrospective longitudinal study.
- Period: CTs registered between January 1, 2004, and September 30, 2024.
- Exclusions: Non-interventional studies and CTs without investigator data.
- Collected Variables: Trial phase, intervention design, masking approach, CT start date, Investigator, qualifications, Trial status
- Analysis: Conducted in 4-year intervals using Python 3.12

## Results

<b>Phase of CT</b> (n, %)	Early Phase-1/Phase-1	50423 (16.28)
	Phase-2	51414 (16.60)
	Phase-3	28994 (9.40)
	Phase-4	26205 (8.50)
<b>Intervention design</b> (n, %)	Parallel	184213 (59.70)
	Single group	86958 (28.20)
	Crossover	24751 (8.00)
	Sequential	8361 (2.70)
	Factorial	4.267 (1.40)
<b>Masking approach</b> (n, %)	Open-label	174046 (56.30)
	Single-blind	45063 (14.60)
	Double-blind	4015 (13.00)
	Triple-blind	20812 (6.70)
	Quadruple-blind	28837 (9.34)
<b>CT status</b> (n, %)	Inactive	27042 (8.70)
	Recruiting	48394 (15.60)
	Completed	161411 (52.10)
	Stopped	3078 (9.90)
	Unknown status	42117 (13.60)
<b>Pharmacists as PI</b> (n, %)	At least one	2080 (0.70)
	└ One only	1875 (0.63)
	└ Two	172 (0.06)
	└ More than two	33 (0.01)

## Evolution of participations of investigators with different degrees



## Conclusions

Pharmacists as PIs remain underrepresented (0.7% of CTs). Barriers include limited recognition, training gaps, and institutional bias. Expanding pharmacist training in clinical trial leadership, advocating for supportive policy changes, and promoting awareness within professional organizations are essential steps to elevate pharmacists' roles, enhancing interdisciplinary research and trial outcomes.

A.N.: 6ER-013

