

REPORT ON CLINICAL TRIALS FOR RARE DISEASES IN SPAIN 2023

Clinical trials are research mechanisms used to determine the safety and efficacy of drugs

Currently, **94%** of rare diseases **do not have a diagnostic tool or treatment**



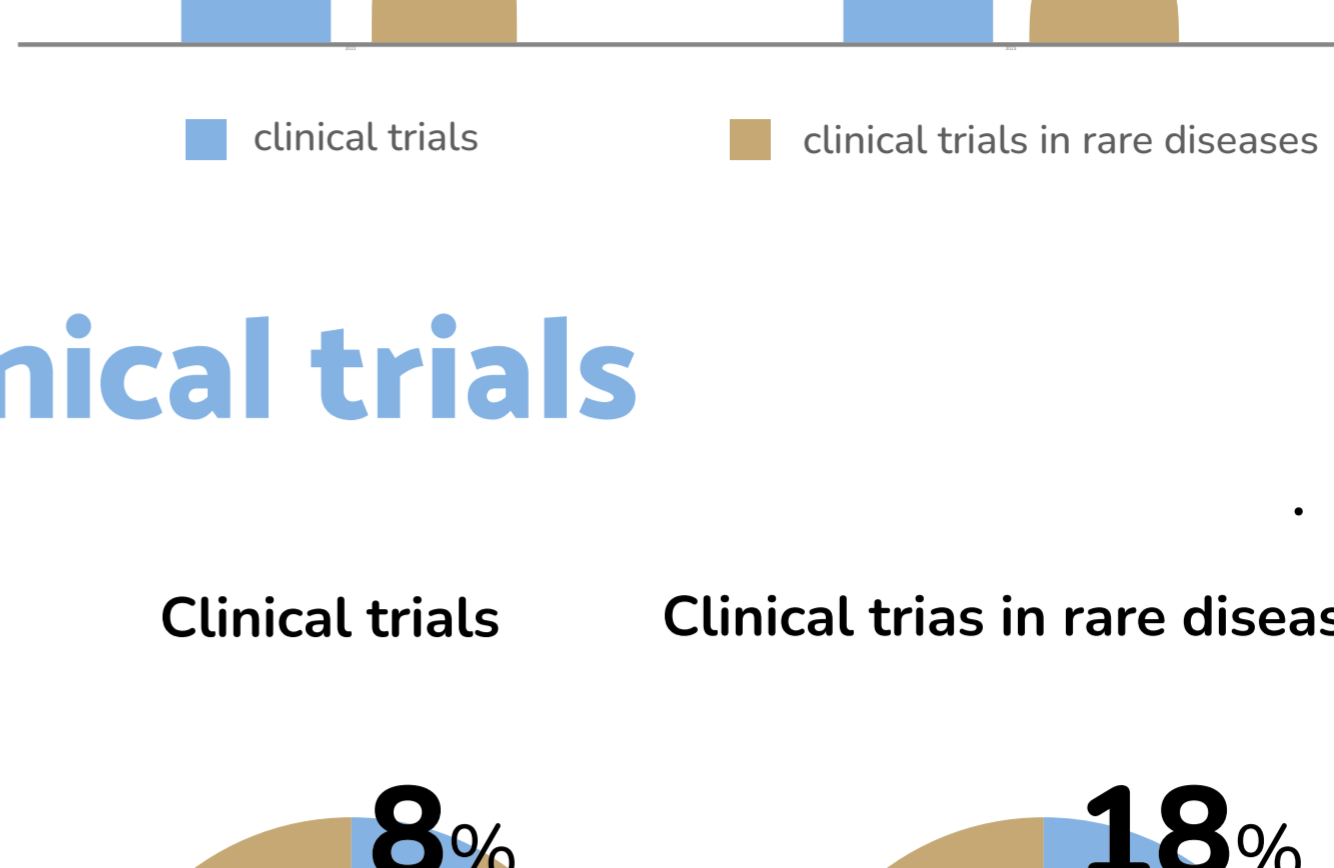
AUTHORIZED CLINICAL TRIALS (2022-2023)

Number of clinical trials

23%

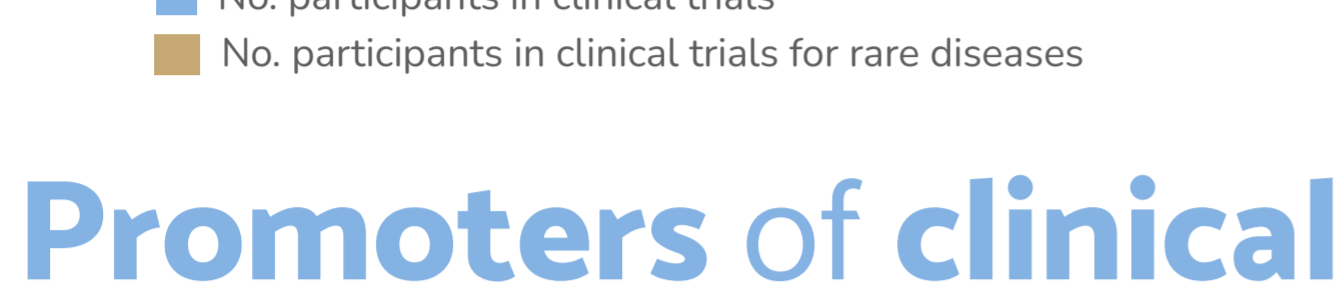
Of clinical trials authorized are for rare diseases

Authorized clinical trials (2022-2023)



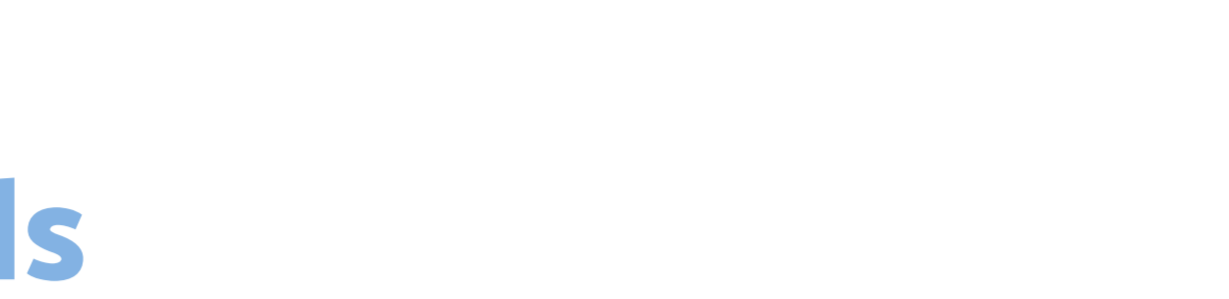
Participants included in clinical trials

Participants in clinical trials (2022-2023)



Clinical trials

Clinical trials in rare diseases

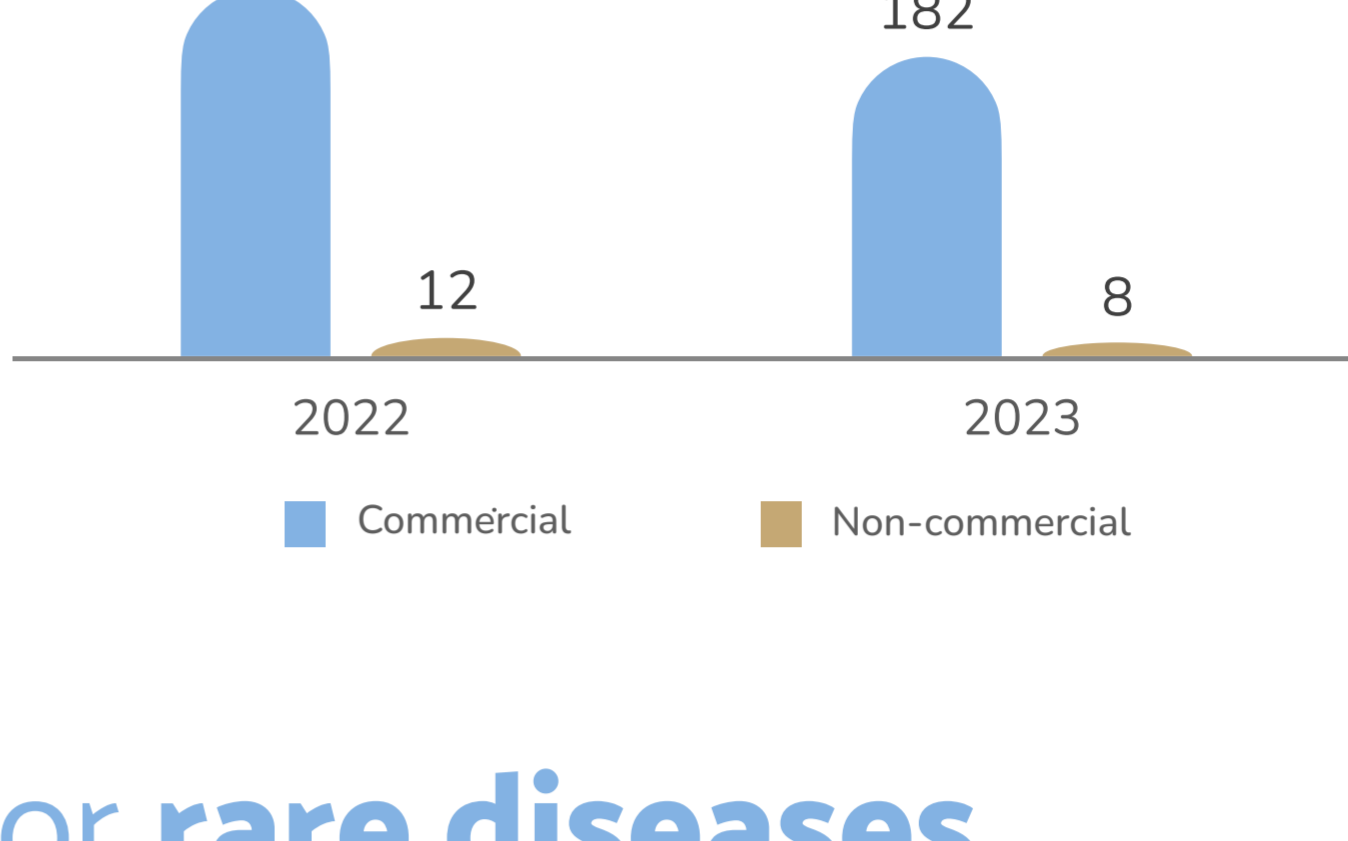


Promoters of clinical trials for rare diseases

96%

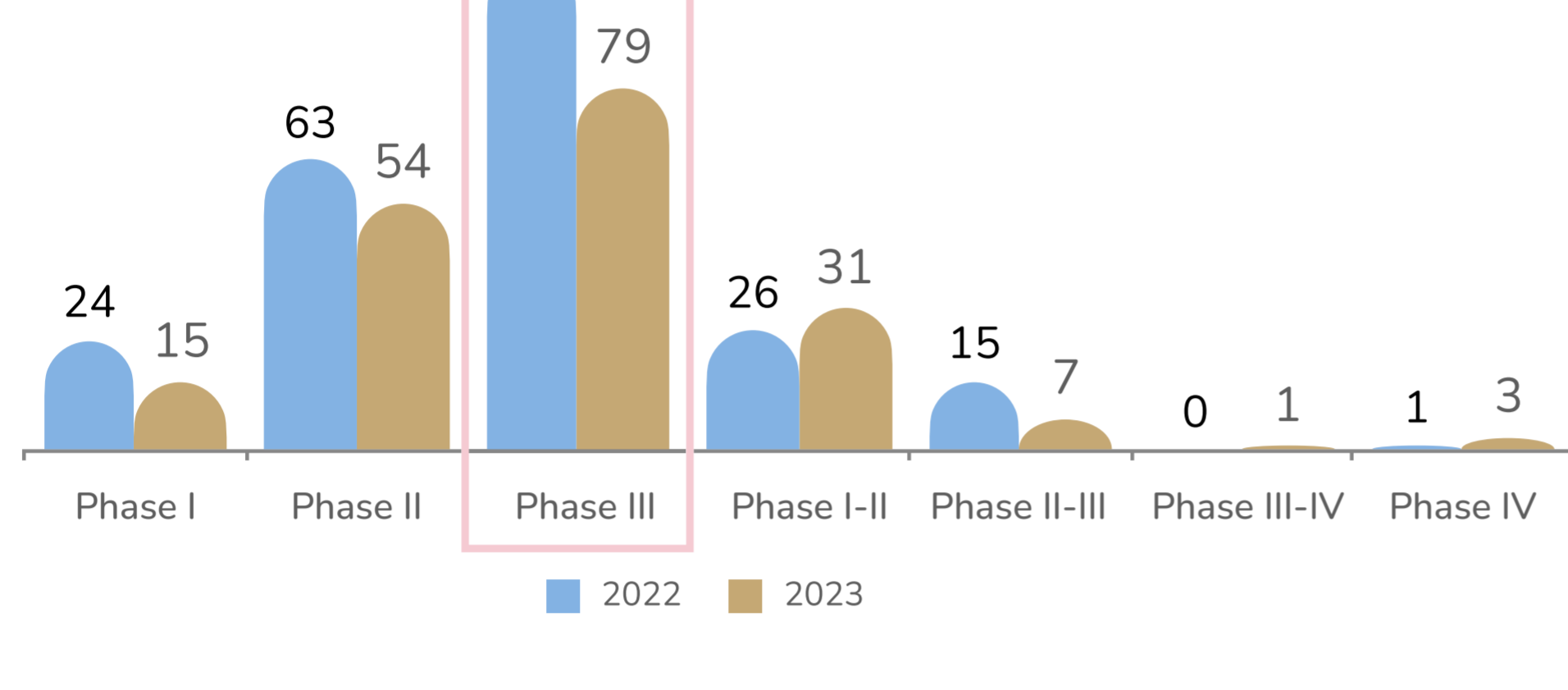
Of clinical trials for rare diseases by commercial promoters

Clinical trials in rare diseases by promoter (2022-2023)

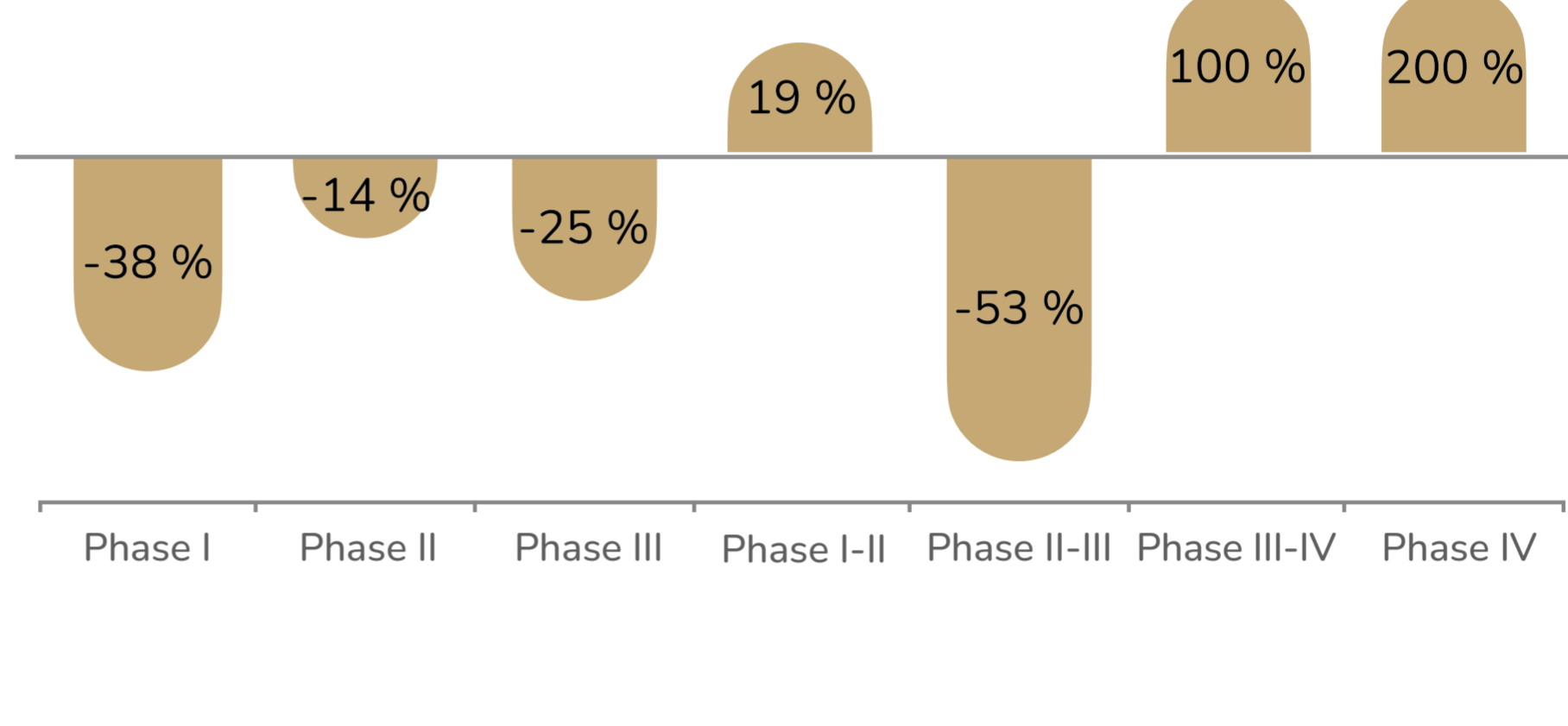


Phases of clinical trials for rare diseases

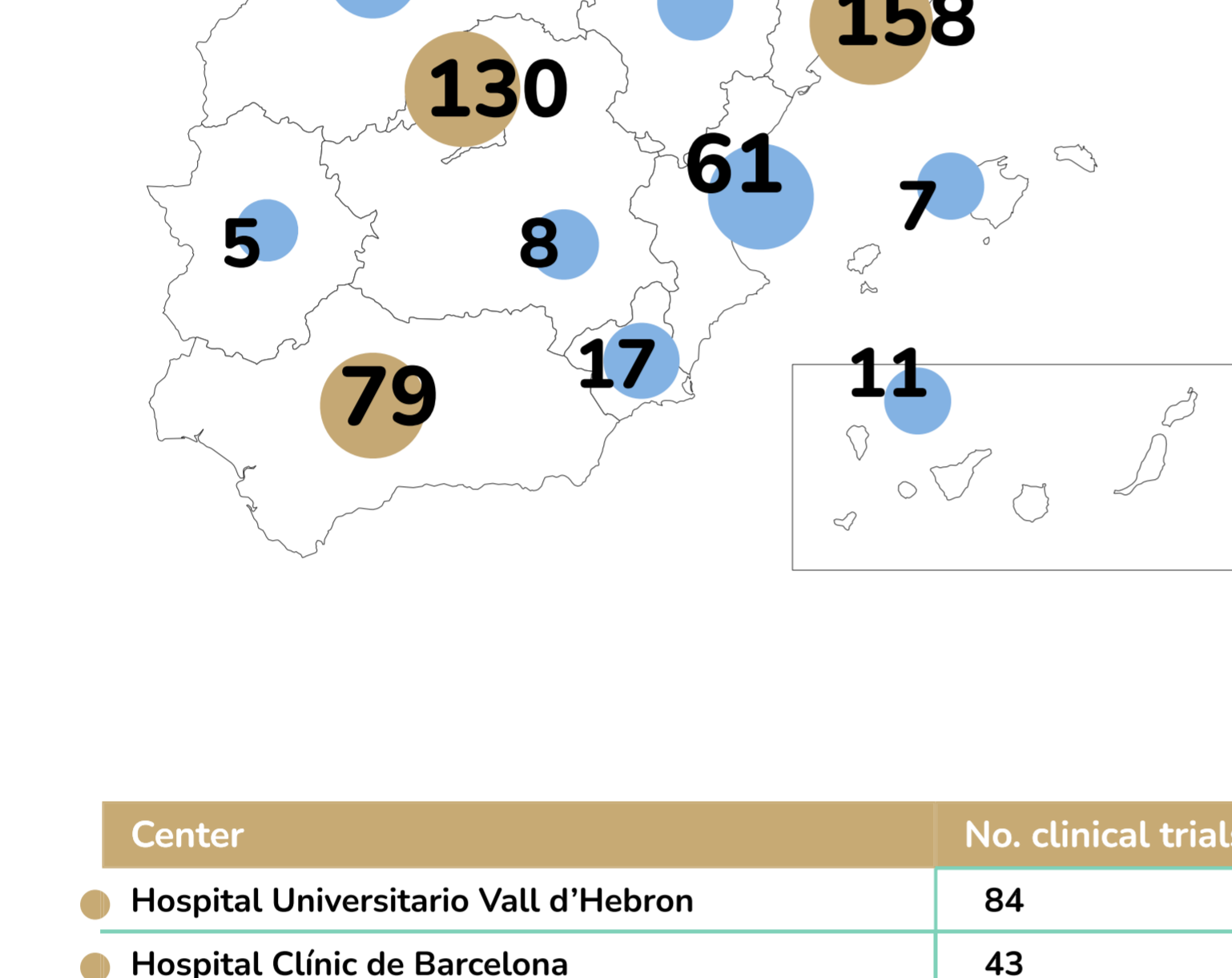
Clinical trials in rare diseases by phase (2022-2023)



Percentage change in clinical trials by phase (2022-2023)



Research centers that have participated in clinical trials for rare diseases



Catalonia, the Community of Madrid and Andalusia are the communities with the highest participation in clinical trials in rare diseases

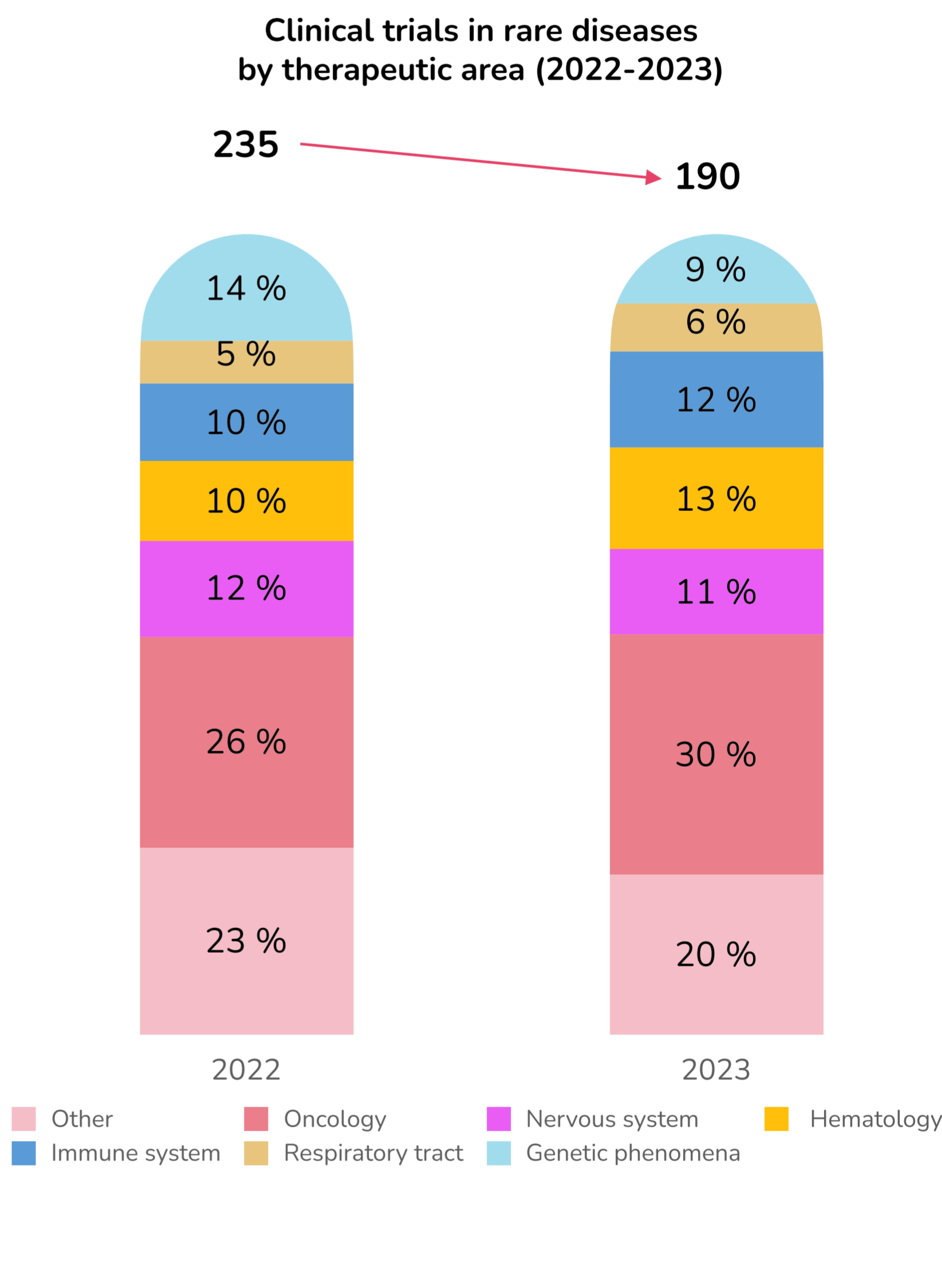
Center	No. clinical trials
Hospital Universitario Vall d'Hebron	84
Hospital Clínic de Barcelona	43
Hospital Universitario 12 de Octubre	41
Hospital Universitario Virgen del Rocío	39
Hospital Universitario La Paz	32
Hospital Universitario Ramón y Cajal	31
Hospital Gregorio Marañón	28
Hospital de Sant Joan de Déu	25
Instituto Catalán de Oncología	24
Clínica Universidad de Navarra	23
Hospital Universitario de Salamanca	22
Hospital Universitario Marqués de Valdecilla	19
Hospital de la Santa Creu i Sant Pau	17
Hospital Universitario y Politécnico La Fe	17
Hospital Universitari Germans Trias i Pujol	16
Complejo Hospitalario Universitario de Santiago	14

Leading hospitals in clinical research for rare diseases (2022-2023)

Research on rare diseases by therapeutic area

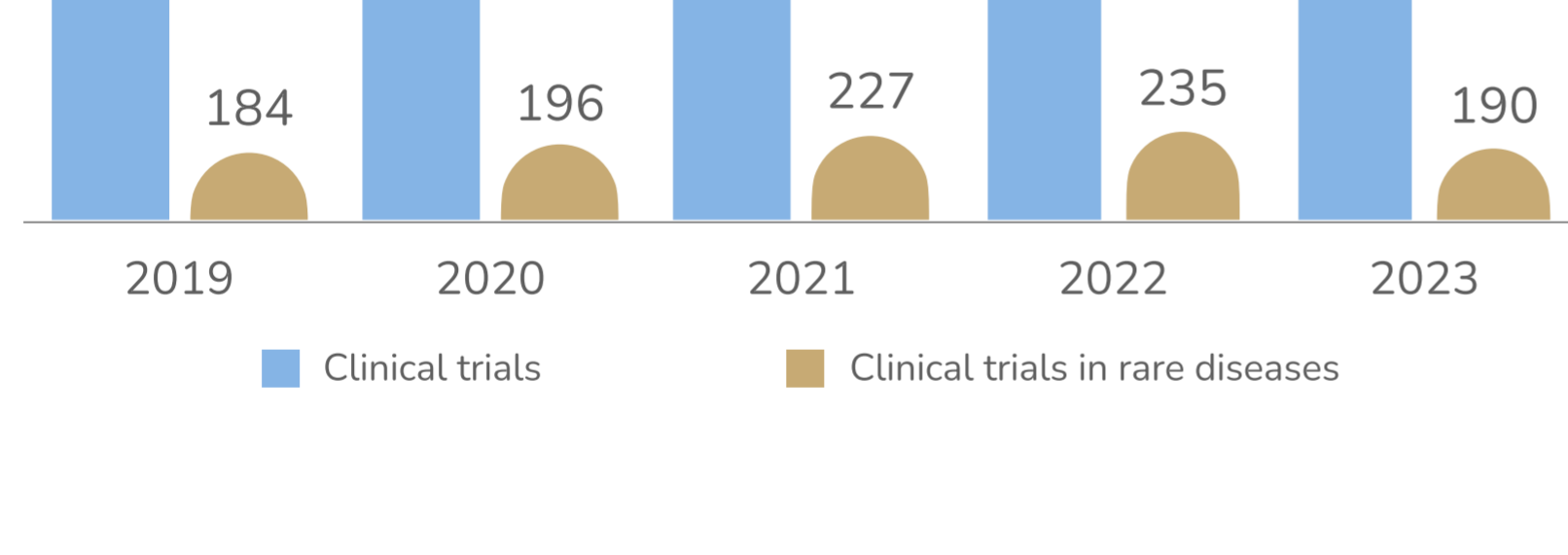
Of the 190 rare disease trials authorised in 2023, **oncology was the leading therapeutic area, with 57 trials (30%)**. Hematology with 24 trials (13%), the immune system with 23 trials (12%) and the nervous system with 20 trials (11%) also occupy leading positions

Clinical trials in rare diseases by therapeutic area (2022-2023)



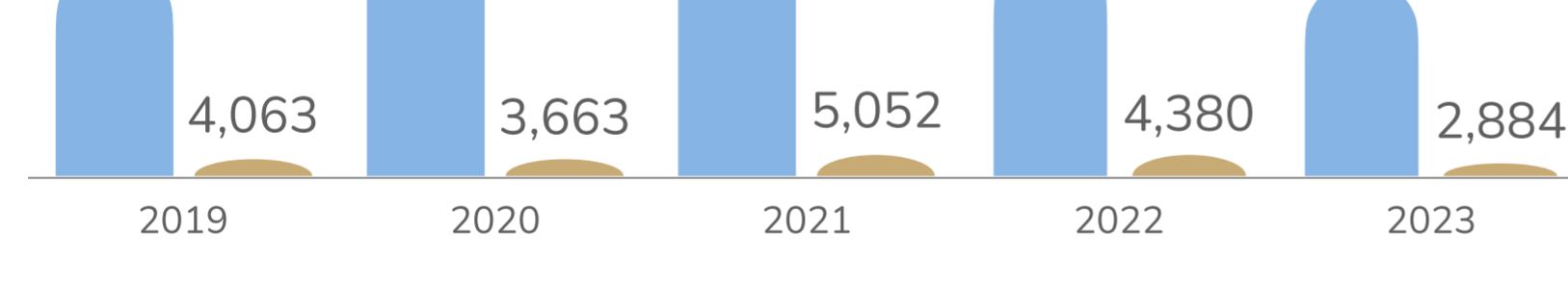
CLINICAL TRIALS 2019-2023

Clinical trials (2019-2023)



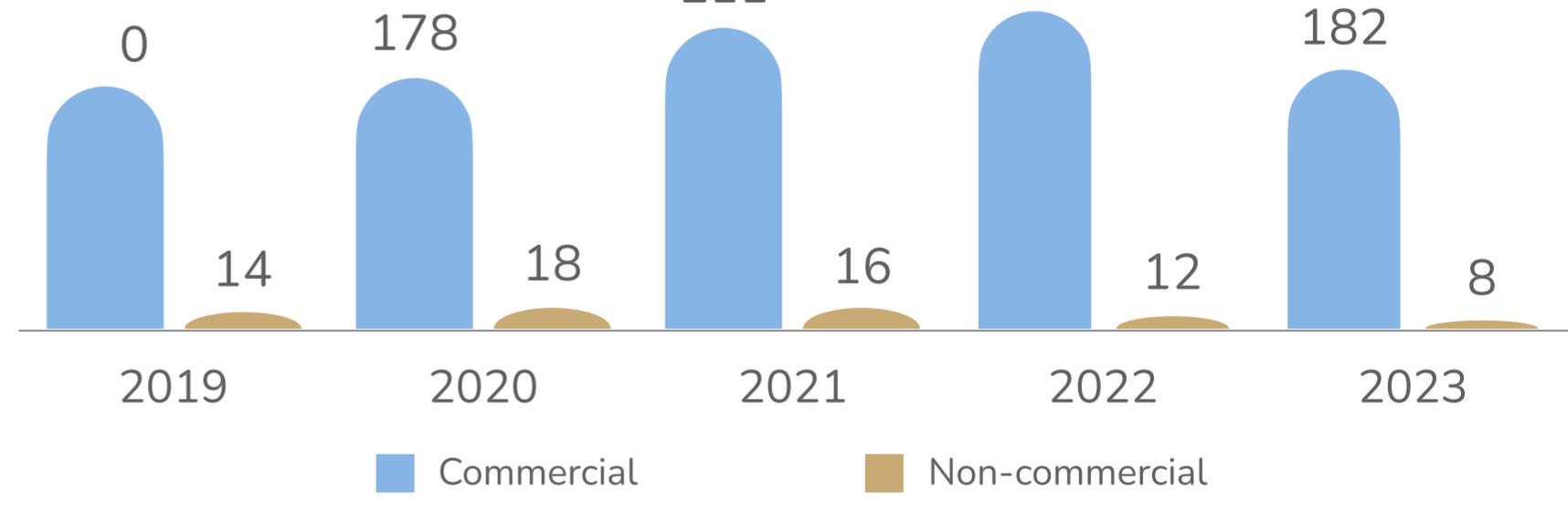
Between 2019 and 2023, **4,610 clinical trials** have been authorised in Spain and **1,032** have been authorised to investigate rare diseases

Participants in clinical trials (2019-2023)



During the last 5 years, 285,429 people participated in a clinical trial, 31,001 in **clinical trials for rare diseases (11%)**

Clinical trials in rare diseases by promoter (2019-2023)

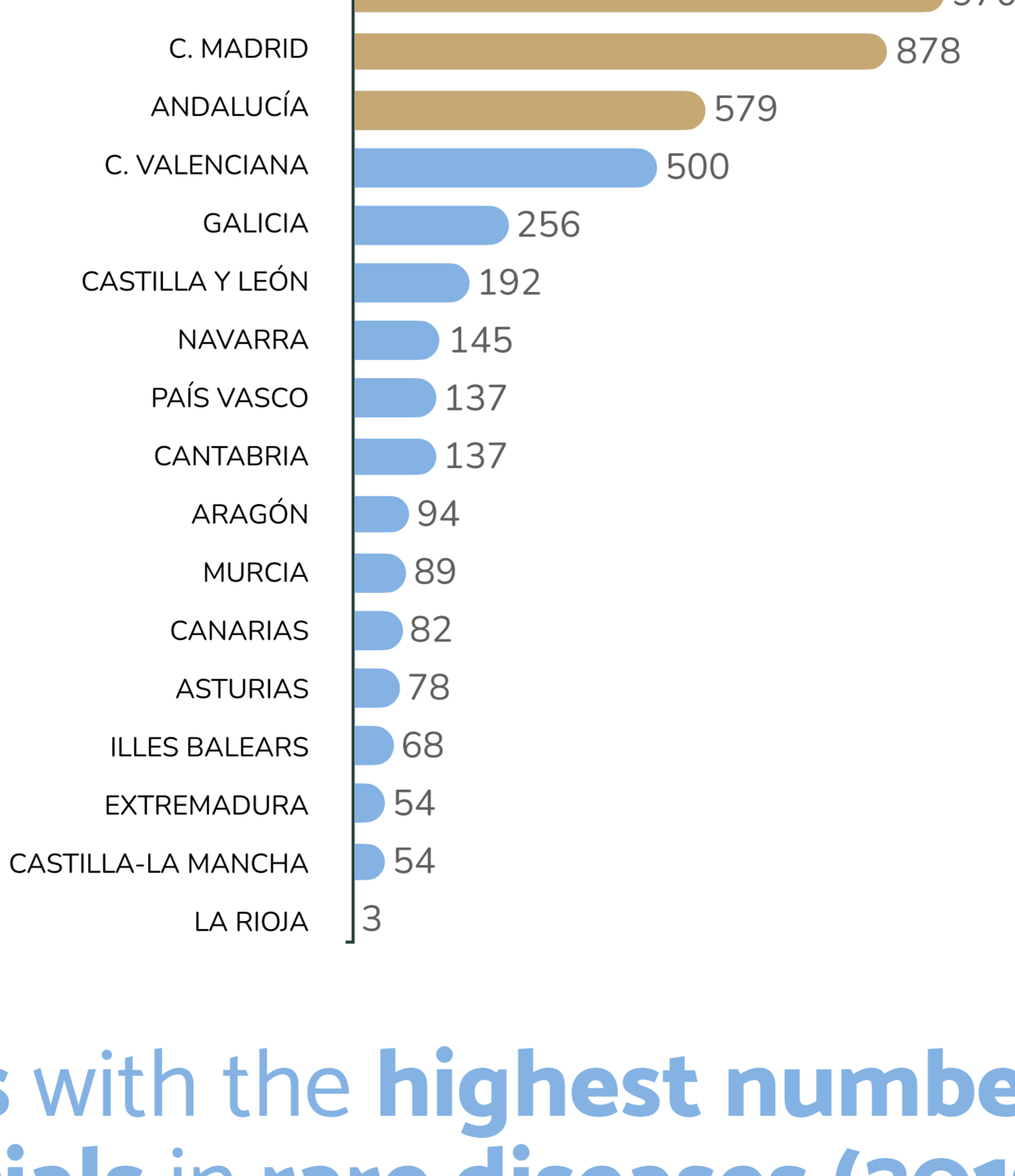


93%

Of the clinical trials for rare diseases have been driven by commercial promoters

Participation of the Autonomous Communities in clinical trials in rare diseases

Clinical trials for rare diseases by Autonomous Communities (2019-2023)

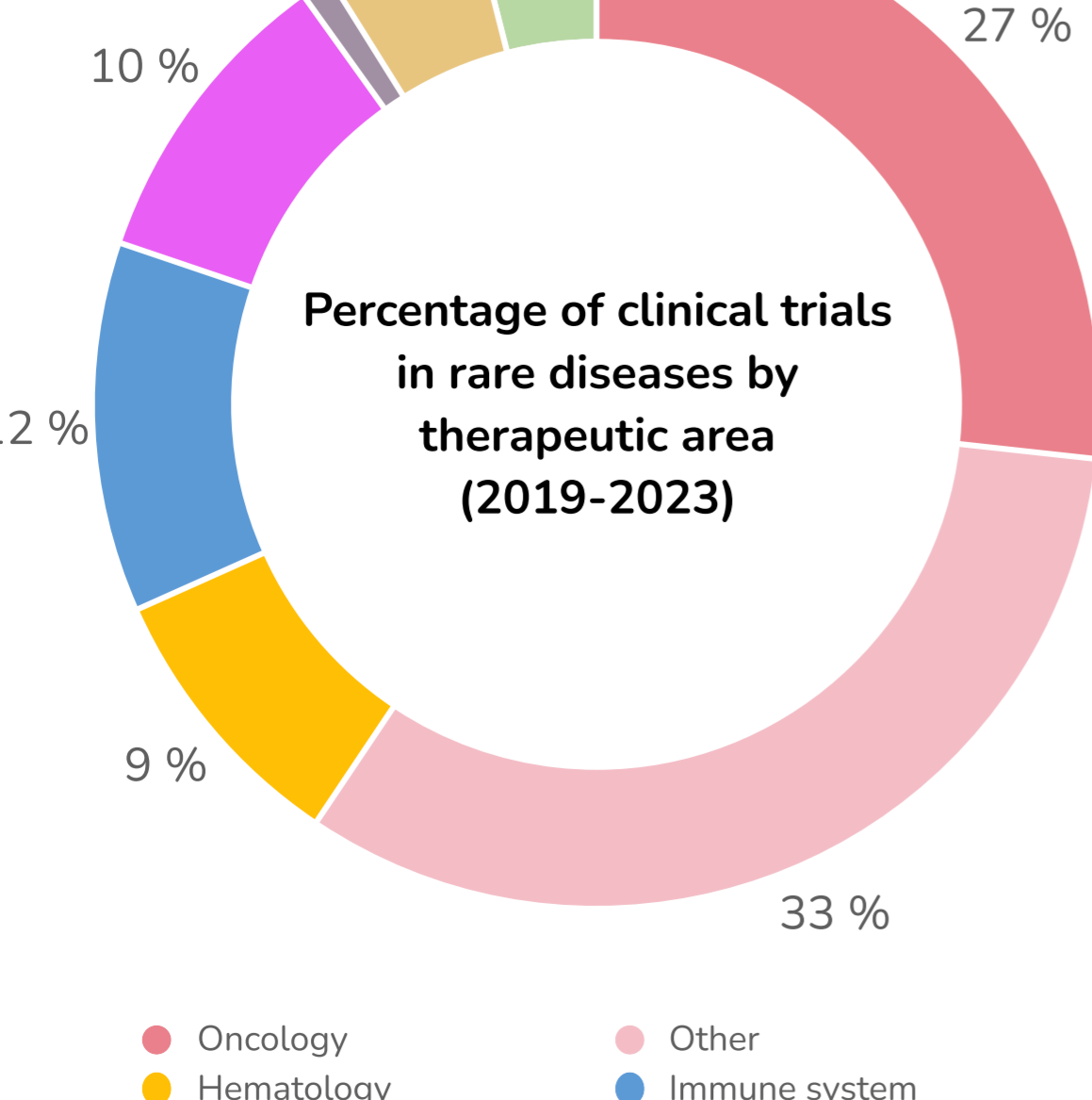


Hospitals with the highest number of clinical trials in rare diseases (2019-2023)

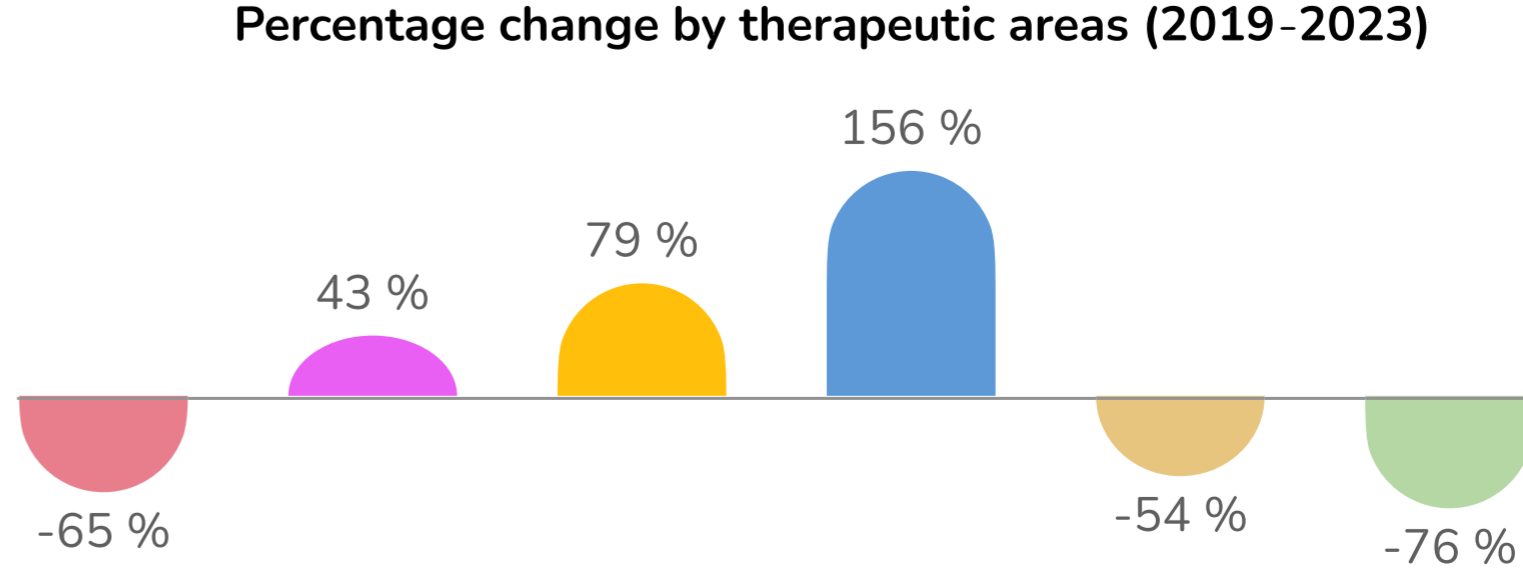
Center	Autonomous communities	No. clinical trials
Hospital Universitario Vall d'Hebron	Cataluña	541
Hospital Universitario y Politécnico La Fe	Comunidad Valenciana	296
Hospital Clínic de Barcelona	Cataluña	294
Hospital Universitario 12 de Octubre	Comunidad de Madrid	284
Hospital Universitario Virgen del Rocío	Andalucía	273
Hospital Universitario La Paz	Comunidad de Madrid	267
Hospital Universitario Gregorio Marañón	Comunidad de Madrid	214
Hospital Universitario Ramón y Cajal	Comunidad de Madrid	205
Hospital de la Santa Creu i Sant Pau	Cataluña	187
Clínica Universidad de Navarra	Navarra	149
Hospital Universitario de Salamanca	Castilla y León	146
Hospital Marqués de Valdecilla	Cantabria	137
Complejo Hospitalario Universitario de Santiago	Galicia	132
Hospital Universitario Fundación Jiménez Díaz	Comunidad de Madrid	125

Clinical trials in rare diseases by therapeutic area

Percentage of rare disease clinical trials by therapeutic area (2019-2023)



Percentage change by therapeutic areas (2019-2023)



Legend for Percentage of clinical trials in rare diseases by therapeutic area (2019-2023): Oncology, Hematology, Nervous System, Respiratory tract, Immune system, Genetic phenomena, Cardiovascular pathologies.

Source: Spanish Registry of Clinical Trials (REEC) - AEMPS. Information consulted in February 2024 and analyzed by Biotinova Consulting.
*Note: The phase IV clinical trial with identifier 2023-506977-36-00, in the therapeutic area of viral diseases, has been excluded from the analysis of the number of patients per clinical trial, as the data was distorted by including 14,001 patients.
The 2022 figures may not coincide with the data in the report published by AELMHU last year, as the 2022 data have been updated after the date of the report.