

**R&D IN THE
PHARMACEUTICAL
INDUSTRY IN SPAIN
2015**

Survey results on R&D activity in 2015

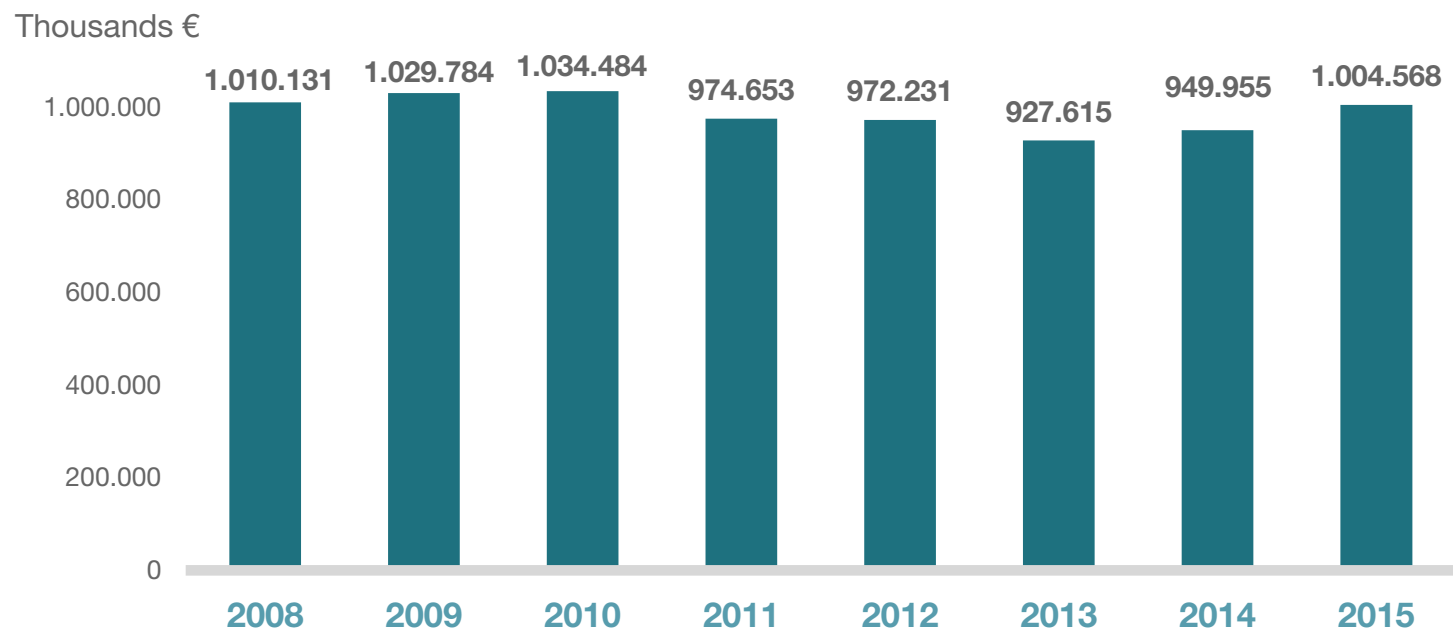
October 2016

Features of the survey

- Results of the survey on R & D expenditure in 2015 associated with Farmaindustria laboratories. The data presented do not include spending on innovation (i).
- Replies received: 53 business groups, representing 72.2% of sales of prescription drugs (IMS) to which the estimated expenditure on R & D companies not associated with Farmaindustria is added, as well as expenditure from non respondents calculated using the information obtained from the Profarma database and the CNMV, in order to gain full coverage of the whole pharmaceutical industry.
- **Data collection:** April-June 2016

Evolution of expenditure on R&D (2008-15)

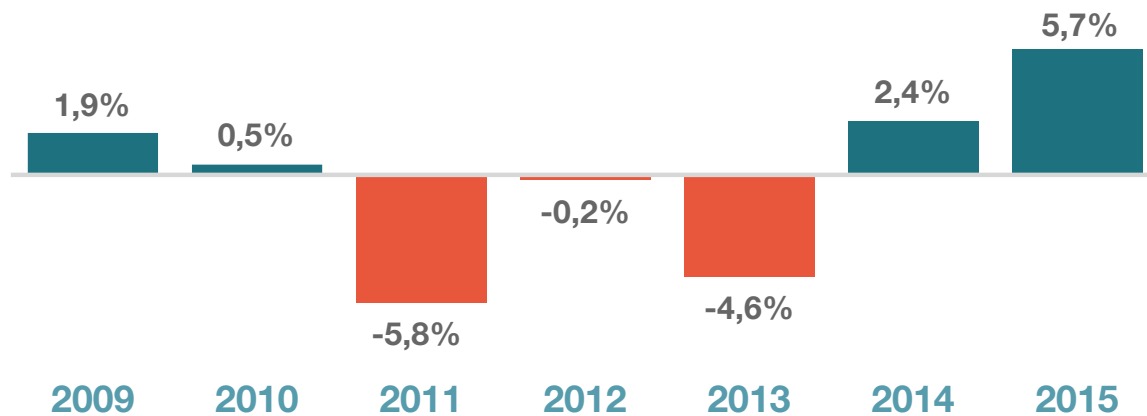
In 2015 the volume of R&D spending in the pharmaceutical industry exceeded €1,000 million for the first time since 2010.



Source: Farmaindustria

Rates of variation on R&D spending (2009-15)

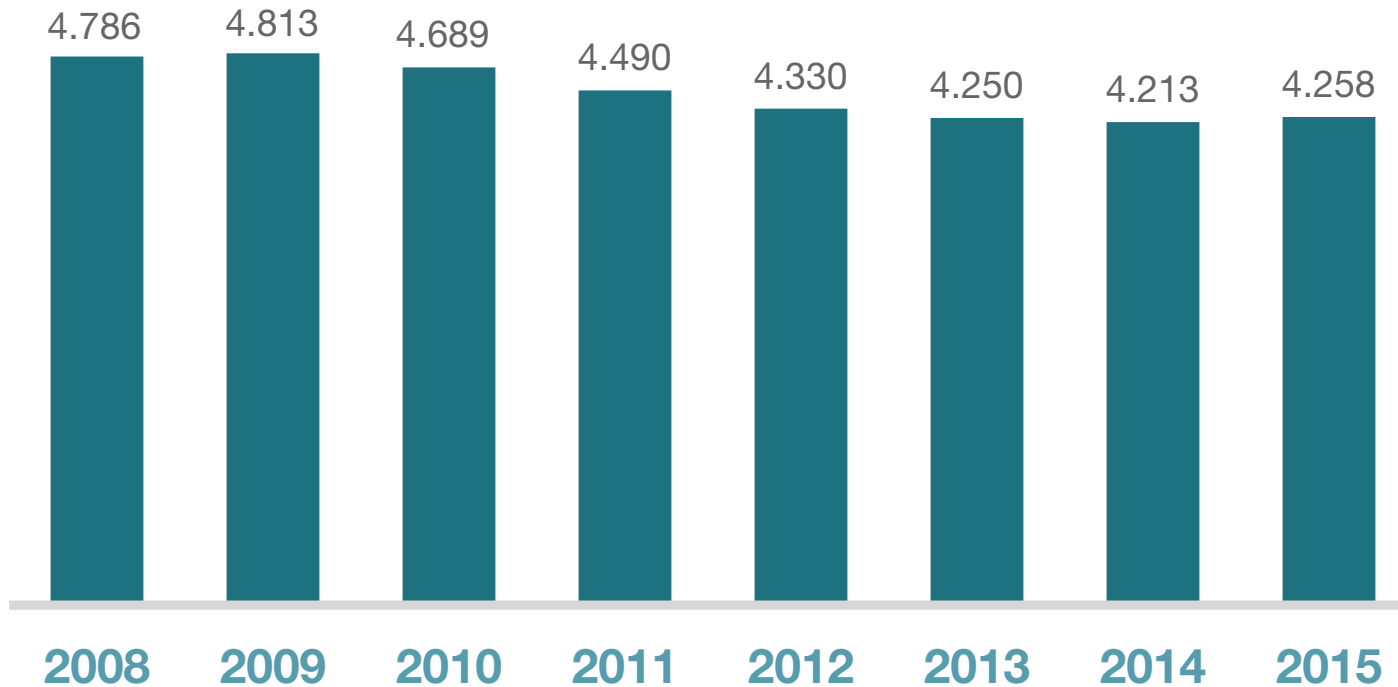
Spending on pharmaceutical R&D grew by + 5.7% in 2015, the best performance recorded in the past seven years.



Source: Farmaindustria

Evolution of R&D personnel (2008-15)

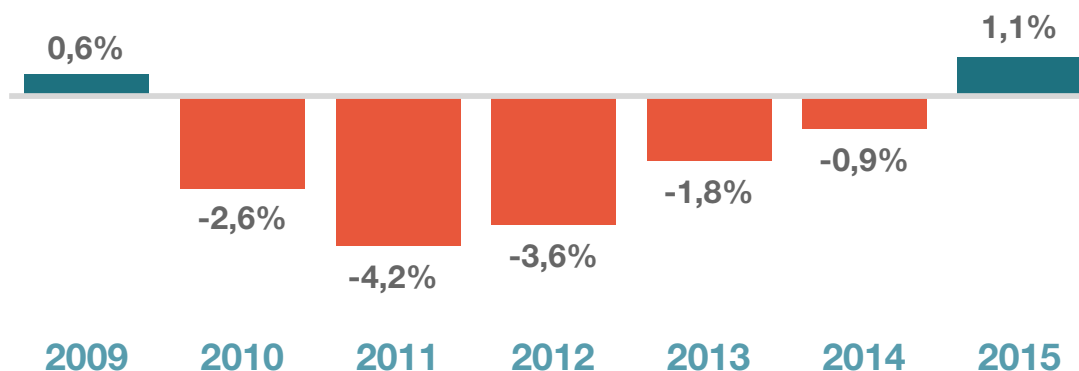
The pharmaceutical industry **employed 4,258** people in 2015 in research and development activities.



Source: Farmindustria

Rates of variation of staff employed in R&D (2009-15)

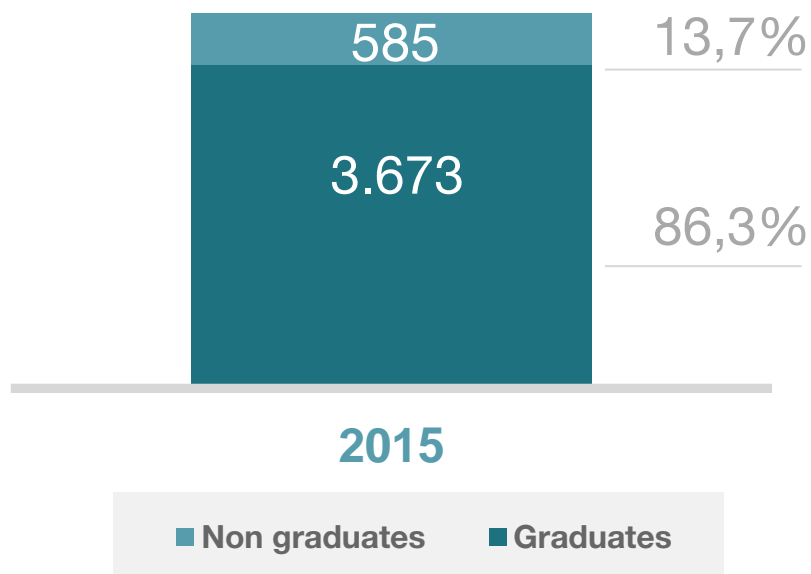
Employment in R&D has begun to increase again after five consecutive years of falling numbers as a result of the cuts in pharmaceutical expenditure.



Source: Farmaindustria

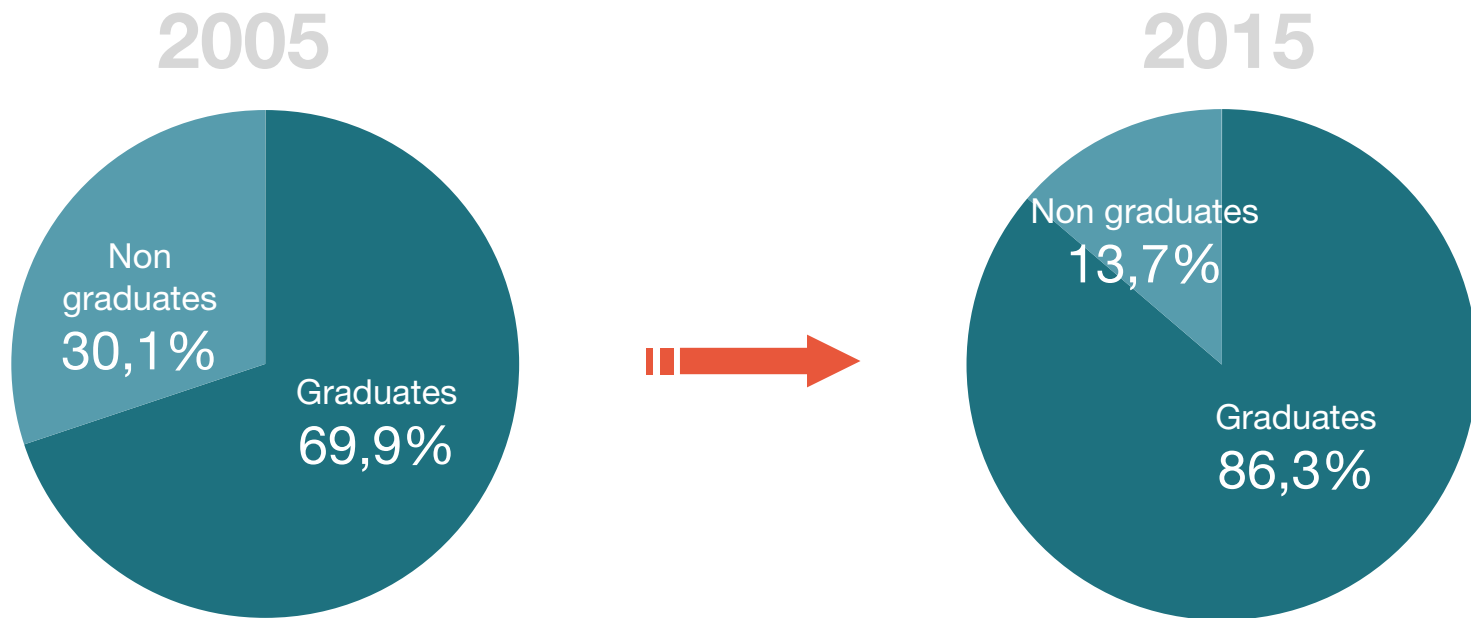
Qualifications of employed personnel in R&D (2015)

Not only have more jobs been generated, but those employed are also more highly qualified: 86% of R&D employees in the pharmaceutical industry are qualified (graduates and doctors).



Evolution of qualified research staff (2005 vs 2015)

Higher qualifications are an important element and key differentiator in R&D employment within the pharmaceutical industry: in the last 10 years the percentage of graduates has increased by 16 percentage points meaning that the number now exceeds 86%.

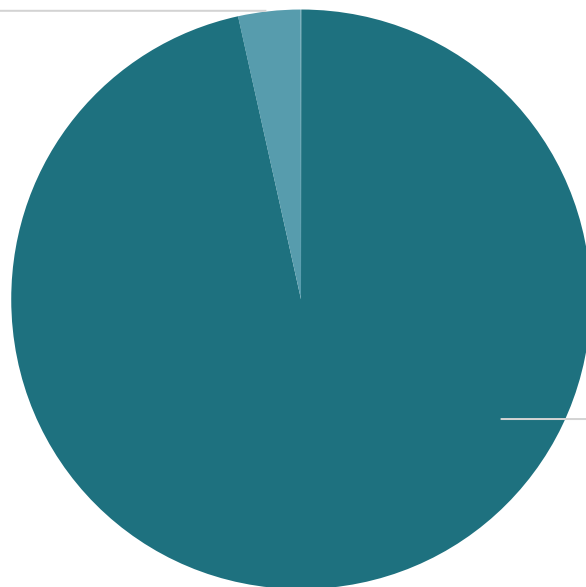


Breakdown of type of spending on R&D (2015)

Out of R&D spending conducted in 2015 by pharmaceutical companies, 96.5% of the total were running costs (personnel expenses, external collaborations, etc.) and the remainder, capital expenditures or new investments in equipment and instruments or other tangible assets.

Data in thousands
of €

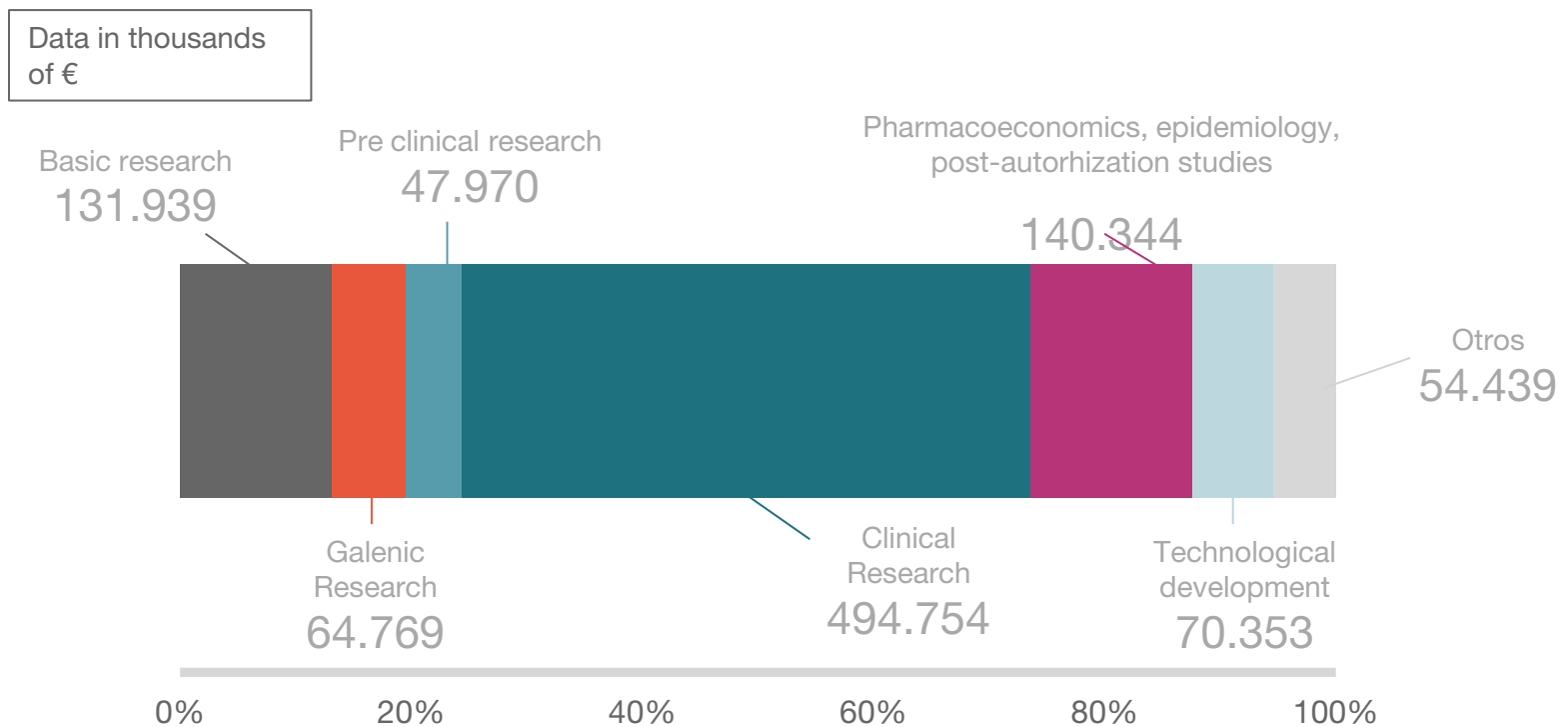
Capital costs
34.989



Running costs
969.578

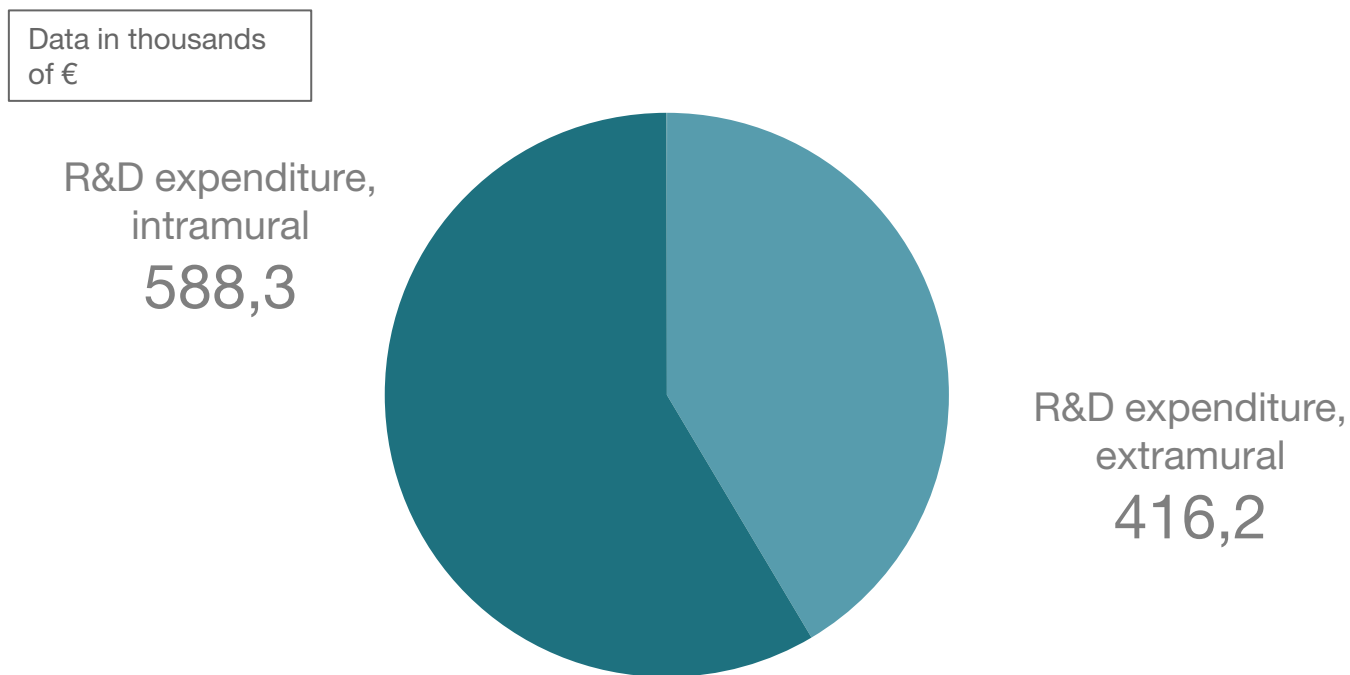
Breakdown of expenditure on R&D by research phases (2015)

Out of the €1,004 million spent on R&D, the main phase, by volume of expenditure, was the clinical trials (€495 million) and €132 million were invested in basic research.



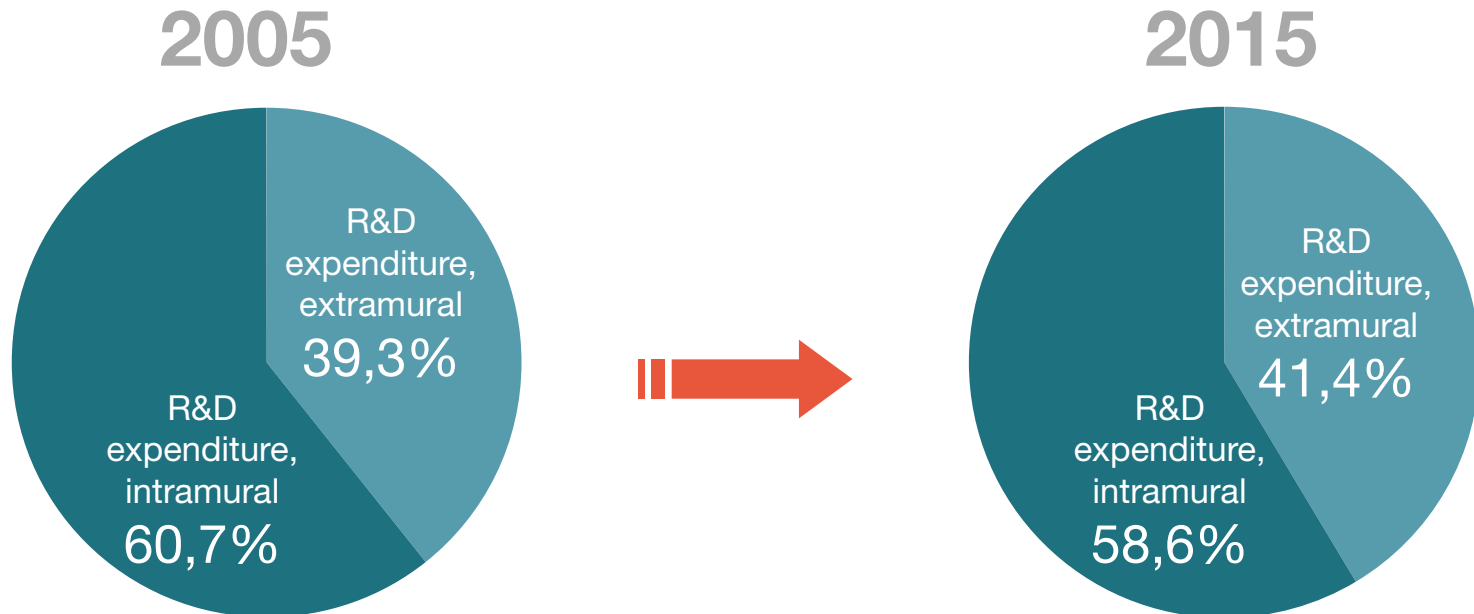
R&D expenditure by location: Intramural / Extramural (2015)

While most of the spending on R&D was generated in the research centers of the pharmaceutical companies themselves, (intramural R&D), 41% of total expenditure in R&D was allocated to research contracts with hospitals, universities and public centers (extramural R&D).



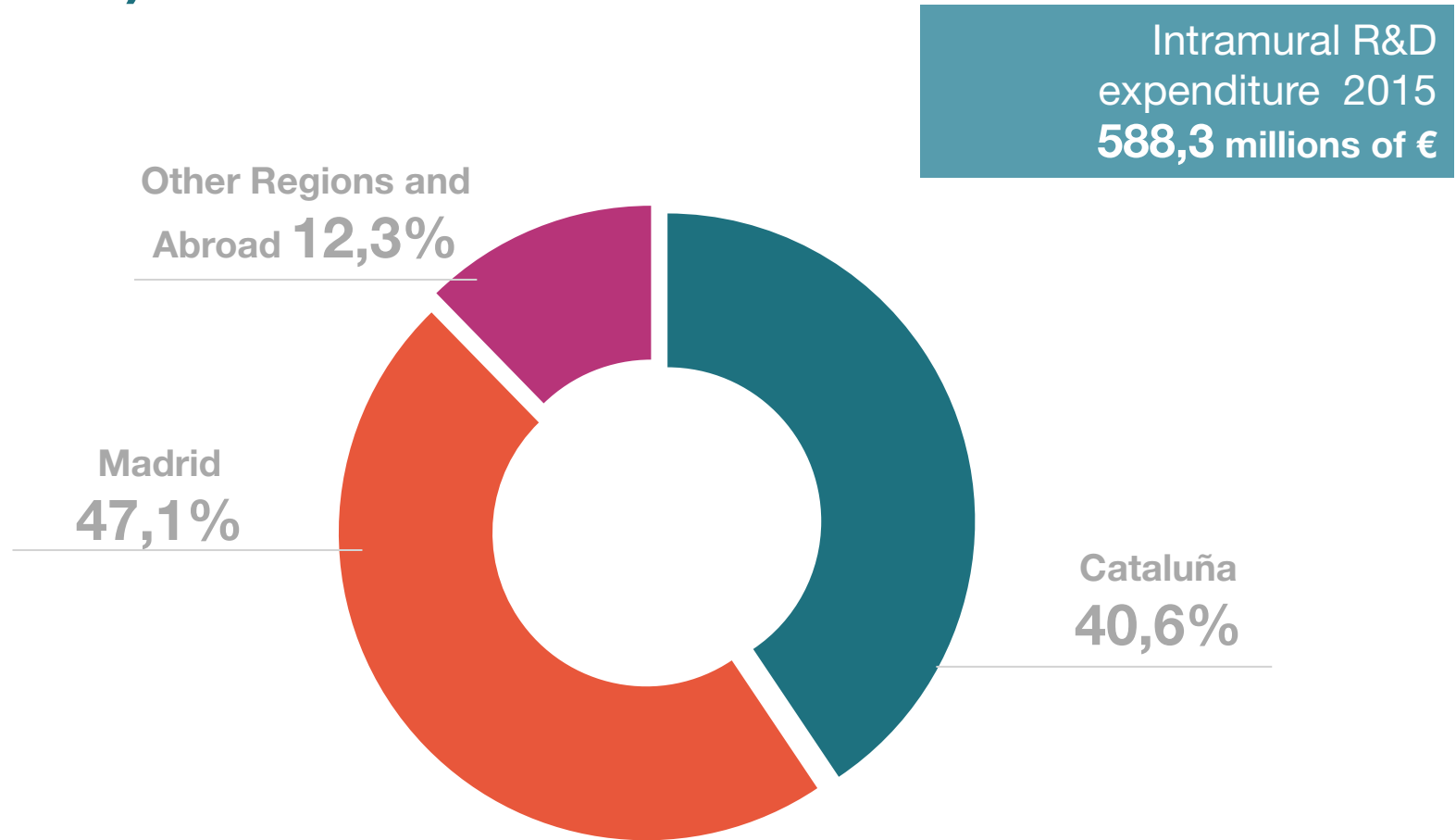
Development of % of expenditure on R&D by location: Intramural / Extramural (2005 vs. 2015)

The structure of expenditure on R&D from pharmaceutical companies shows how there has been an increase in the weight of external collaborations (R&D extramural expenditure).



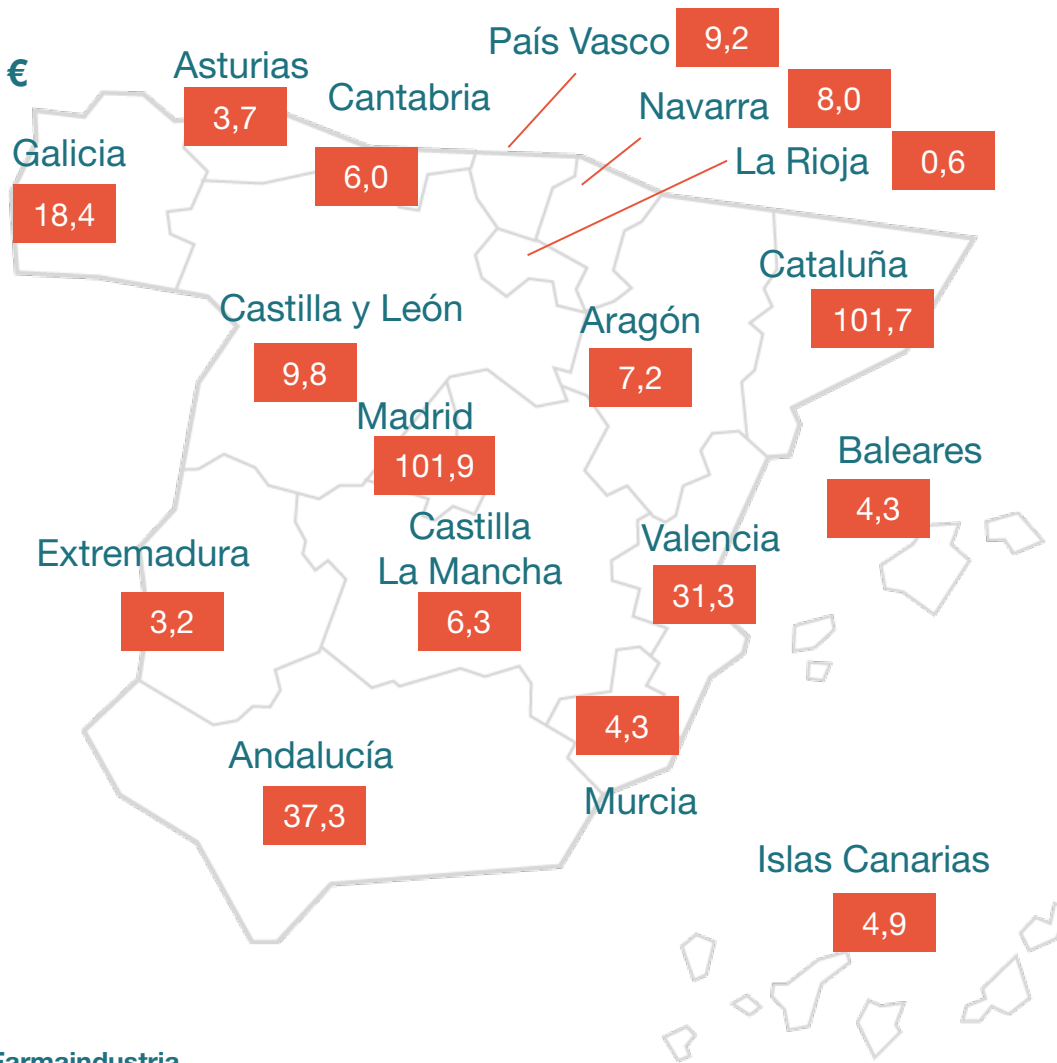
Source: Farmaindustria

Geographical distribution of expenditure on intramural R&D (2015)



Geographical distribution of extramural expenditure on R&D (2015)

Millions of €



Extramural R&D expenditure 2015
416,2 millions €

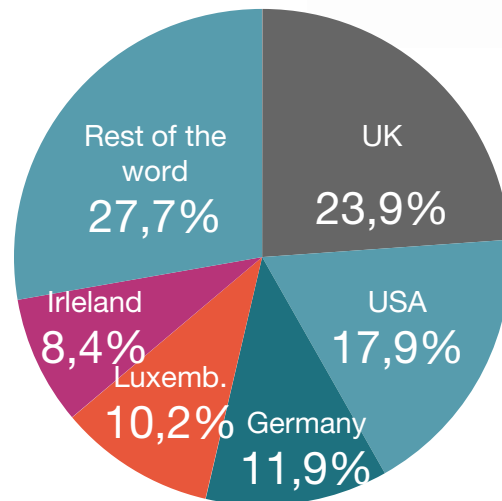


Geographical distribution of expenditure on extramural R&D carried out abroad (2015)

Extramural R&D expenditure
2015 ABROAD
58,2 millions €



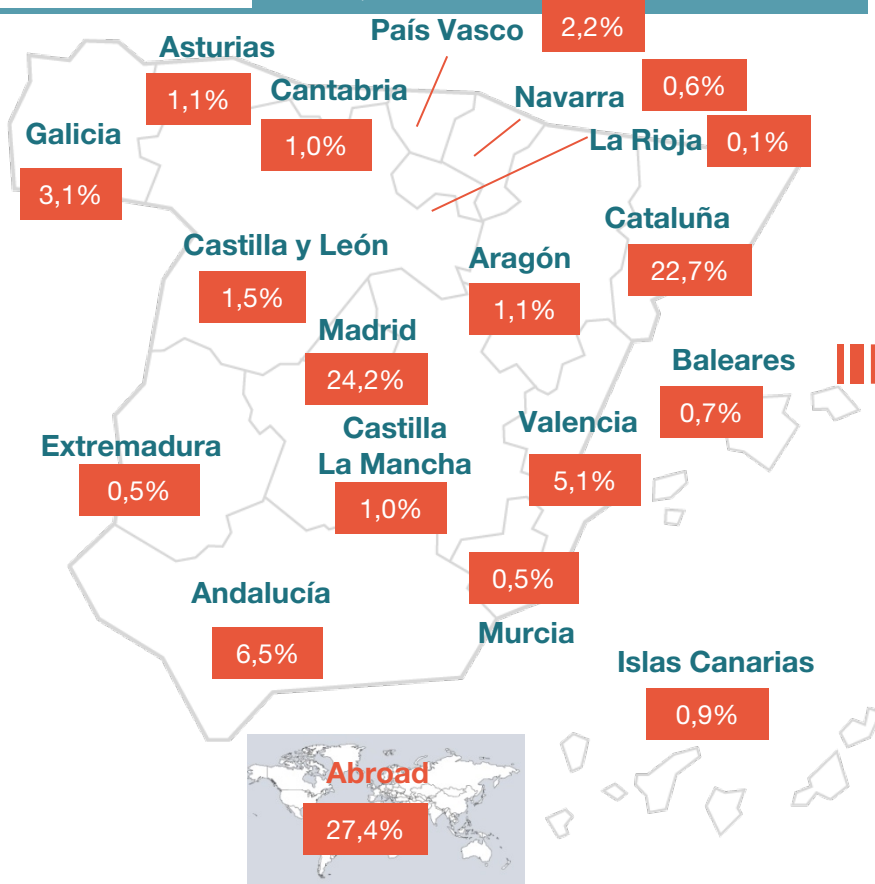
Receiving countries



Evolution of the distribution of expenditure on extramural R&D (2005 vs. 2015)

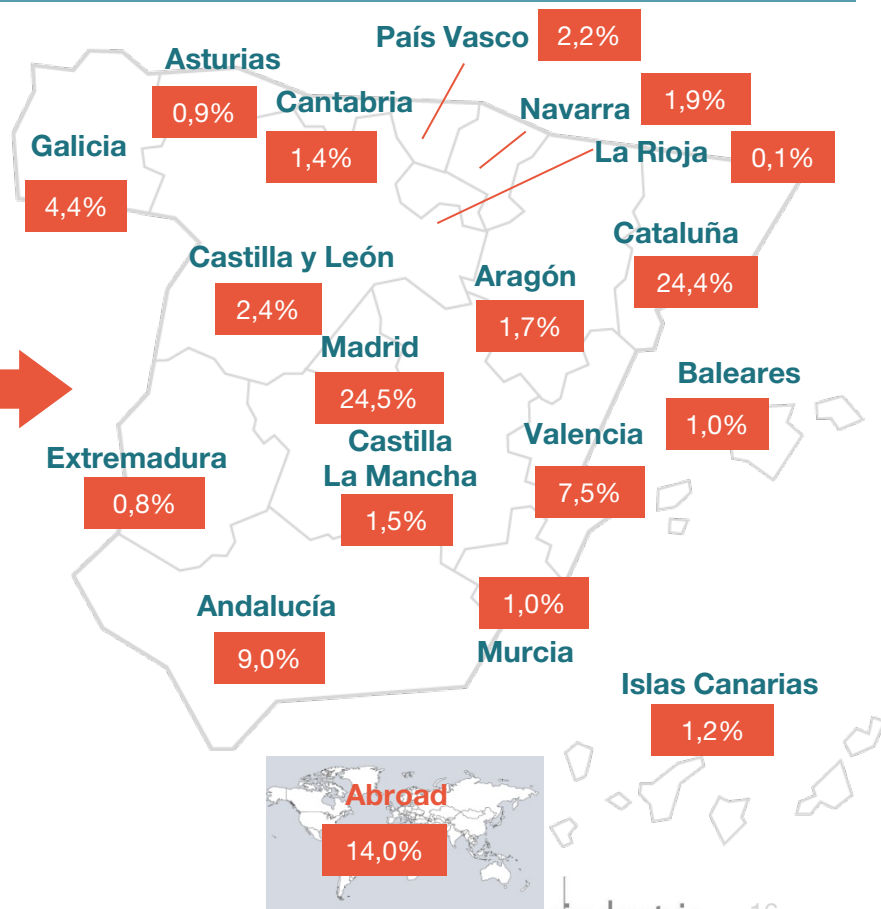
Extramural R&D expenditure: 2005

% over total **301,0** millions €



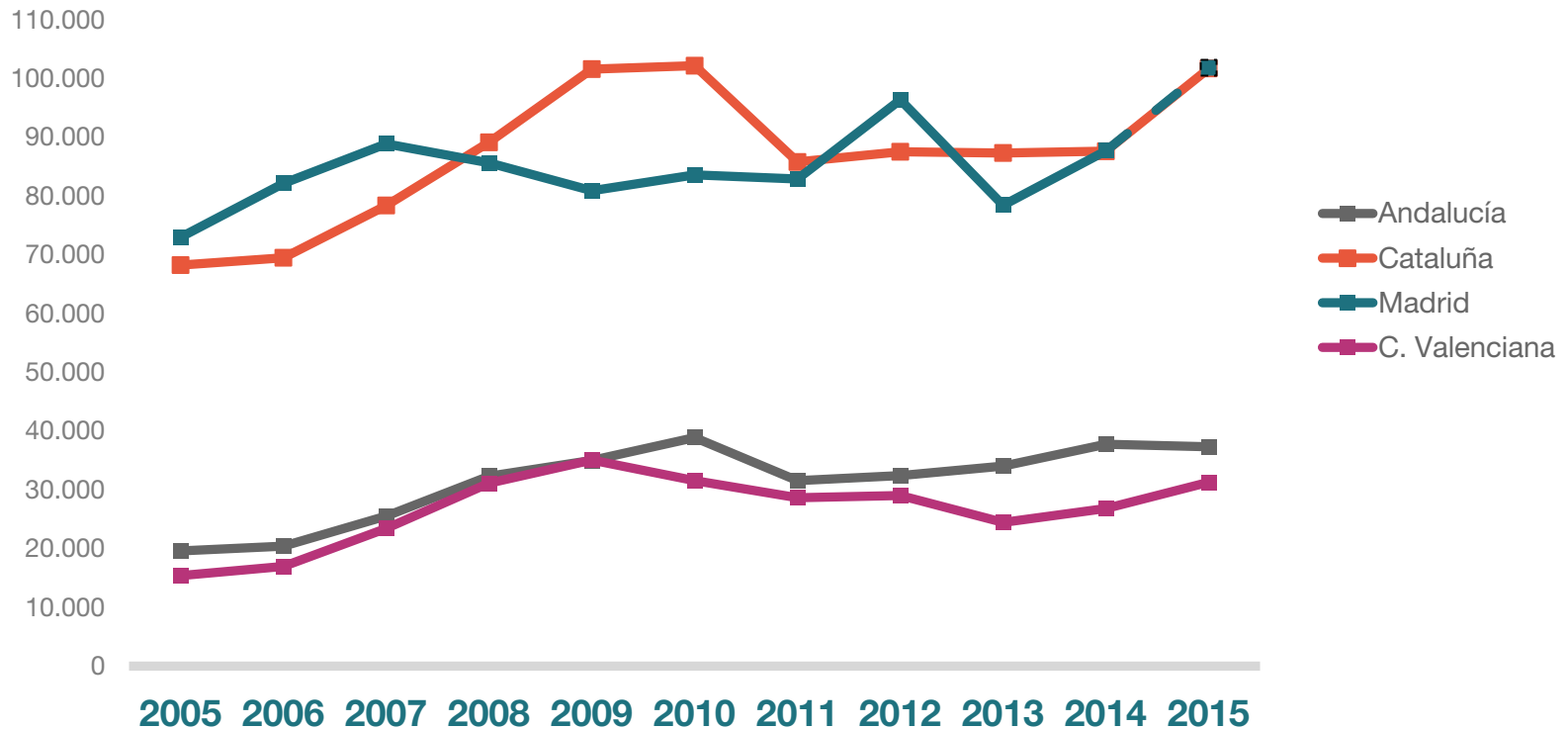
Extramural R&D expenditure 2015: **416,2**

% over total **millions €**



Evolution of expenditure on extramural R&D in the CCAA with more than 4 million inhabitants (2005-15)

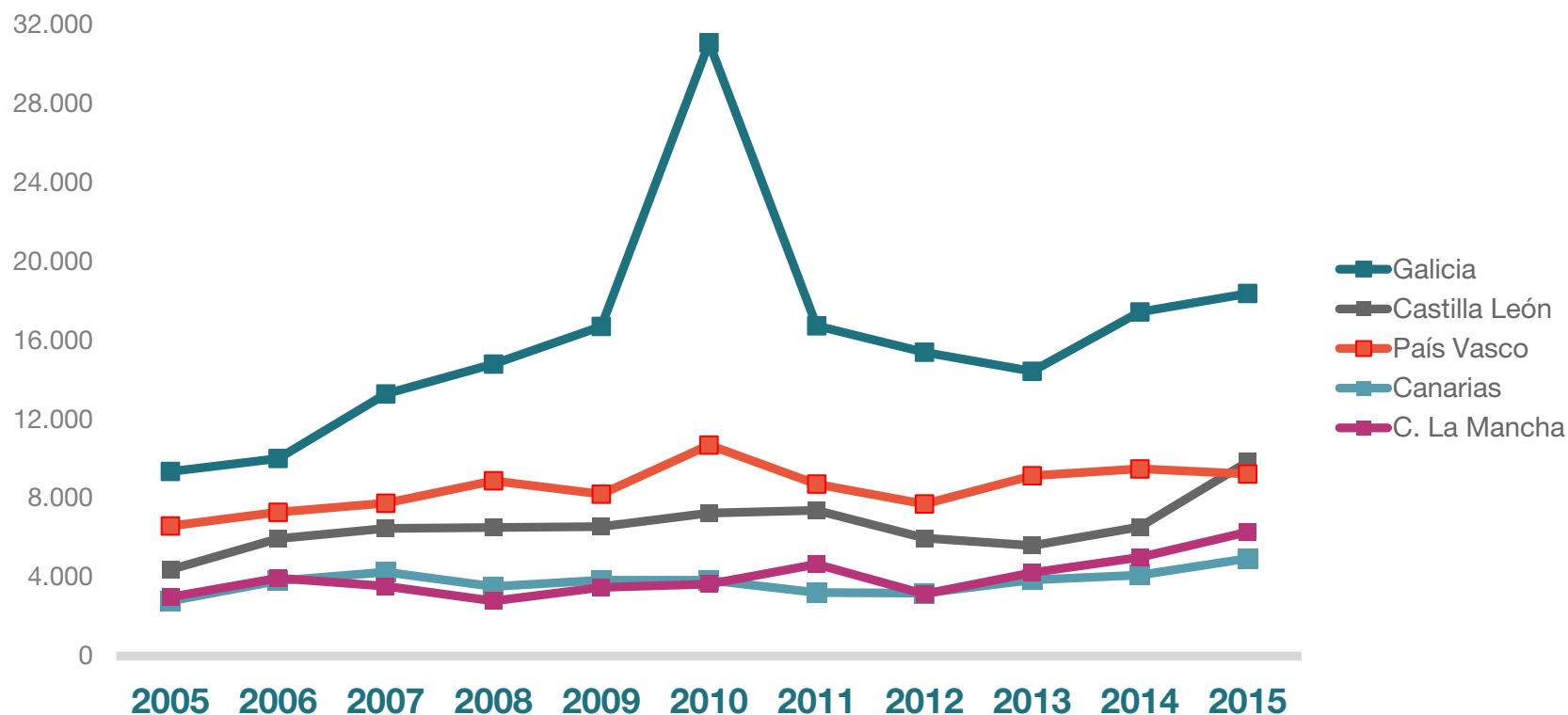
(thousands of €)



Source: Farmaindustria (data R&D) e INE (cifras oficiales de población Padrón municipal a 1/1/2014)

Evolution of expenditure on extramural R&D in the regions with between 2 and 3 million inhabitants (2005-15)

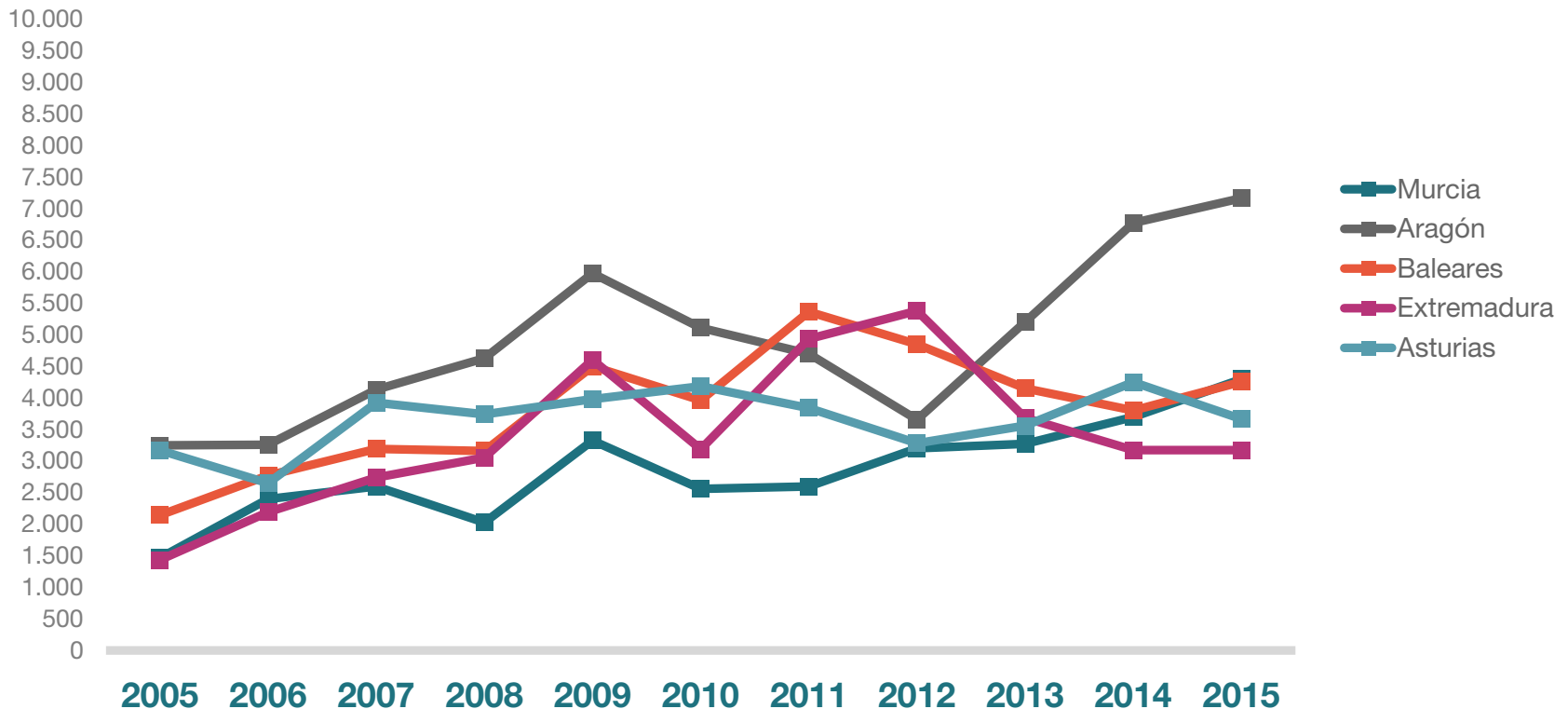
(thousands of €)



Source: Farmaindustria (datos R&D) e INE (cifras oficiales de población Padrón municipal a 1/1/2015)

Development of expenditure on extramural R & D in the regions with between 1 and 2 million inhabitants (2005-15)

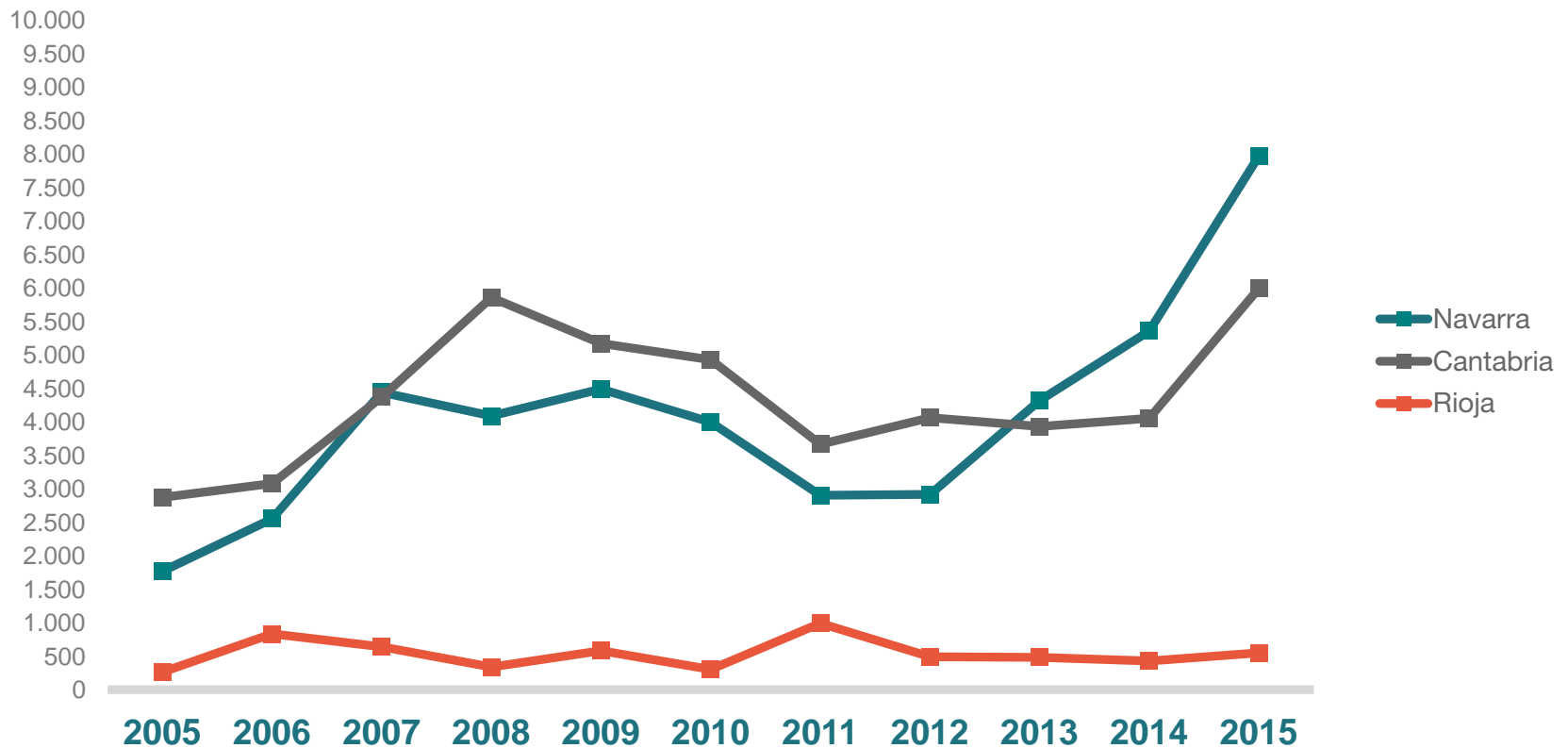
(thousands of €)



Source: Farmaindustria (datos R&D) e INE (cifras oficiales de población Padrón municipal a 1/1/2015)

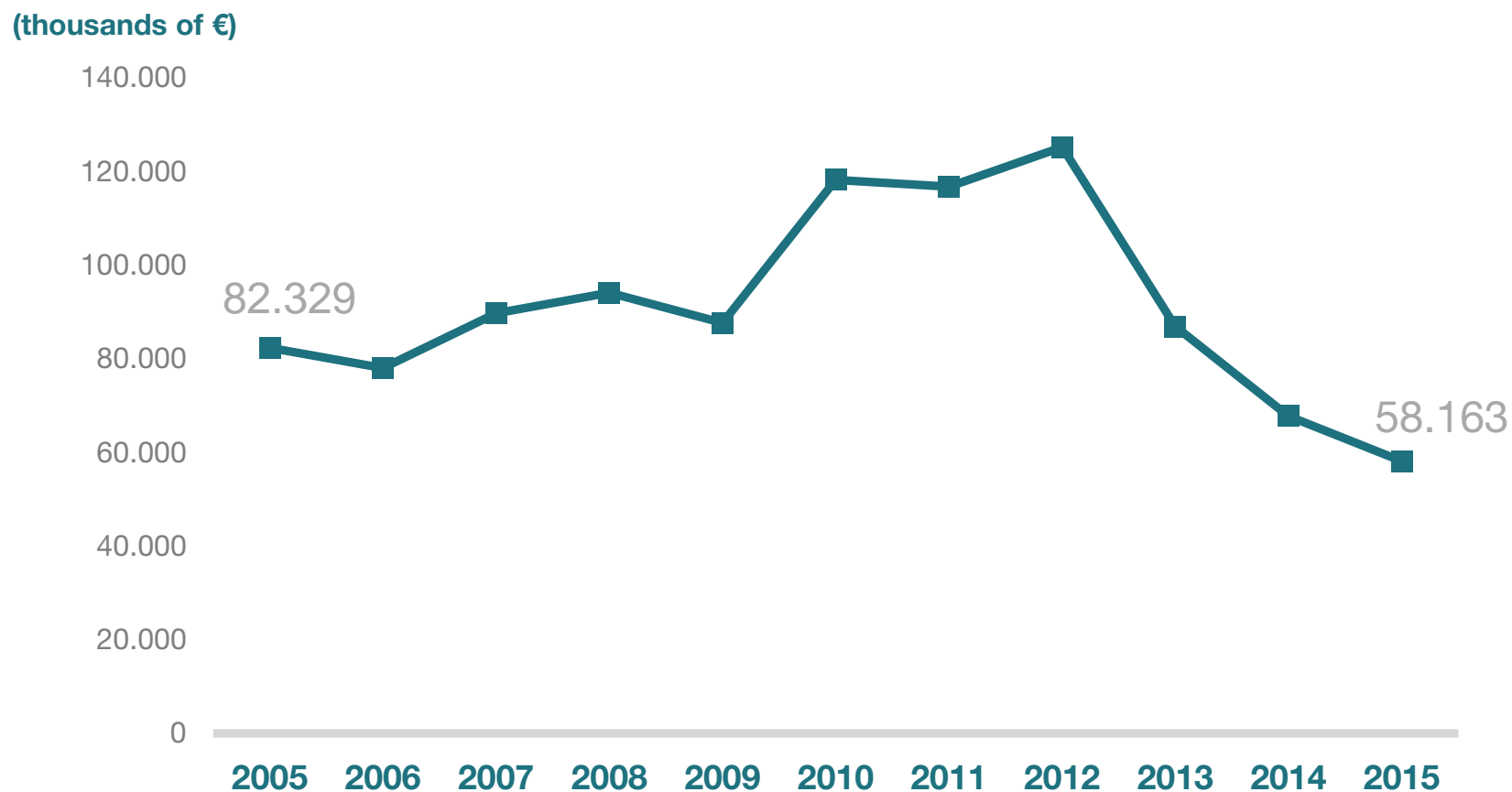
Development of expenditure on extramural R & D in the regions with less than 1 million inhabitants (2005-15)

(thousands of €)



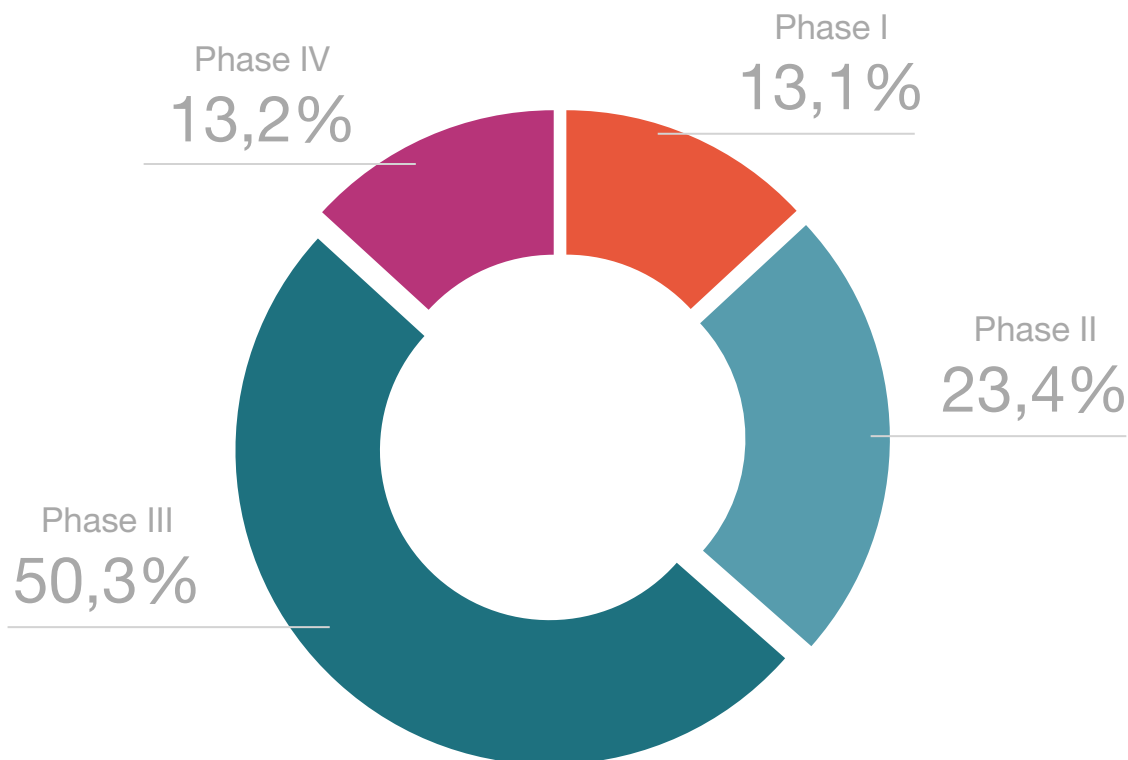
Source: Farmaindustria (datos R&D) e INE (cifras oficiales de población Padrón municipal a 1/1/2015)

Development of spending on extramural R&D abroad (2005-15)



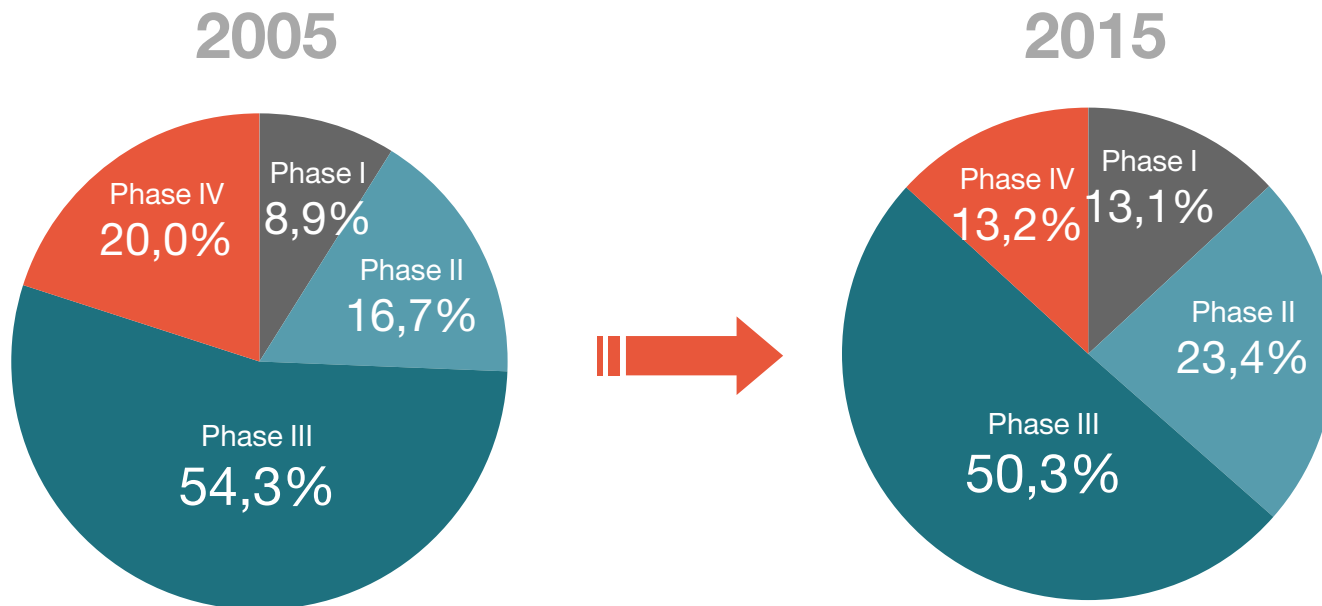
Spending on clinical research: Breakdown by phase (2015)

In 2015, €495 million were invested in clinical research, of which 36% were for phases I and II.



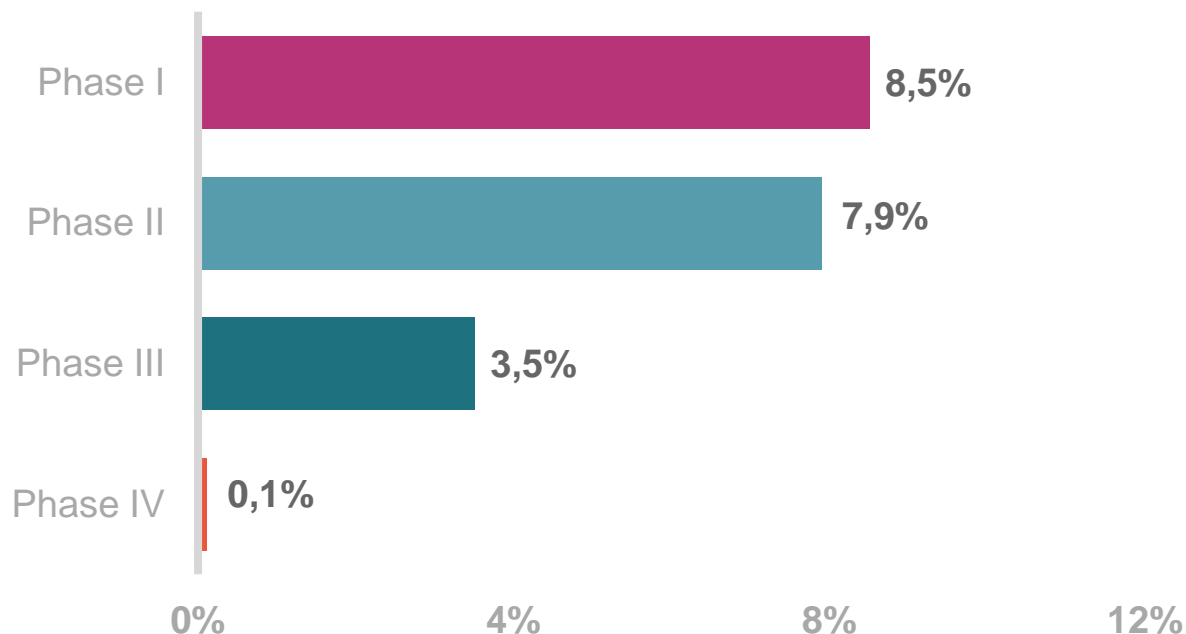
Spending on clinical research: Evolution of the distribution of expenditure broken down by phases (2005 vs. 2014)

By comparing the distribution of spending on clinical research in 2005 to 2015, there is a visible loss in the weight of the later stages in favor of the early stages, which have gone from representing 25.6% of total expenditure to 36.5%



Spending on clinical research: Average annual variation rate of expenditure from phases (2005-15)

Spending on clinical research conducted by the pharmaceutical industry has grown at an average annual rate of + 4.3% over the last 10 years, from €324 million in 2005 to €495 million in 2015.



Biotechnology: General Considerations

- 30 business groups filled out a questionnaire on biotechnology.
- These groups represent 50.2% of sales of prescription drugs (IMS Health).
- In 2015, the pharmaceutical industry invested €252 million in biotechnology in our country, representing 25.1% of pharmaceutical R&D in Spain.
- The data presented below is exclusively from the informant group.

Biotechnology: Preclinical Phase

- 47% of the respondent group uses biotechnology or some tool of biotechnological origin in the preclinical phase.
- The biotechnology tools most commonly used in this phase are, in this order, molecular biology (cloning, sequencing, expression analysis), using functional tests with cell lines expressing proteins and the use of recombinant proteins in screening tests.
- These tools are mainly used in the phases of identification and therapeutic targets, hit to lead, optimization of leads and high throughput screening.
- 64% of companies using biotechnology at this stage do so through its own means, combined, in many cases, with others from collaborations and acquisition of commercial reagents.
- 79% of companies using biotechnology in this phase develop all or part of these activities in Spain.
- The ongoing research projects being reported on, and that rely on biological active principles with recombinant origin, are mainly focused on the areas of oncology, allergy and ophthalmology.
- The main research projects for chemical synthesis molecules in which biotechnology tools have been used, are being developed in the areas of dermatology, anti-infectives and neurology.

Biotechnology: Clinical Phase

- 60% of the respondent group use biotechnology or some tool of biotechnical origin in the clinical stage
- The most widely used biotechnology tools used in this phase are, in this order, the use of recombinant proteins, gene expression analysis and genotyping SNPs.
- These tools are widely used in the early stages (I-II) and late (III-IV) and to a lesser extent in pre-clinical development trials.
- 83% of companies using biotechnology in this phase do so through their own means, and in many cases combine with other collaborations and acquisition of commercial reagents.
- 84% of companies using biotechnology in this phase develop all or part of these activities in Spain.
- There has been a reported 135 biotechnical drugs of a recombinant nature being used in clinical trials, with 449 trials underway in Spain (or managed in Spain), mainly in the areas of oncology, hematology, diabetes and immunology.
- Also, the clinical development of 48 drugs of a chemical synthesis has been reported, in which biotechnology tools have been used, with 101 trials managed in Spain and, developed in a basic manner, within the areas of oncology, hematology, endocrinology and respiratory.

Biotechnology: Phases of Production and Marketing

- 7% of the reporting sample produce biotech drugs in our country, companies in the same group are basically intended for export.
- Also, 20% of the informants questioned use biotechnology during the marketing phase for both biotechnical products and chemical synthesis.
- It covers mainly international companies, although there also national capital laboratories producing these drugs.
- The use of biotechnology in this phase is mainly channeled through molecular diagnostic kits and diagnostic services.
- 60% of biotechnology tools used in this phase are proper; the rest are obtained through third parties.
- Similarly, in 83% of cases the use of these techniques takes place in Spain, although in some cases it is done simultaneously both in Spain and abroad.
- It has been reported that, 24 active ingredients with a biological-recombinant origin, have been marketed in the last ten years in Spain, mainly in the areas of oncology, hematology, endocrinology and dermatology.

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