

# R&D IN THE PHARMACEUTICAL INDUSTRY 2014

R&D activities survey report

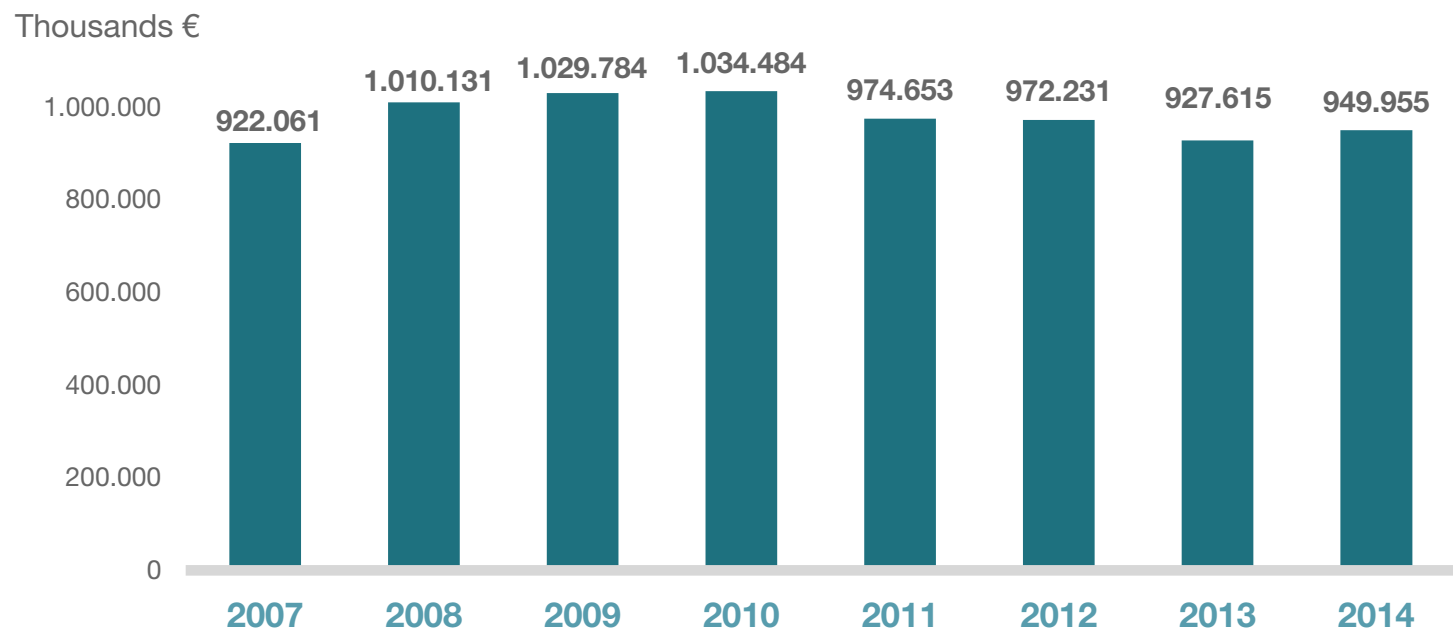
September 2015

## Features of the survey

- Results of the survey about R&D investments in 2014 reflects Farmaindustria's member companies: data presented here do not include innovation expenditure (i)
- Received responses: 57 business groups, representing 74.4% of sales of prescriptions medicines (IMS) to which the estimation of R&D expenditure by companies which are not Farmaindustria Members is added, as well as those derived from non-responding companies, on the basis of the Profarma database and the CNMV, to obtain the total coverage of the pharmaceutical industry
- Because data was collected before the audited clearance of accounts, those corresponding to 2014 are provisional.
- **Data collection: March-June 2015**

## Evolution of R&D investments (2007-14)

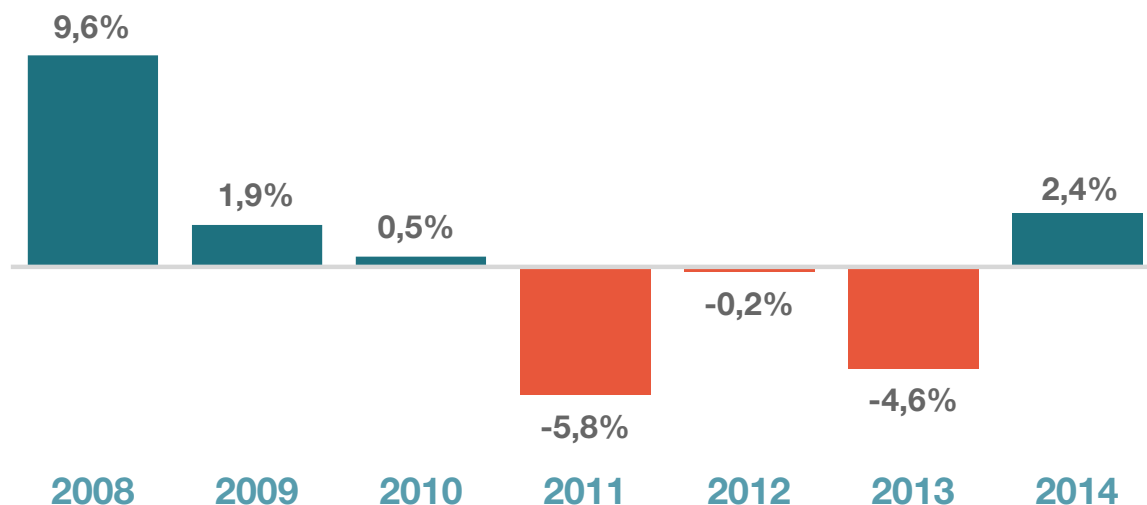
In 2014 , the R&D investment of the pharmaceutical industry in Spain sat at 950 €M



Source: Farmaindustria

## R&D variation rates (2008-14)

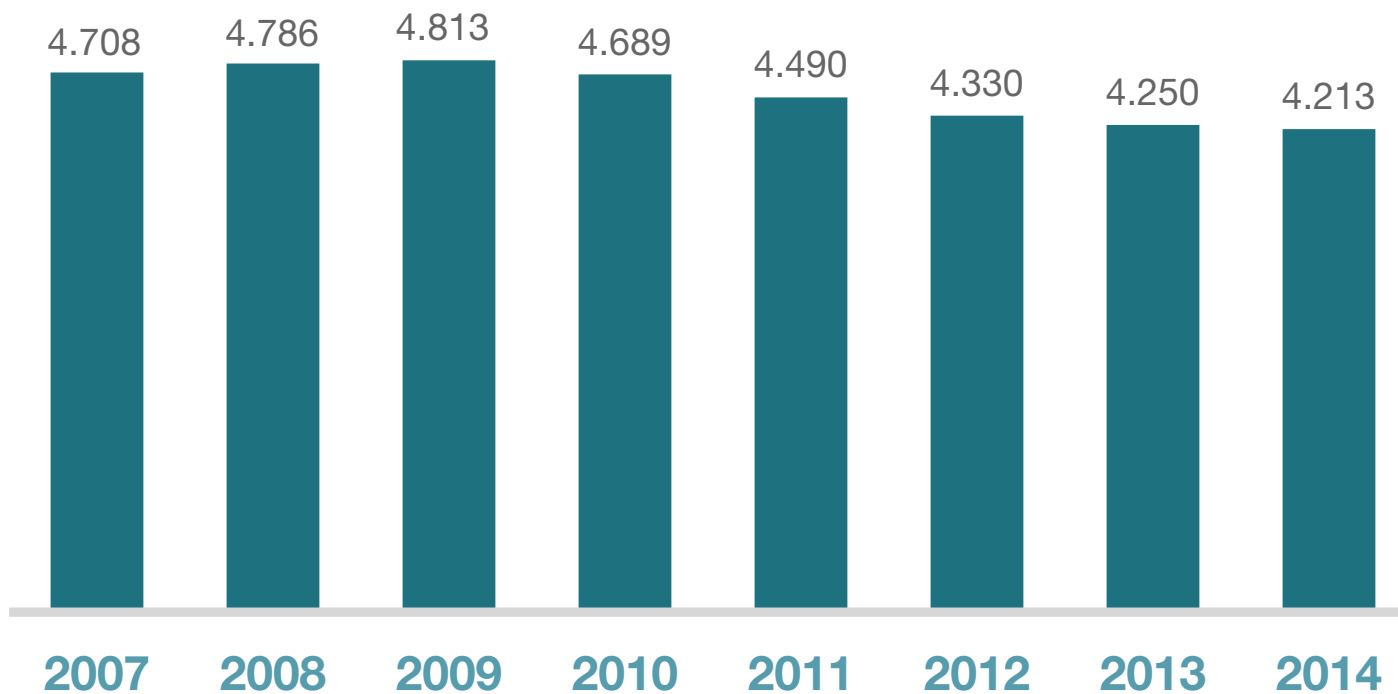
The pharmaceutical industry R&D expenditure started growing again in 2014 after three consecutive years of drops, registering its best evolution since 2008



Source: Farmaindustria

## Evolution of personnel in R&D (2007-14)

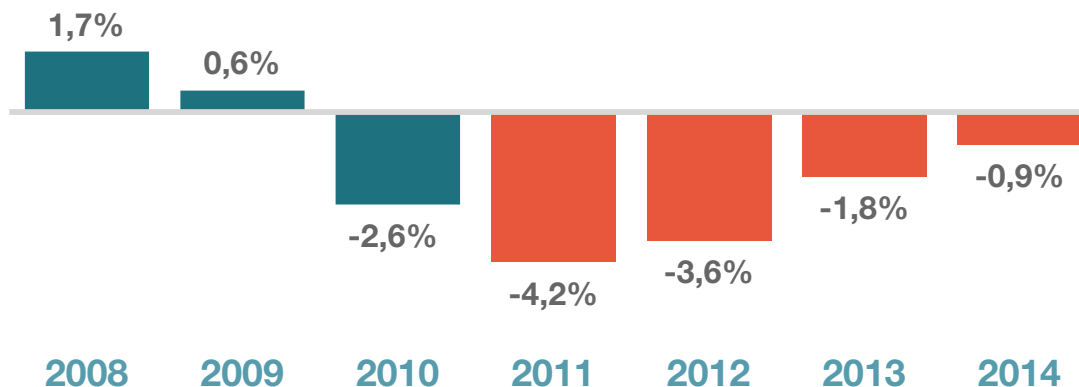
The pharmaceutical industry employed 4,213 people in research and developments activities during 2013



Source: Farmaindustria

## Variation rates in R&D personnel (2008-14)

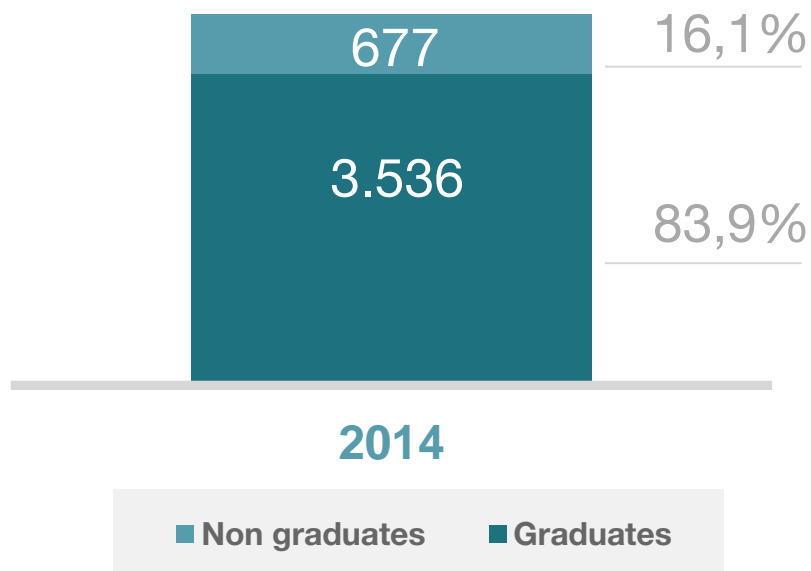
Employment in R&D has suffered the effects of decreasing levels of income for pharmaceutical companies during the economic crisis, whereas the falling trend has been softening itself each year



Source: Farmaindustria

## Qualification of R&D personnel (2014)

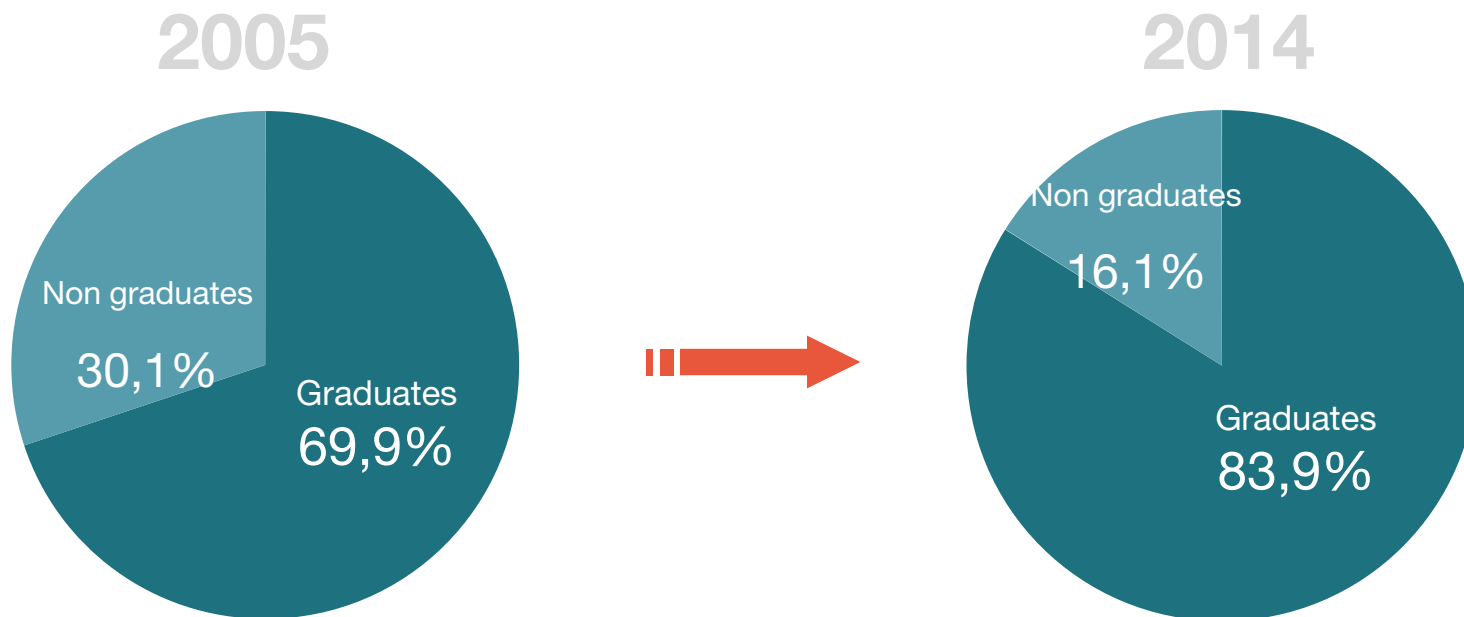
Even though less employments have been created, these are all of a higher qualification: 84% employments in pharmaceutical industry's R&D correspond to qualified professionals (bachelors and PhDs)



Source: Farmaindustria

## Evolution of the qualifications of research employees (2005 vs 2014)

The high level of qualifications constitute the differential and key asset in the pharmaceutical industry's R&D: during the last 10 years, the share of graduate professional has risen by 14 points up to 84%

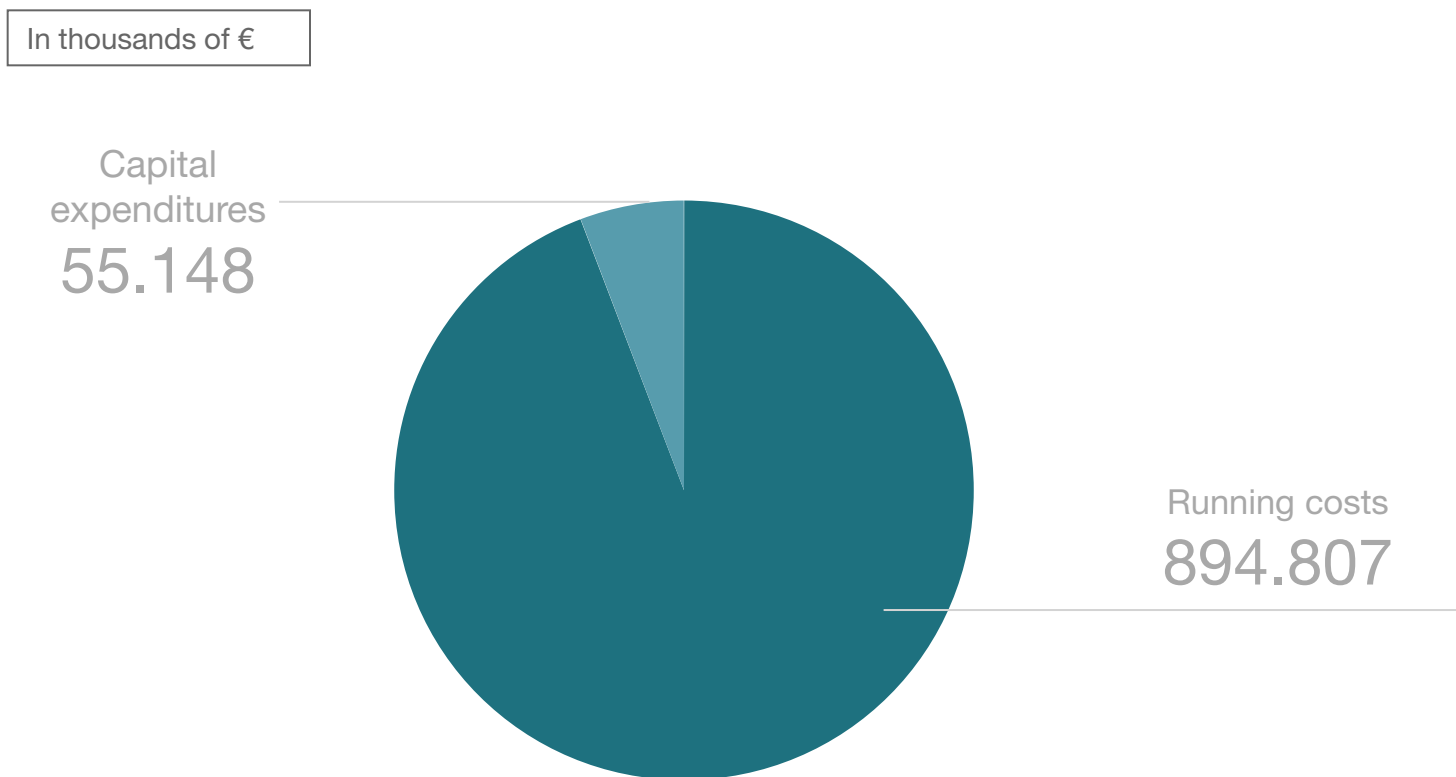


Source: Farmaindustria



## Breakdown by nature of investment in R&D (2014)

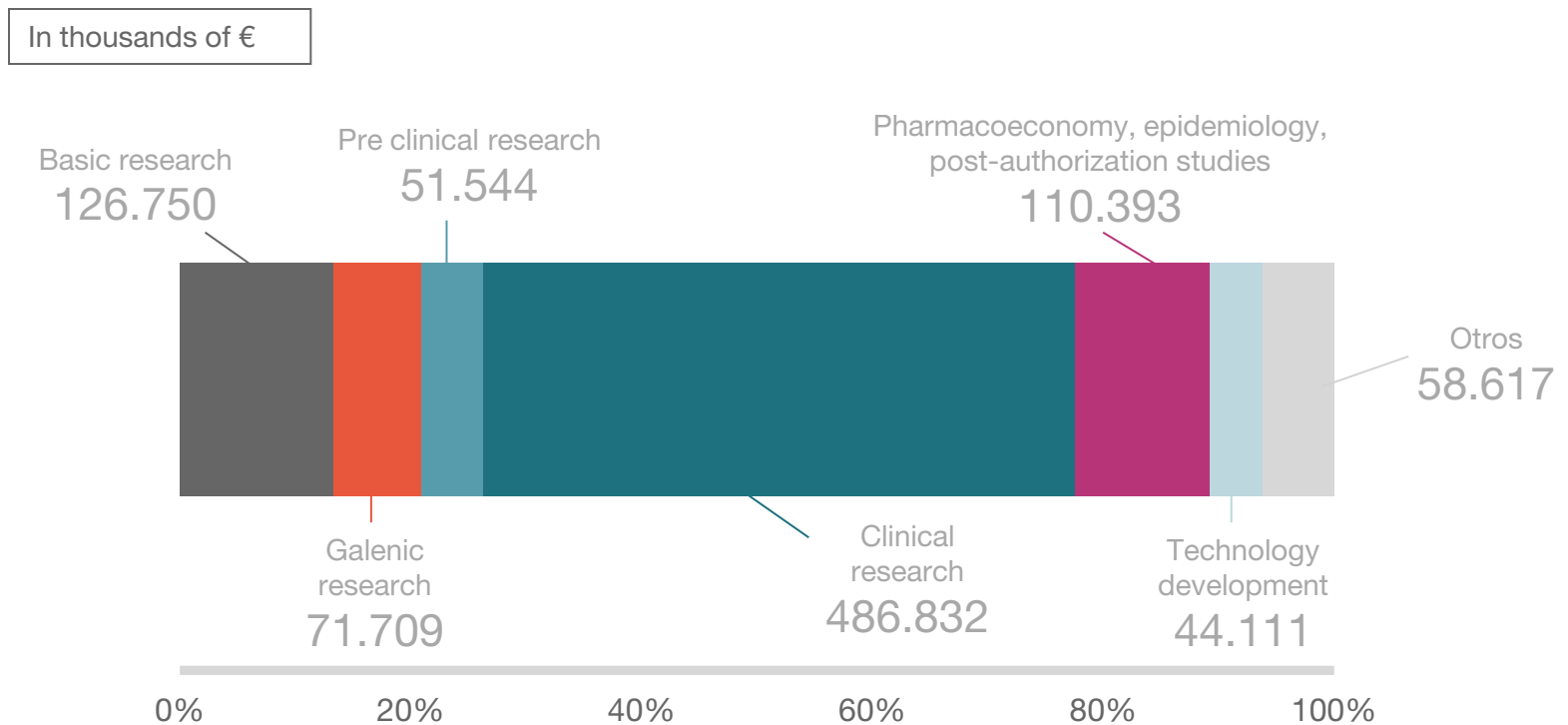
94.2% were running costs and the rest were investments of capital associated expenditures



Source: Farmaindustria

## Breakdown of R&D investments by research phase (2014)

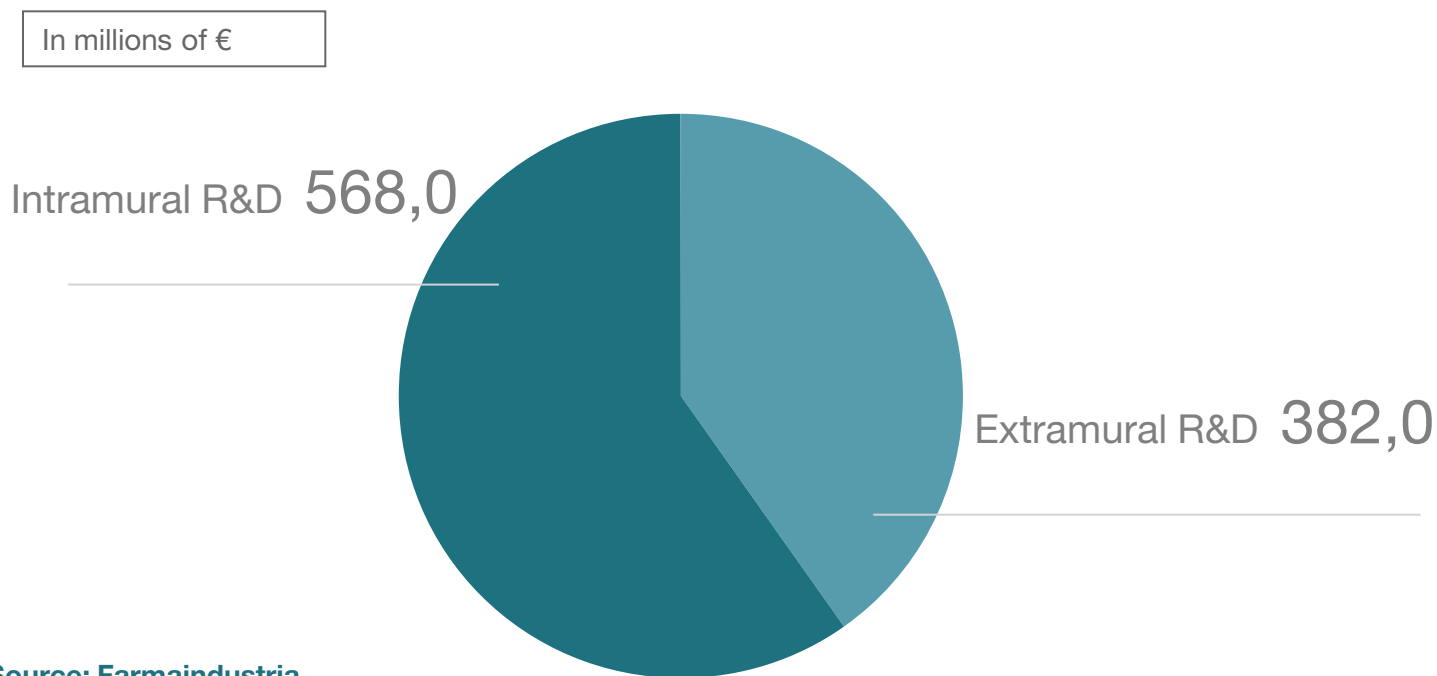
The most important phase according to expenditure volume in R&D was clinical research (486 millions), and more than 126 million were invested in basic research.



Source: Farmaindustria

## R&D investments by allocation: Intramural/Extramural (2014)

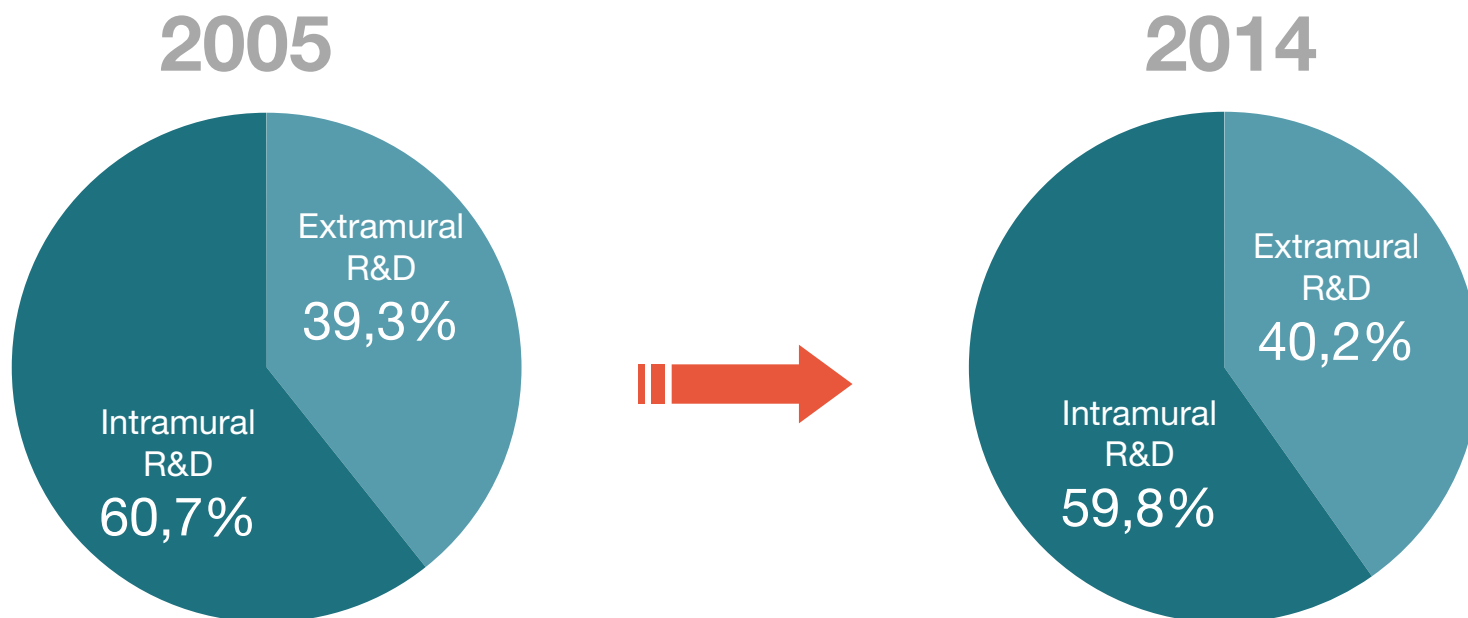
Whereas the main part of expenditure in R&D was undertaken in research centers of pharmaceutical companies themselves (intramural), 40 % of the total expenditure in R&D was destined to research contracts with hospitals, academia and public centers (extramural R&D).



Source: Farmaindustria

## Evolution of % of R&D investments by allocation : Intramural/Extramural (2005 vs 2014)

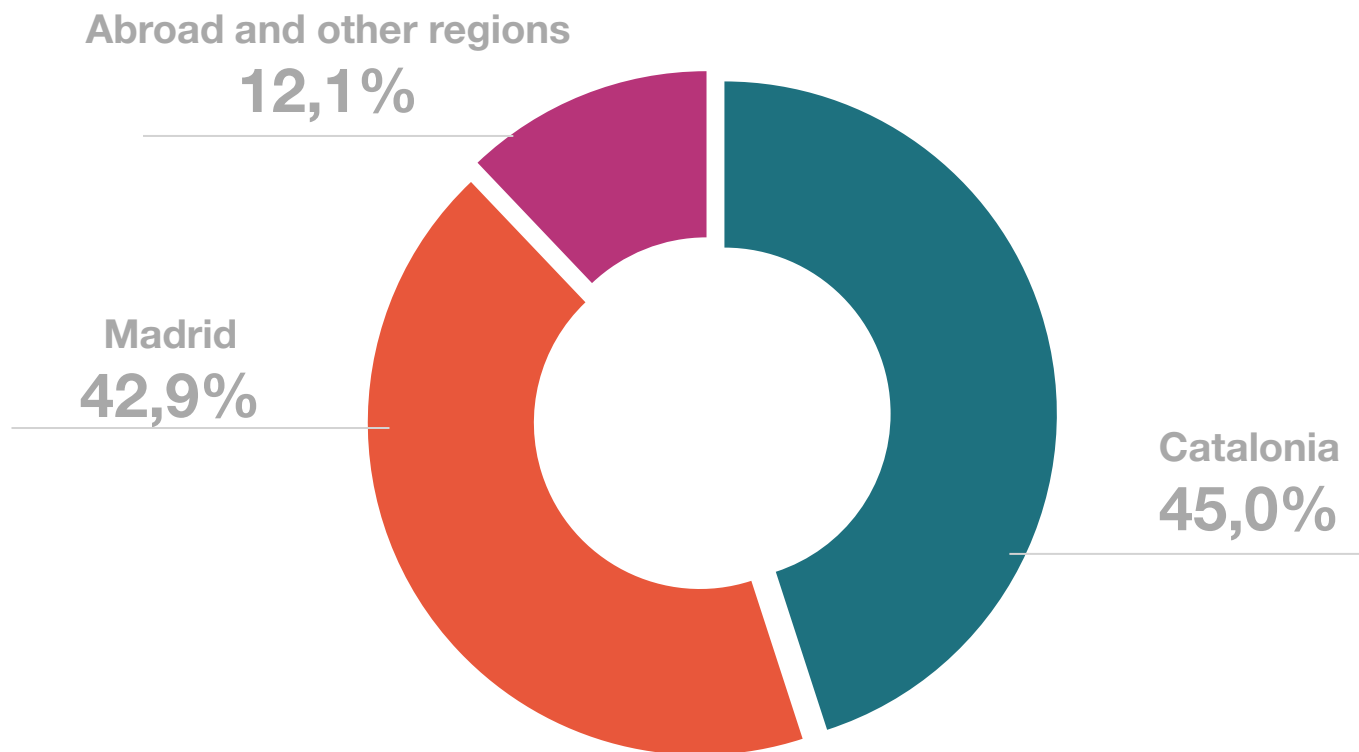
The structure of pharmaceutical companies' R&D expenditure has maintained itself relatively steady during the last ten years, though a slight raise in external collaborations has been experienced (extramural R&D expenditure)



Source: Farmaindustria

## Geographical distribution of intramural R&D (2014)

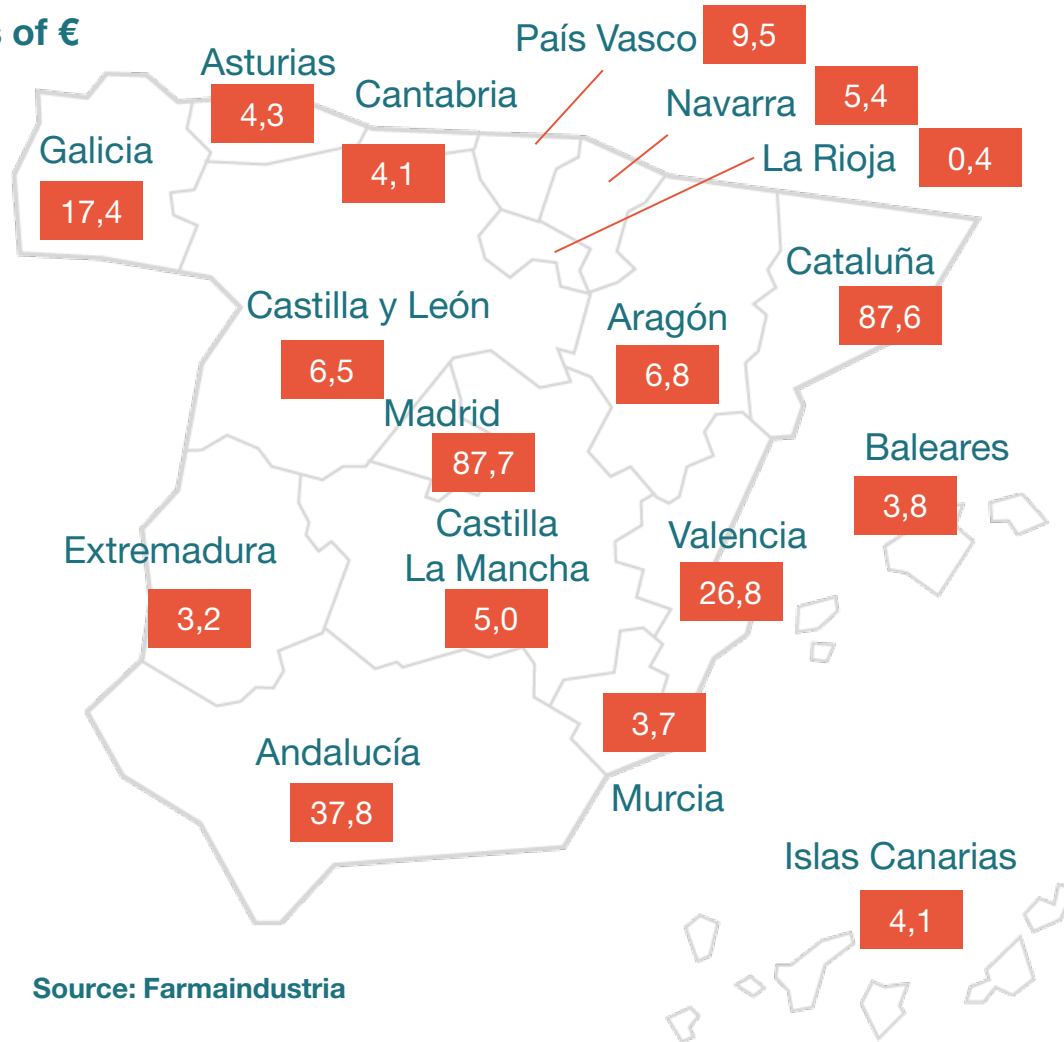
**Intramural R&D (2014)**  
568,0 millones de euros



Source: Farmaindustria

## Geographical distribution of extramural R&D (2014)

Millions of €



Source: Farmaindustria

Extramural R&D  
(2014)  
**382,0 M€**

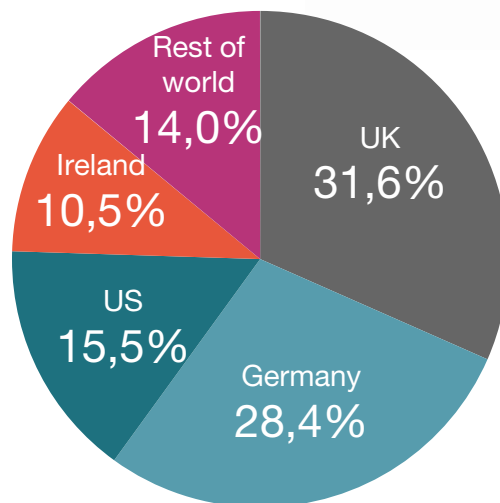


## Geographical distribution extramural R&D undertaken abroad (2014)

Entramural R&D  
ABROAD 2014  
**67,8 millones €**



### Receiving countries



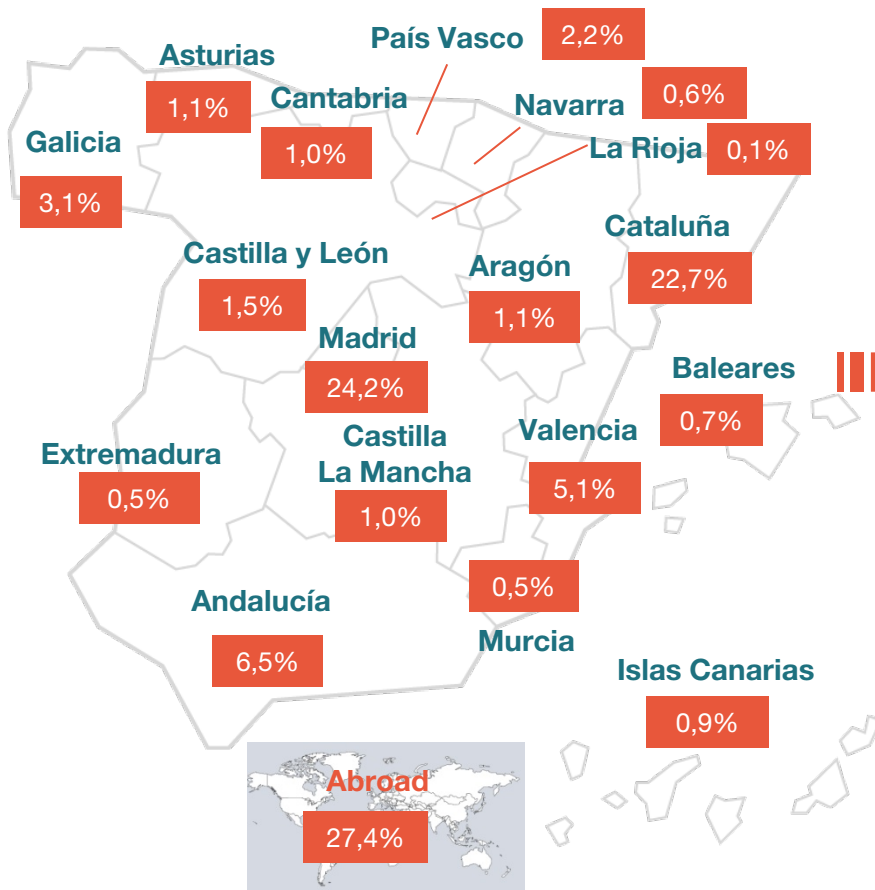
Source: Farmaindustria

## Evolution of the distribution of extramural R&D (2005 vs 2014)

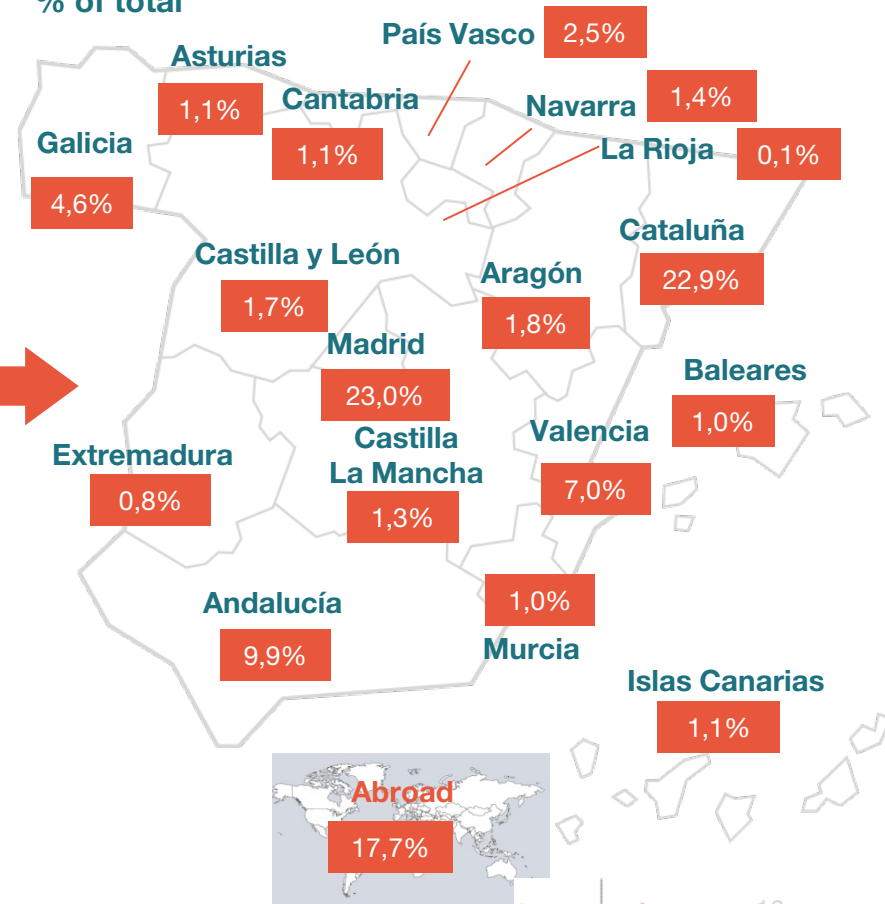
Extramural investments 2005: **301,0 M €**

Extramural investments 2014: **382,0 M €**

% of total



% of total



Source: Farmaindustria

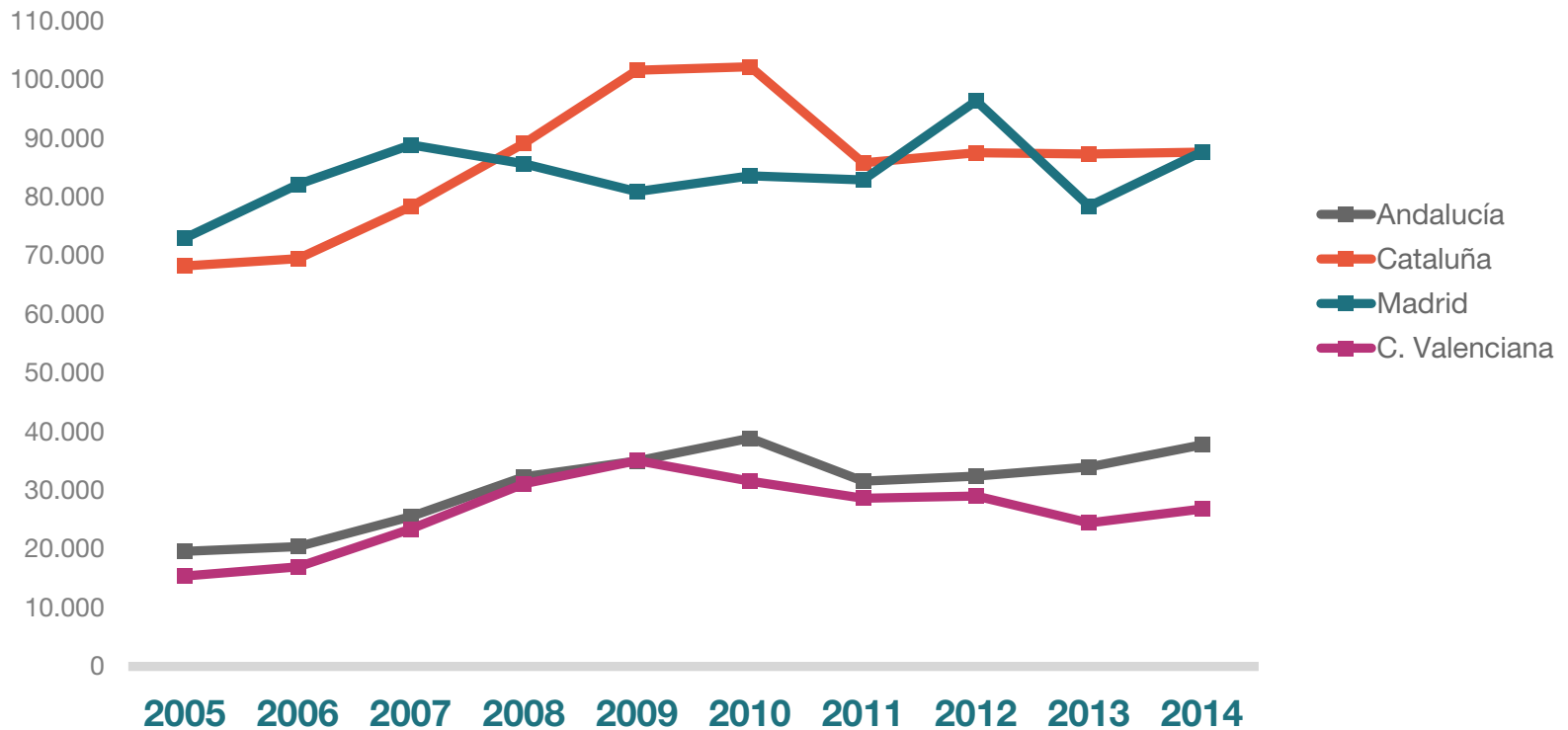
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Source: Farmaindustria



## Evolution of extramural R&D in Regions with + 5 millions citizens (2005-14)

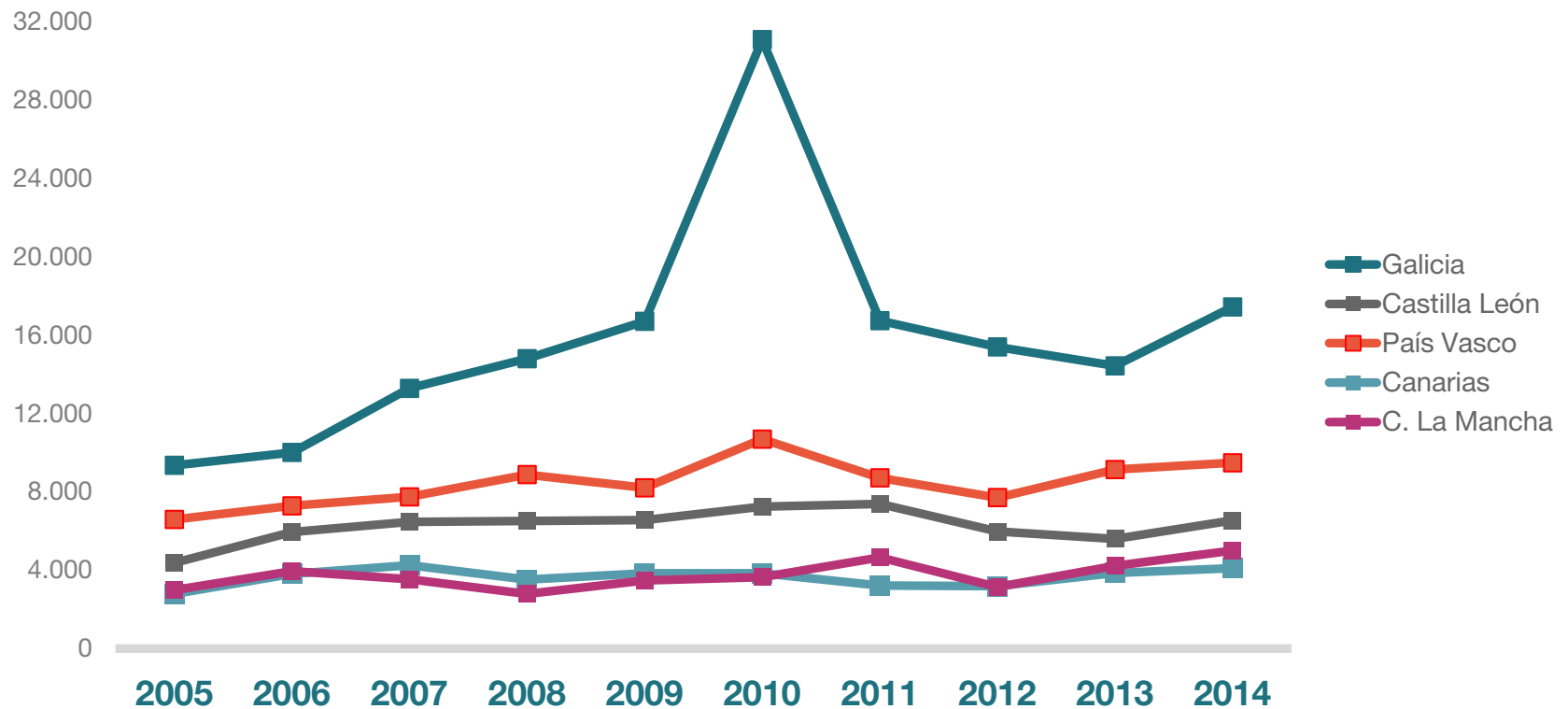
(thousands of €)



Source: Farmaindustria (R&D survey) and INE (1/1/2014)

## Evolution of extramural R&D in Regions with between 2 and 3 million citizens (2005-14)

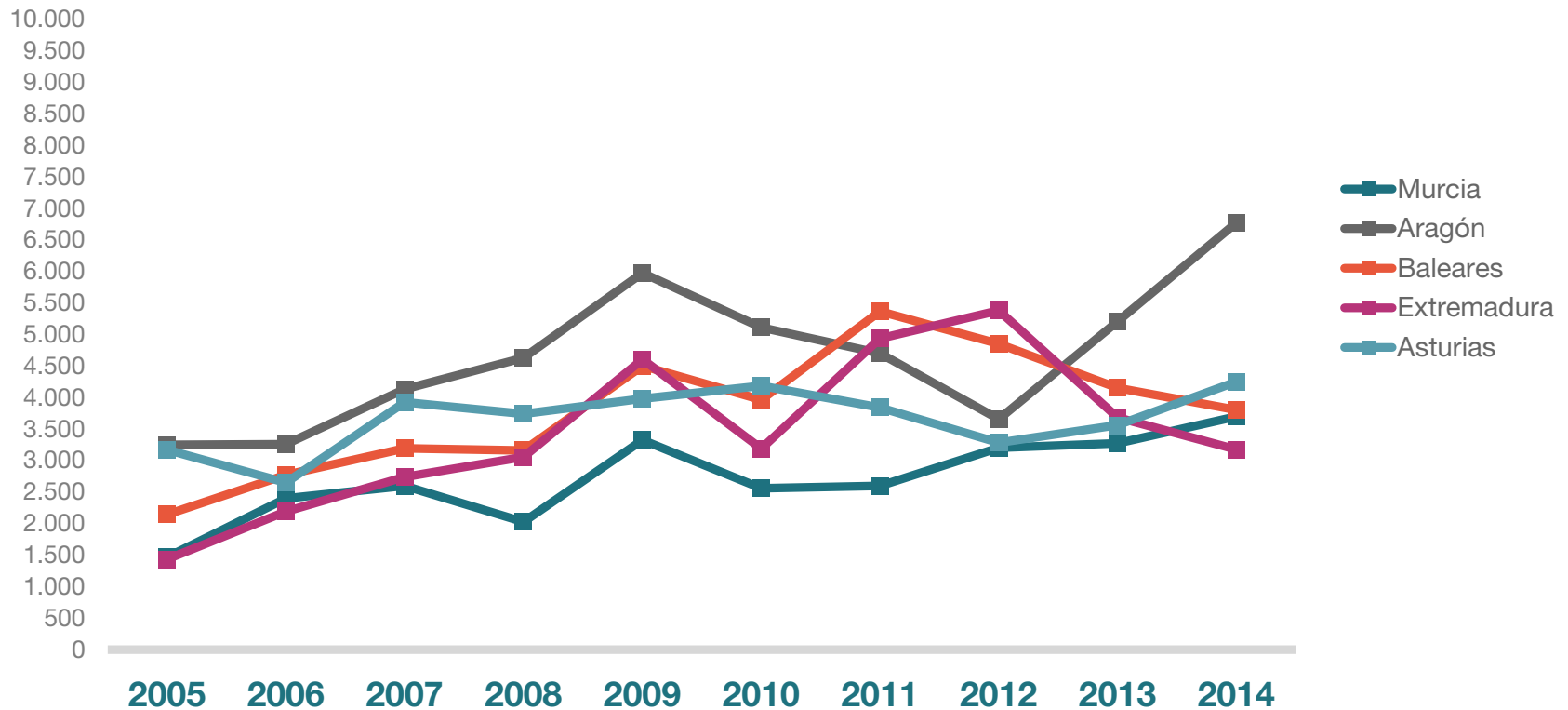
(thousands of €)



Source: Farmaindustria (R&D survey) and INE (1/1/2014)

## Evolution of extramural R&D in Regions with between 1 and 2 million citizens (2005-14)

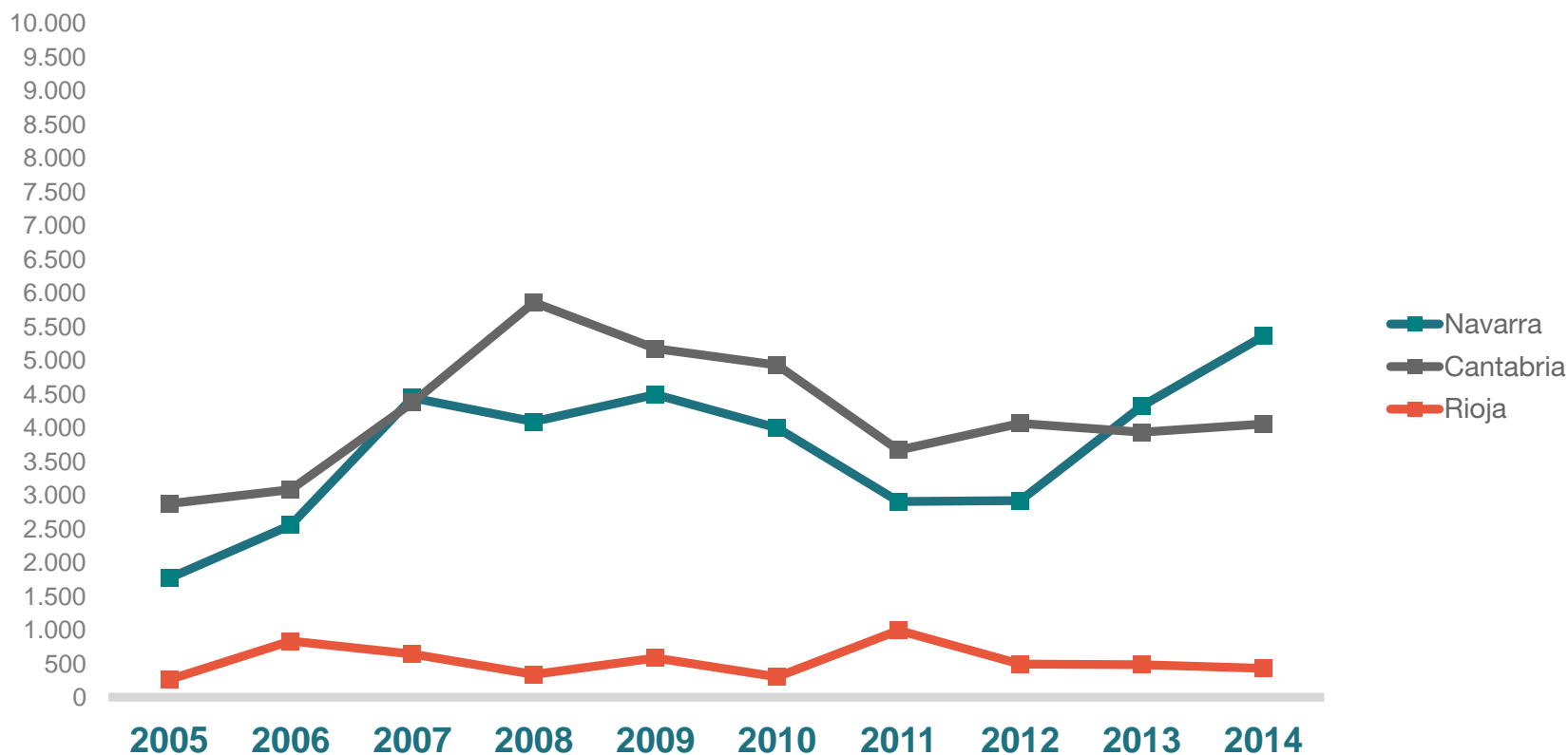
(thousands of €)



Source: Farmaindustria (R&D survey) and INE (1/1/2014)

## Evolution of extramural R&D in Regions with < 1 million citizens (2005-14)

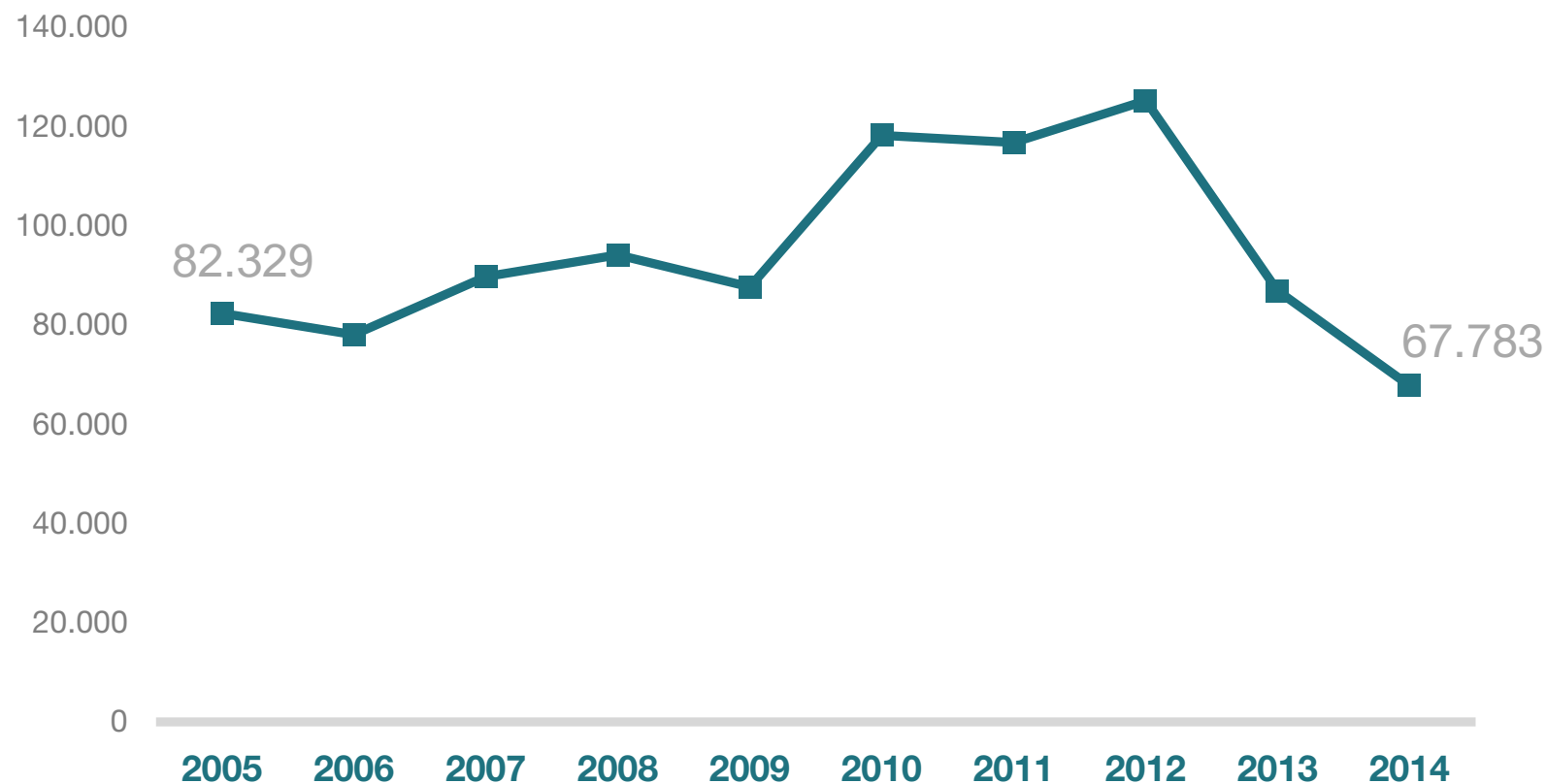
(thousands of €)



Source: Farmaindustria (R&D survey) and INE (1/1/2014)

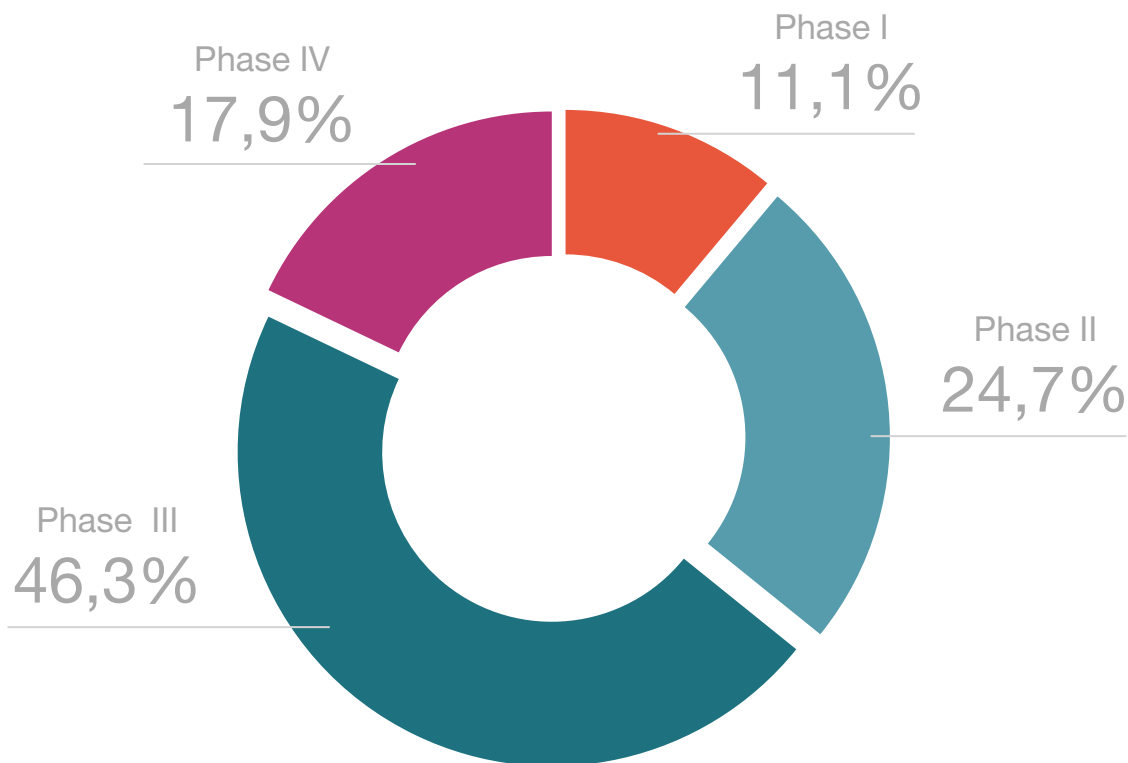
## Evolution of extramural R&D abroad (2005-14)

(thousands of €)



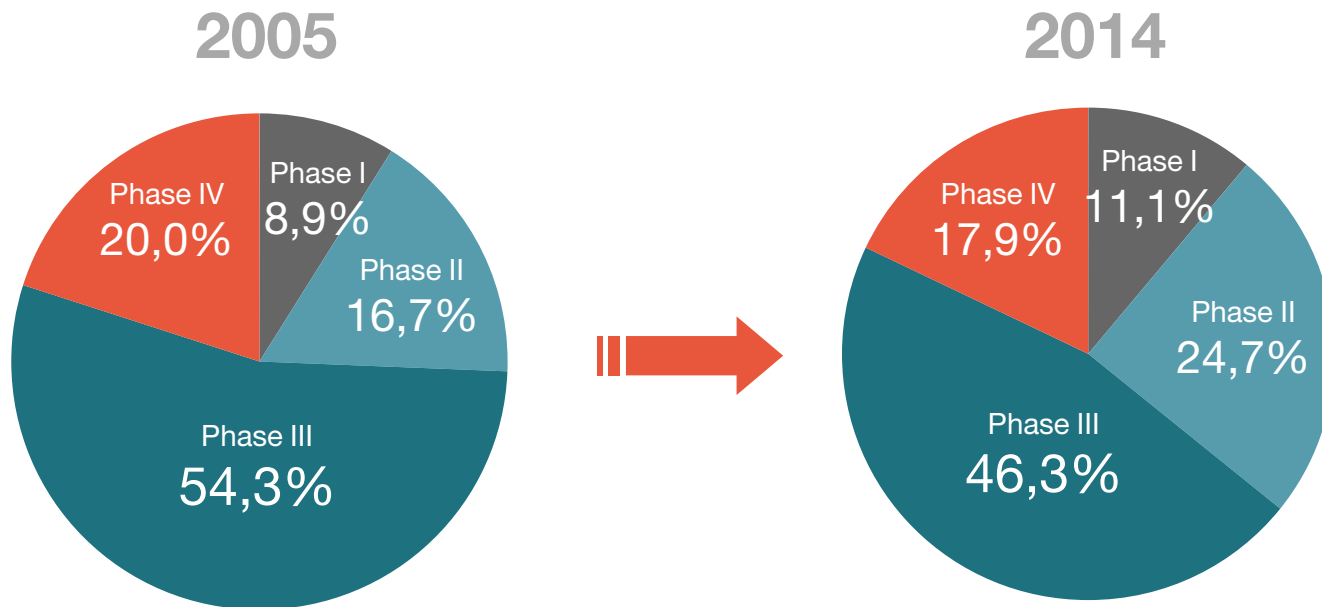
## Clinical research expenditure: Distribution per phases (2014)

During 2014, 486 million € were invested in clinical research, from which 36% were allocated to phases I and II



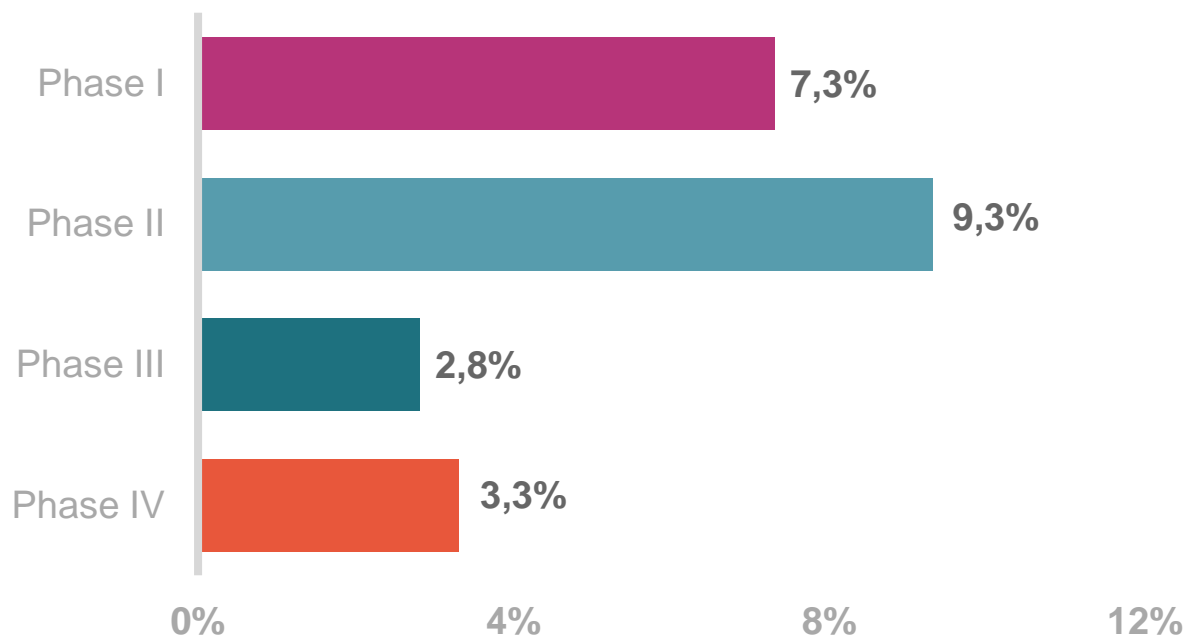
## Clinical research expenditure : Evolution of expenditure allocation per phases (2005 vs 2014)

When comparing the distribution of clinical research expenditure in 2005 to that of 2014, a loss of weight is perceived in late stage phases in favor of early stage phases, which have come to represent 35.8% of total expenditure, coming from 25.6% in 2005



## Clinical research expenditure : Annual variation rate of expenditure per phase (2005-14)

The expenditure in clinical research undertaken by the pharmaceutical industry has augmented at an average annual pace of +4.6% during the last ten years, raising from 324 M€ in 2005 to 486 M€ in 2014





### Biotechnology : General considerations

- **32** business groups have filled in the biotechnology form
- These groups represent 50.9% of sales of prescription medicines (IMS Health)
- In 2014, the pharmaceutical industry has invested 224 €M in biotechnology in our country, which accounts for 23.6% of the pharmaceutical industry's R&D in Spain
- Data which is now presented reflects only the data provided by responding companies

## Biotechnology: Preclinical Phase

- 59% of the informing collective uses biotechnology or some biotechnological origin tool in the preclinical phase.
- The most commonly used biotechnology in this phase are, in this order, molecular biology (cloning, sequencing, expression analysis), the usage of recombining proteins in screening trials and the use of functional trials with cellular lines expressing proteins.
- These tools are mainly used in the phases of high throughput screening, target identification and validation hit to lead and leads optimization.
- These tools are the company's own in 63% of the cases, obtaining the rest from collaborations and acquisitions of commercial reactivities
- 68% of the companies using biotechnology in this phase partially or totally develop their activities in Spain
- Ongoing research projects of which information has been given, based in biological recombining origin active ingredients are mainly focused in the areas of oncology, dermatology and allergology
- The main research projects for chemical synthesis molecules in which biotechnology has been used are being developed in the areas of immunology, oncology and ophthalmology

## Biotechnology: Clinical Phase

- 71 % of the informing collective uses biotechnology or some biotechnological origin tool in the clinical phase.
- The most commonly used biotechnology used in this phase are, in this order, the usage of recombining proteins, the genetic expression analysis and SNP genotyping
- These tools are used both in early phases (I—II), and late phases (III-IV), and less frequently in the preclinical development trials.
- These tools are the company's own in 73% of the cases, obtaining the rest from collaborations and acquisitions of commercial reagents
- 76% of the companies using biotechnology in this phase partially or totally develop their activities in Spain
- The reports include 112 recombinant origin biotechnological medicines in development phases, with 370 ongoing clinical trials in Spain (or managed in Spain), mainly in the areas of oncology, diabetes and hematology.
- Likewise, the reports include 42 chemical synthesis medicines in development in which biotechnological tools have been used, with 84 ongoing clinical trials managed in Spain and which are mainly developed in the areas of oncology, neurology, endocrinology and respiratory disorders

## Biotechnology: Production and marketing phases

- A 10% of the informing sample produces biotechnological medicines in our country, which are mainly exported to the companies of the same business group.
- Likewise, 20% of the informing sample uses biotechnology during the marketing phase, both for biotechnological products as for chemical synthesis.
- They are mostly international companies, though there are also national capital companies producing this kind of medicines.
- The use of biotechnology in this phase is normally channeled through molecular diagnosis kits and diagnosis services.
- 60% of biotechnological tools used in this phase are the company's own; the rest are obtained through third parties.
- Likewise, in 83% of the cases the use of these techniques takes place in Spain, though sometimes it is simultaneously undertaken abroad.
- Reports include 46 active ingredients which have been marketed in Spain during the last year with a biological recombining origin, mainly in the areas of immunology, oncology and hematology

# farmaindustria

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