

# **Successfully embedding clinical research as part of healthcare - Spanish model**

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# Declaration of Interests

- Scientific consultancy role for Alentis Therapeutics, Amgen, AstraZeneca, Aveo Oncology, Boehringer Ingelheim, Cardiff Oncology, CARSGen Therapeutics, Chugai, Daiichi Sankyo, F. Hoffmann-La Roche Ltd, Genentech Inc, hC Bioscience, Immodulon Therapeutics, Inspirna Inc, Lilly, Menarini, Merck Serono, Merus, MSD, Mirati, Neophore, Novartis, Ona Therapeutics, Orion Biotechnology, Peptomyc, Pfizer, Pierre Fabre, Sanofi, Scandion Oncology, Scorpion Therapeutics, Seattle Genetics, Servier, Sotio Biotech, Taiho, Takeda Oncology and Tolremo Therapeutics.
- Stocks: Oniria Therapeutics, Alentis Therapeutics, Pangaea Oncology and 1TRIALSP.
- Employed by the Vall d'Hebron Hospital Campus and Institute of Oncology (VHIO).
- Chair of Cancer Core Europe (CCE) and member of the Executive Board of OECl.

# Spanish Health System in a nutshell

Population: 48.37  
millions (2023);  
20.3% >65 yr

GDP per capita  
PPP: 46,332  
(2022)

% HE: 7.8; (+2.9  
voluntary/out-of-  
pocket);  
10.7 in total

HE from public  
sources (%): 15%

Public coverage by  
the NHS (regions):  
99%; Beveridge  
model

Additional private  
insurance: 30%  
(limited coverage in  
severe diseases)

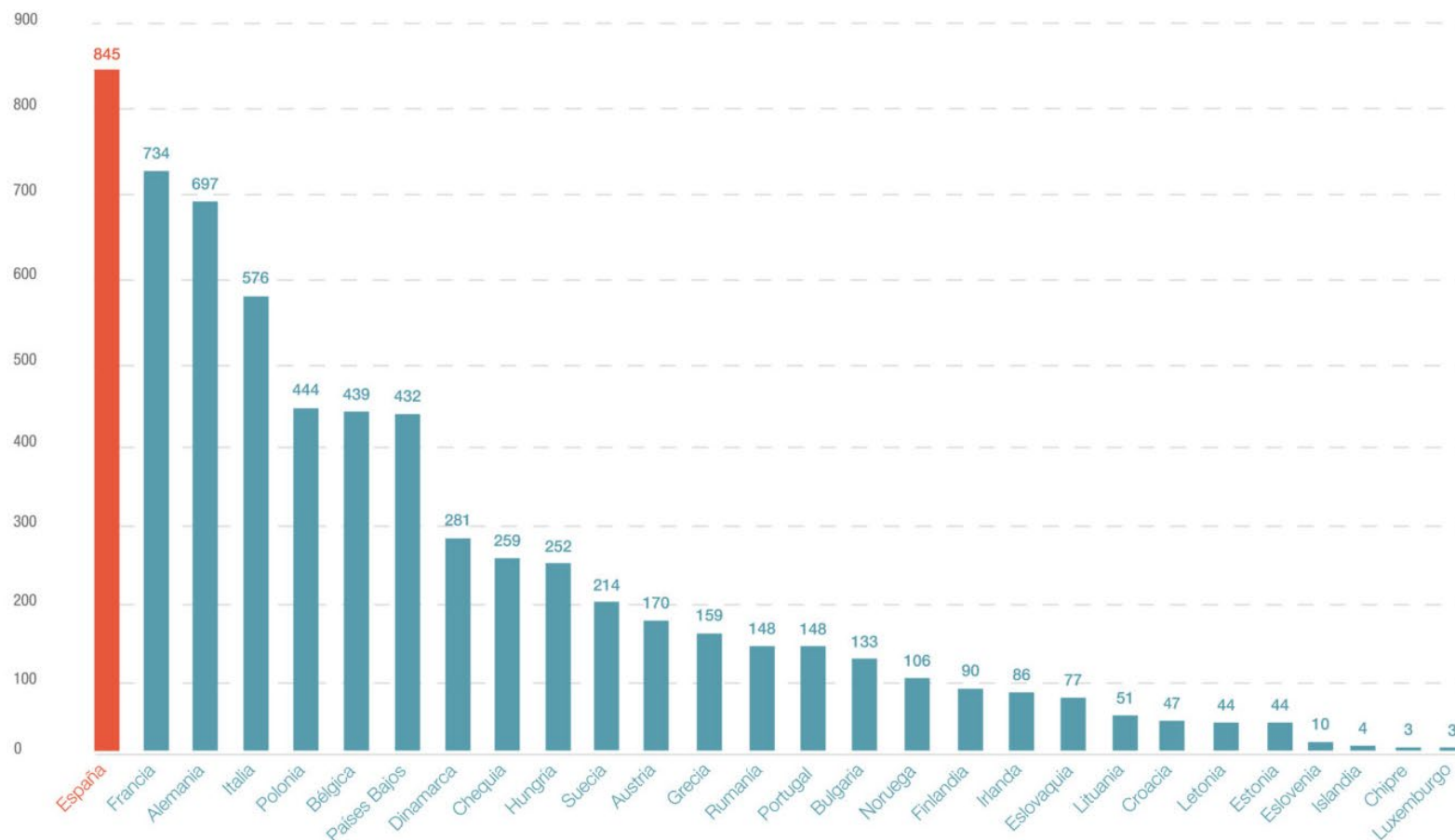
Within the referral  
regions, good  
system

For rare diseases,  
good referral  
between the  
regions (ERNs)

Life expectancy:  
82.2 (79.5 ♂, 85♀)

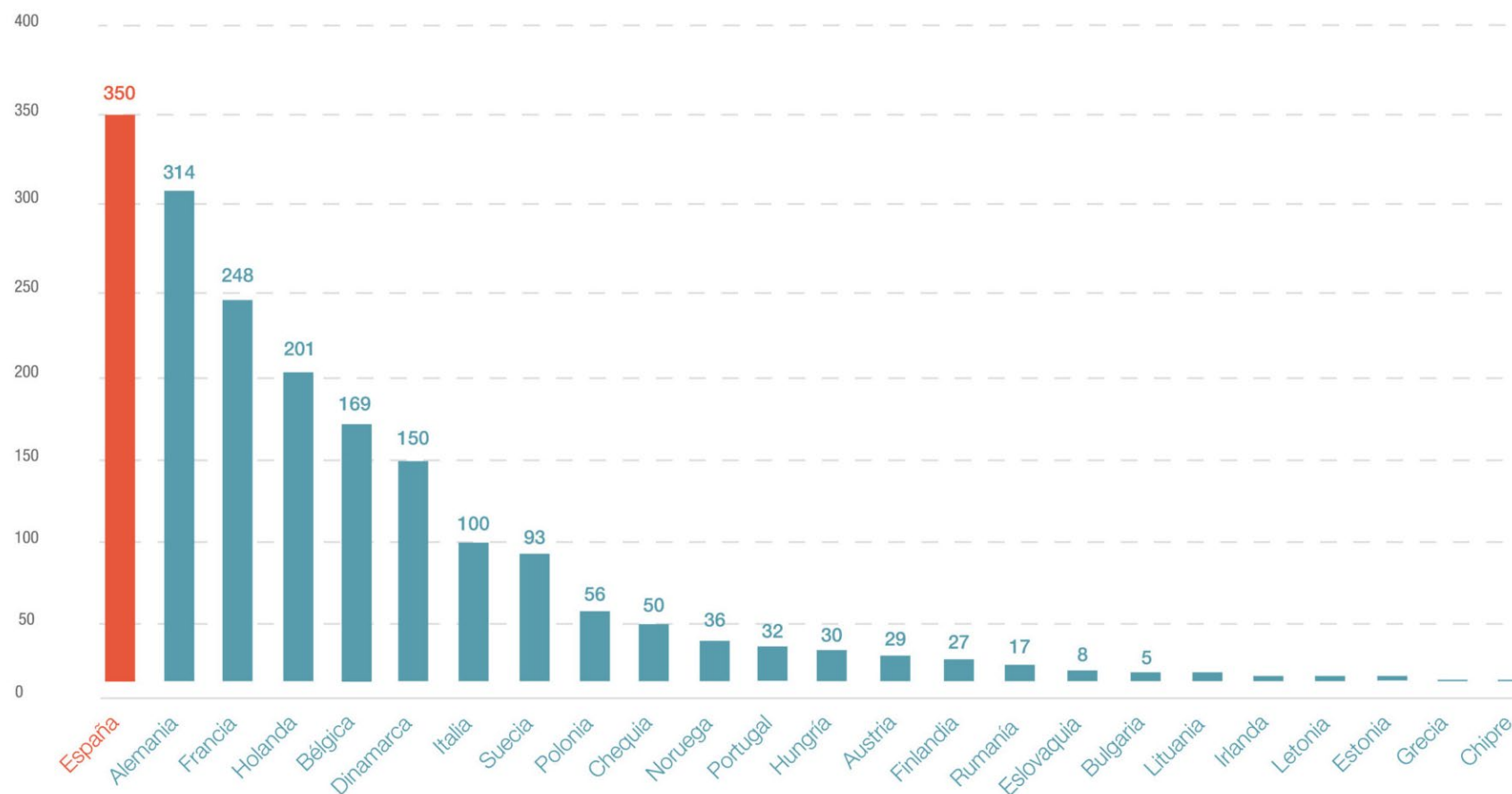


# Participation in clinical trials by state member



Of the 1,944 clinical trials authorized in the European Union through the new European Information System, Spanish centers participated in 845, 43% of the total

# Clinical trials approval by state member



Spain was the first country in the EU to implement the European Clinical Trials Regulation (ECTR, 2022)  
The Spanish Medicines Agency (AEMPS) was responsible for coordinating the authorization of 350 multinational trials

# Some facts on clinical studies in Spain

- Some 170,000 people in Spain are currently participating in an active clinical trial
- 40% of them in cancer
- 58% of clinical trials launched in Spain are in early phases (I/II)
- 1 in 4 trials is focused on rare diseases
- Paediatric clinical trials already account for up to 15%

# The experience of the Vall d'Hebron Institute of Oncology (VHIO) – Vall d'Hebron University Hospital



- One of the largest general hospitals in Spain
- University Hospital
- Public hospital
- Referral hospital for >500,000 inhabitants
- Comprehensive Oncology Department since 1997:
  - Referral area
  - Reference for other geographical areas
  - Main research interest: translational model





# Some data from the Oncology Departments

- **Medical Oncology**

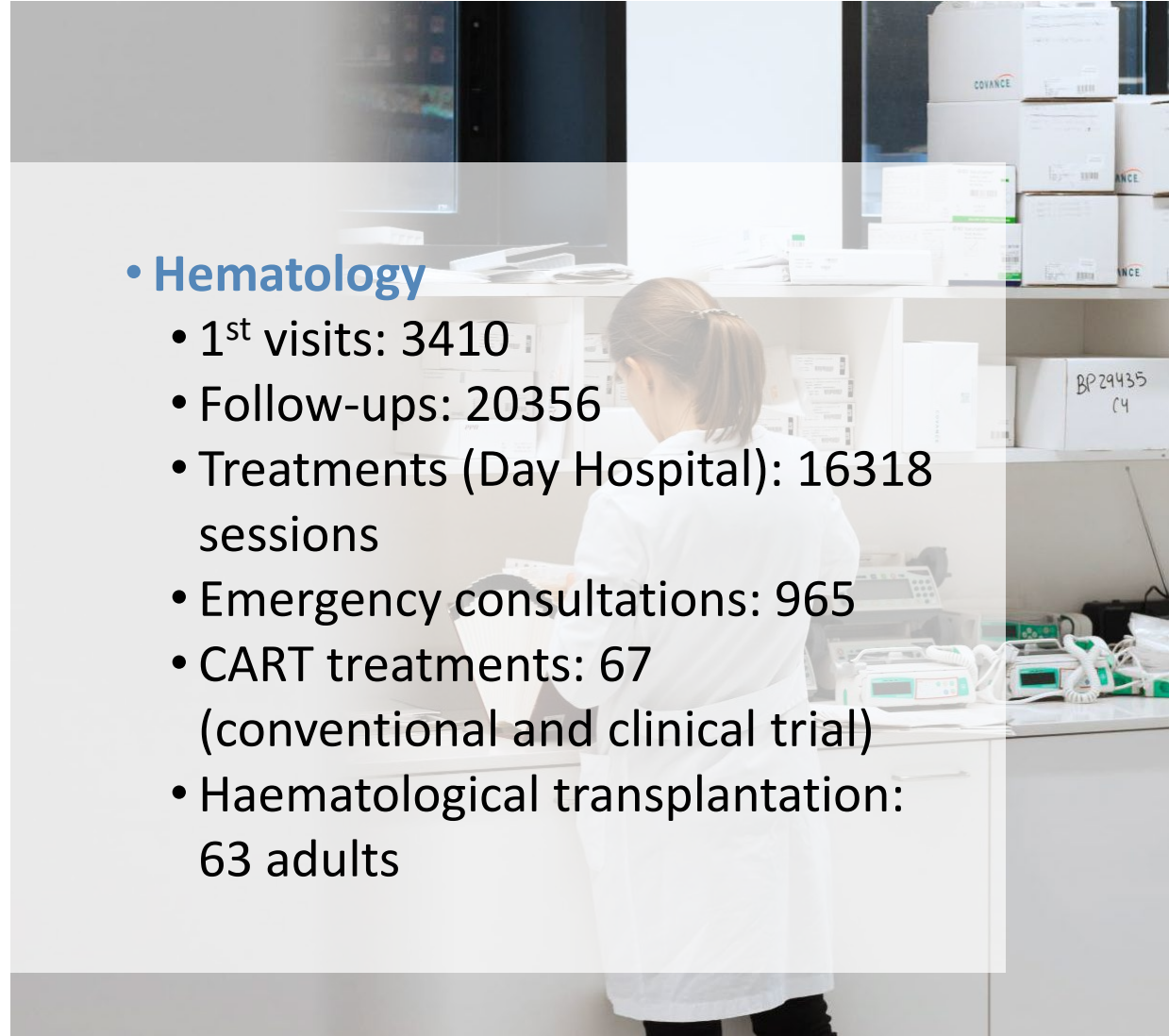
- 1<sup>st</sup> visits: 6729
- Follow-ups: 71300
- Treatments (Day Hospital): 40071 sessions
- Emergency consultations: 4559

- **Radiotherapy**

- 1<sup>st</sup> visits: 2029
- Follow-ups: 11301
- Treatments: 26069 sessions

- **Hematology**

- 1<sup>st</sup> visits: 3410
- Follow-ups: 20356
- Treatments (Day Hospital): 16318 sessions
- Emergency consultations: 965
- CART treatments: 67 (conventional and clinical trial)
- Haematological transplantation: 63 adults















# Clues for success of the Spanish environment

- Spain, pioneer country in regulation (RD 1090/2015)
- AEMPS: an agency regulatory committed
- Robustness of National Health System
- Excellence of the health care professionals
- Involvement and generosity of the patients
- Ethics and transparency
- Bet of the pharmaceutical industry for Spain
- The BEST project, catalyst of the clinical research
- A European system harmonized
- A model of success settled in the public-private collaboration



# Challenges/opportunities for the future

- Acceleration of procedures for the clinical trials authorization in early stages
- Promotion of clinical research in Primary Care
- Streamlining and reducing bureaucracy in the clinical trials procedures
- Decentralization and expansion of the research networks
- Fostering the participation of patients (in all phases of Biomedical R&D)
- Technology and data use to foster clinical research (RWD/RWE/AI)
- National/Regional/Local interpretation/application of GDPR
- Evolution of IVDR implementation (early clinical trials)

# Take home messages

01

Clinical trials are the cornerstone of medical advancements in cancer treatment, leading to improved patient outcomes and survival rates.

02

Robust National Health Services with well-established referral networks constitute an ideal space to promote clinical research

03

Recent regulatory changes in Europe aim to enhance patient safety and data protection but have introduced complexities that threaten the efficiency of clinical research.

04

Navigating these challenges is essential to continue delivering innovative treatments to patients without unnecessary delays and to continue being competitive in clinical research.



# Thank you

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