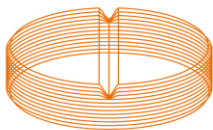


The BEST Project: fostering Clinical Trials in Spain

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Deputy Director General, Farmaindustria

Athens, February 2016



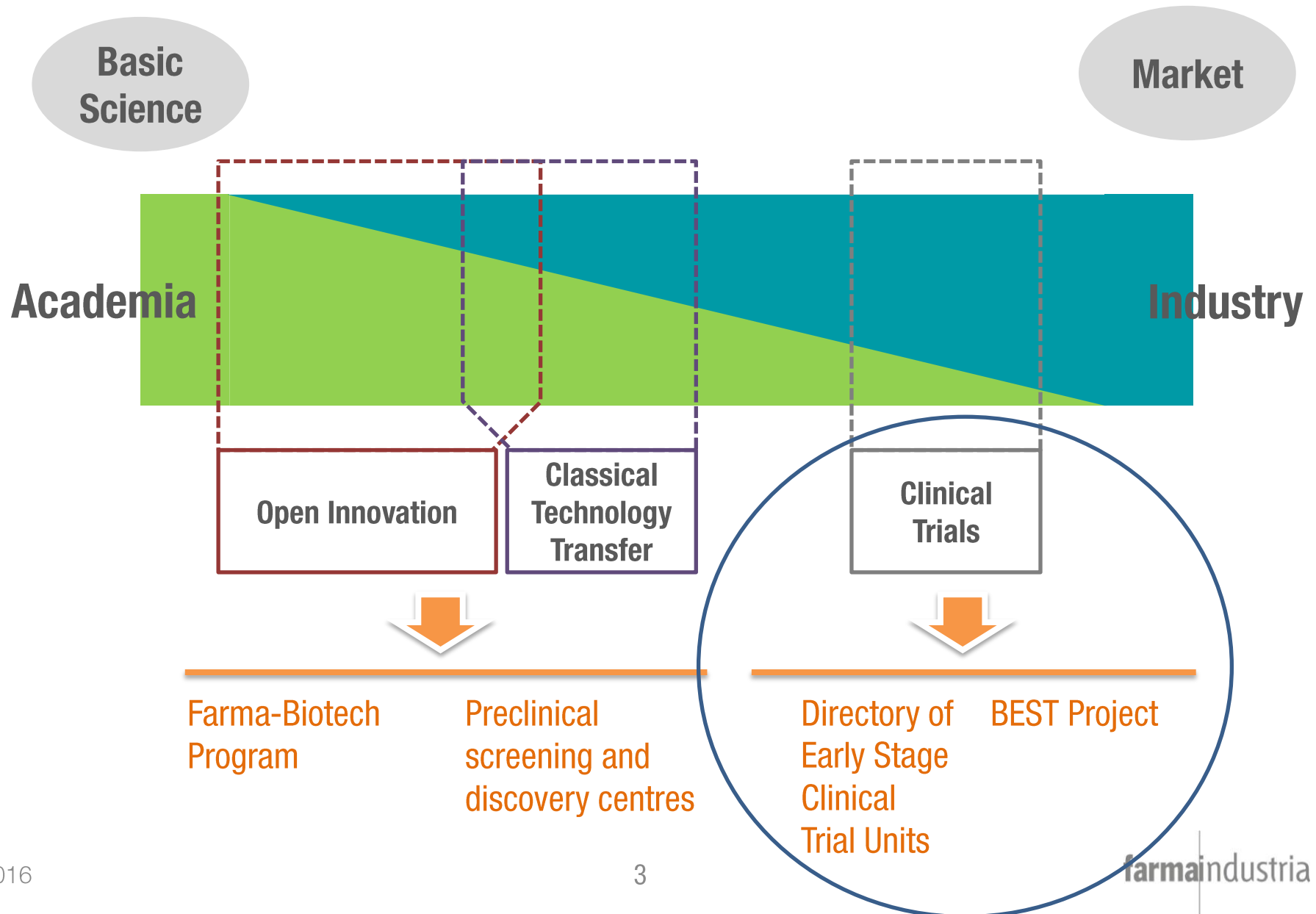
MEDICAMENTOS INNOVADORES
Plataforma Tecnológica Española

farmaindustria

Spain as an opportunity in pharmaceutical R&D

- Strong and dynamic **industrial tissue**, leader in R&D (1 Bn € per year, 20% of Spanish industrial research).
- Relevant **pharmaceutical market** (5th Europe; 8th Worldwide), and high public healthcare investments.
- **Excellent science** and vibrant network of **biomedical research** (Academia, R&D Public Centers and start up co.).
- **National Health System** with universal coverage and a good network of hospitals with excellent healthcare professionals.
- Wide **public awareness** about healthcare and biomedical research.

Public-private Cooperation Platforms



Directory of Early Stage Clinical Trial Units in Spain

The aim: fostering early stage CT in Spain

A complete **Directory** published in English and Spanish describing in depth the **facilities, competences, resources and track record** of the Units specialized in Phase-I and Early Stage Clinical Trials operating in Spain.

First edition in 2007, second edition in 2009, third edition **(37 Units and 1 network of centres)** published in **October 2015**.

Available at: www.medicamentos-innovadores.org

Individual information for each Unit

- ▶ General Information
- ▶ Ownership
- ▶ Accreditations and Audits
- ▶ Facilities
- ▶ Staffing and Resources
- ▶ Services Capabilities
- ▶ Study Participants
- ▶ Pharmacodynamic/Pharmacokinetic Capabilities
- ▶ Experience
- ▶ Annexes

BEST Project: excellence in clinical research



January 2016:

45 companies

4 independent research groups

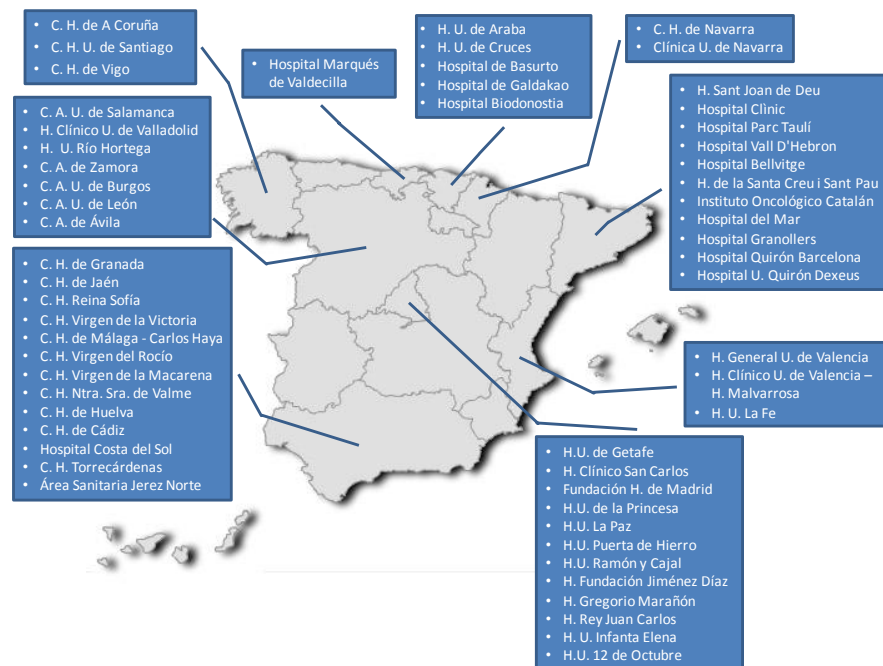
50 hospitals

13 regions

BEST is a strategic project launched by the pharmaceutical industry in 2006

The final goal is to make Spain an **attractive country for clinical trials**, building up a wide public-private platform of excellence in clinical research involving all stakeholders.

The key: sharing **objectives** and **parameters** to measure results. Strong and robust **database** with over 2,365 CT since 2004.



BEST Project: excellence in clinical research

Successful outcomes of the BEST project

Background: started in January 2006 to tackle the risk of **losing clinical research** following Royal Decree 223/2004. Perceived loss of competitiveness and need to measure this situation.

Aim: to make Spain an **attractive country** for clinical research

After **9 years** we have made **huge progress**:

- ▶ **Stakeholder engagement:** hospitals, investigators, scientific associations, clinical research groups, patients, autonomous communities, the Spanish Agency for Medicinal Products and Medical Devices (AEMPS), ethics committees.
- ▶ **Cultural change:** clinical research is good for all stakeholders. We **share aims and metrics** with everyone.
- ▶ **Competitiveness: metrics** have helped us strengthen our competitiveness in Spain (timelines and recruitment). They enable companies and healthcare centres to benchmark with the group as a whole in order to pinpoint where improvements can be made
- ▶ **Smoother dialogue** between **strategic agents** (industry, healthcare centres, regions). Greater proximity **helps to resolve** issues (insurance, contracts, biological samples, etc.).

BEST Project: excellence in clinical research

Successful outcomes

		2004	2014	%Δ	CAGR
1	Number of clinical trials in BDMetrics	117	2.365	n.a	n.a
	Number of industry trials authorised by AEMPS	473	554	17%	2%
2	Industry expenditure in clinical research (€M)	299**	487	63%	5%
	Industry expenditure in R&D (€M)	706**	950	35%	3%
3	Global start time of a trial (days) <i>first patient-in</i>	244	179	-27%	-3%
	Differential with first European patient (days)	95	34	-63%	-10%
	Authorisation after EC opinion (days)	37	16	-57%	-8%
	Processing of agreement, contract (days)	164	112	-32%	-4%
4	Efficiency of recruitment (recruited/planned %)	95%	106%	12%	1%
5	Trials in early phases (I and II in % over total)	37%	46%	23%	2%
6	Trials in Oncology (% over total)	28%	50%	79%	6%

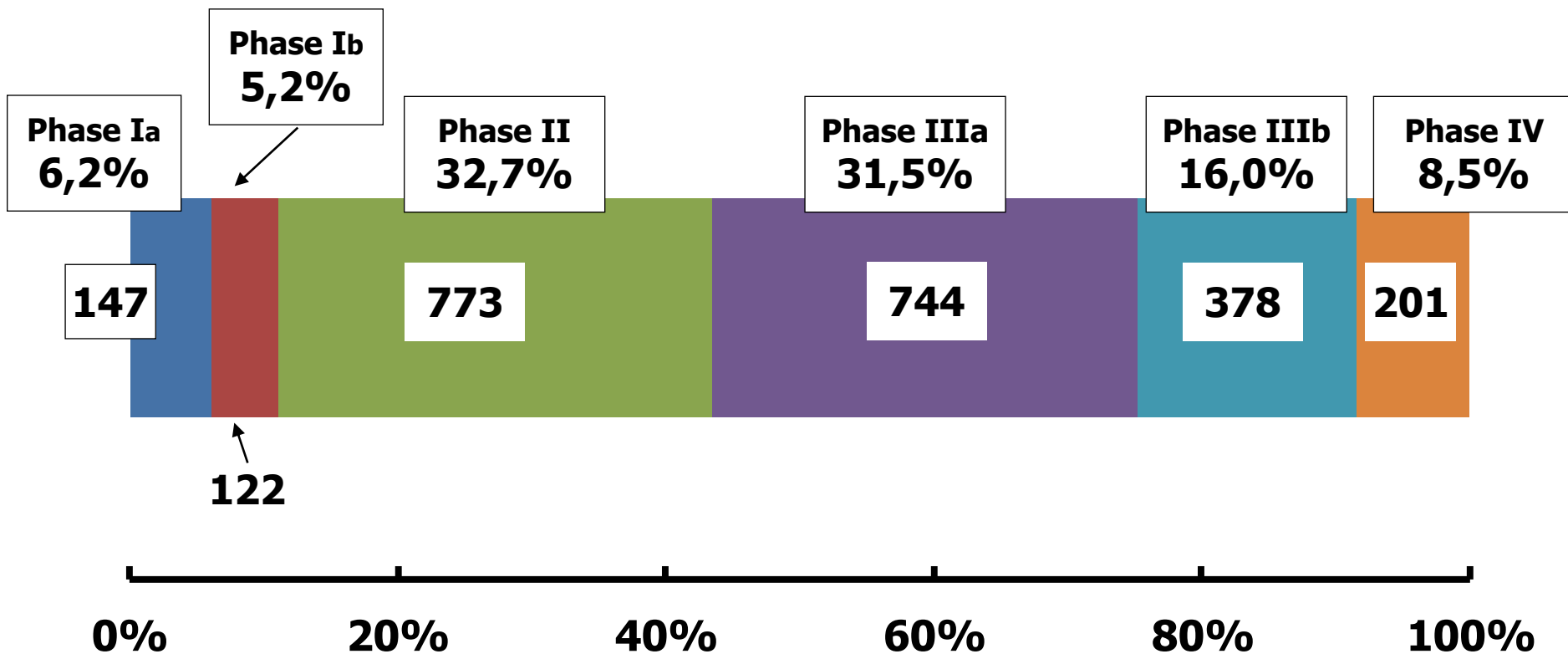
CAGR: Compound Average Growth Rate

2. Data 2005 and 2014

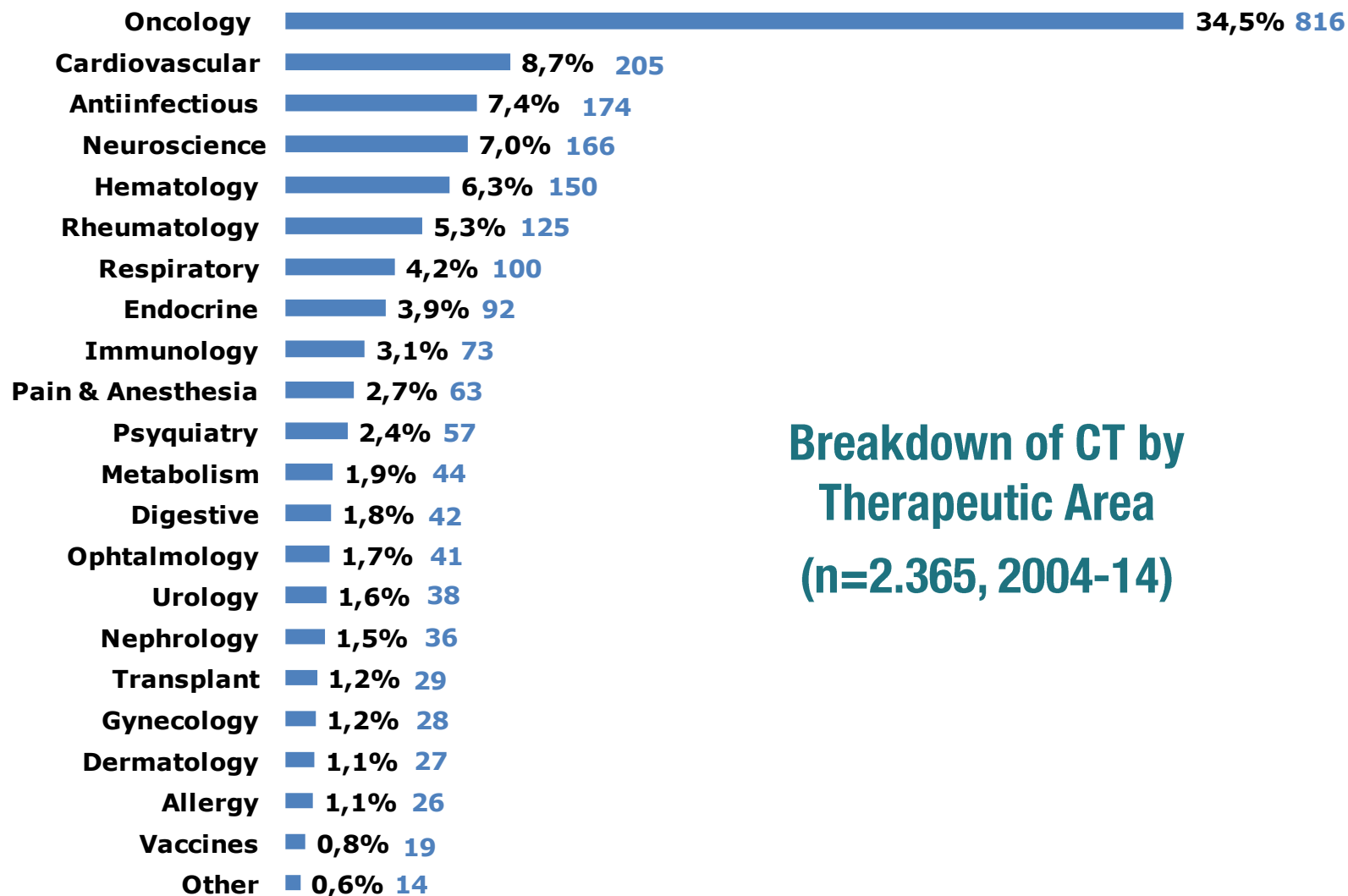
4. Data 2005 and 2014. Finalized CT in the year. The % varies significantly by therapeutic area and region. Percentage of non-recruiting sites: 9%

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Distribution of clinical trials by phase (n=2.365, 2004-14)



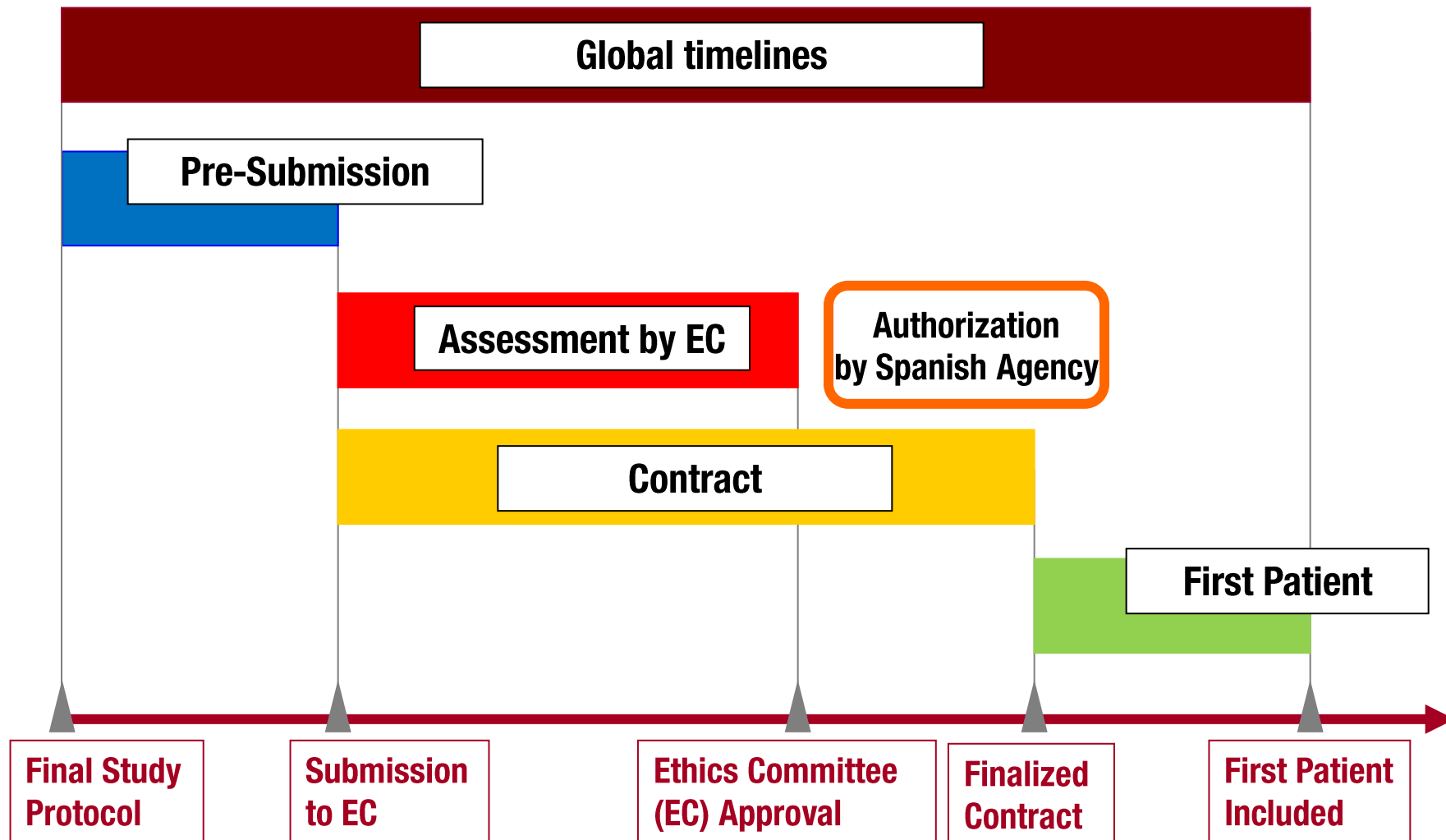
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**Breakdown of CT by
Therapeutic Area
(n=2.365, 2004-14)**

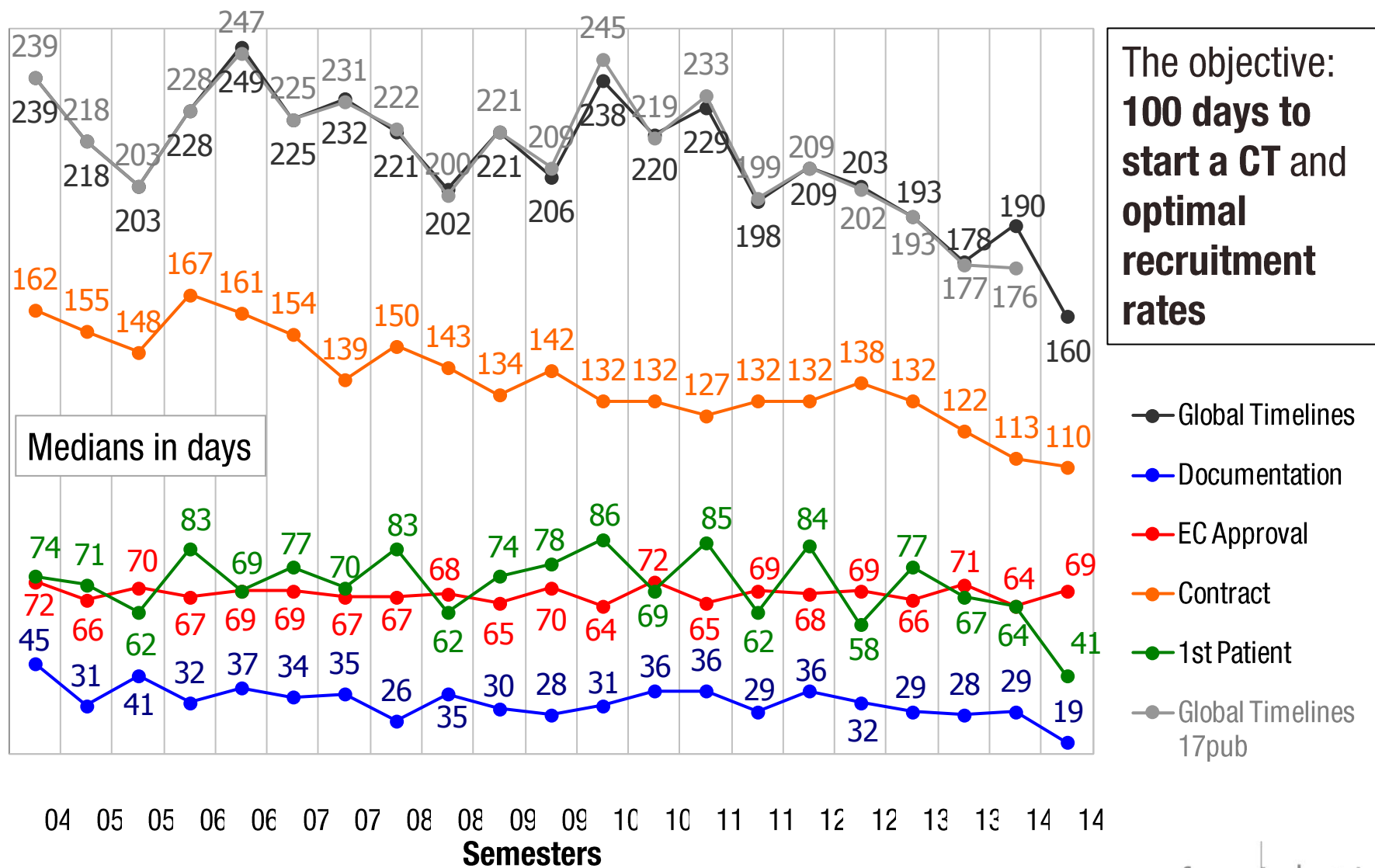
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Description of start-up process and performance indicators



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Evolution of timeline KPI



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International benchmark: Recruitment KPI

Average of planned patients
per Participating Site in each
country

The comparison is made for
the **same finished Clinical
Trials involving Spanish
sites and other sites in the
country concerned** with
final study protocol
reception date between
2010 and 2014

	Patients/PS Country	Patients/PS Spain	Country-Spain	Nº CT
Bulgaria	12,2	6,8	5,3	13
Ukraine	9,7	4,5	5,1	10
Poland	10,0	6,2	3,8	50
Hungary	8,6	6,4	2,2	49
Czech Republic	9,1	7,1	2,1	42
Denmark	8,8	6,8	2,0	30
Lithuania	9,0	7,4	1,6	12
Slovakia	8,8	7,5	1,3	18
Romania	8,6	7,4	1,2	27
Russian Federation	7,2	6,1	1,1	33
Germany	6,5	5,5	1,0	126
United Kingdom	5,9	4,9	1,0	78
Italy	5,5	4,8	0,7	115
Spain	5,7	5,7	0,0	172
Netherlands	6,2	6,7	-0,5	34
Finland	6,0	6,7	-0,6	30
Sweden	5,1	5,9	-0,8	31
Belgium	5,5	6,4	-0,8	67
Austria	5,2	6,2	-1,0	34
France	4,3	5,4	-1,0	103
Greece	6,6	7,9	-1,3	20
Norway	6,2	8,3	-2,1	12
Switzerland	3,7	6,1	-2,3	27
Ireland	4,0	6,7	-2,7	11
Portugal	5,1	9,0	-3,8	14
Turkey	3,8	7,7	-4,0	21

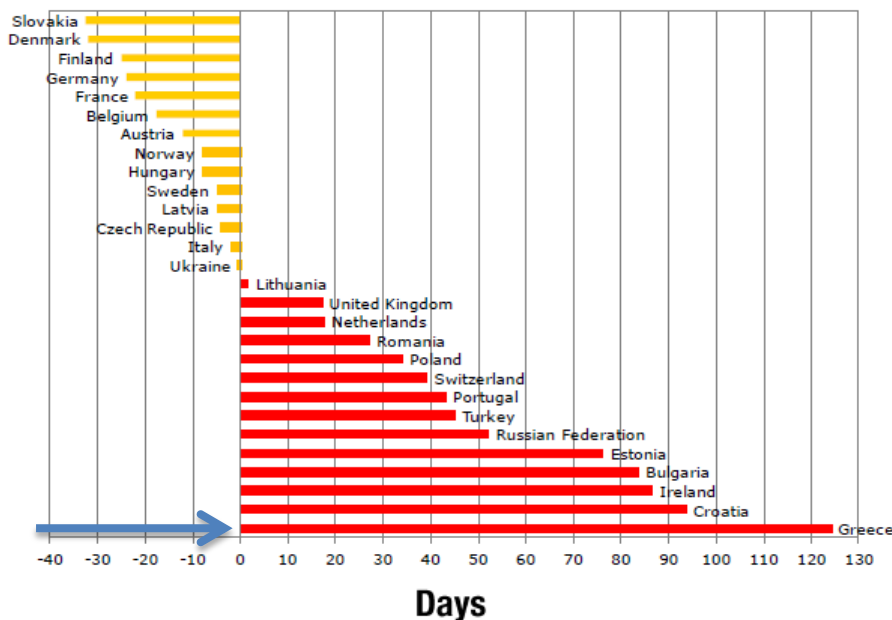
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International benchmarking: timeline KPI

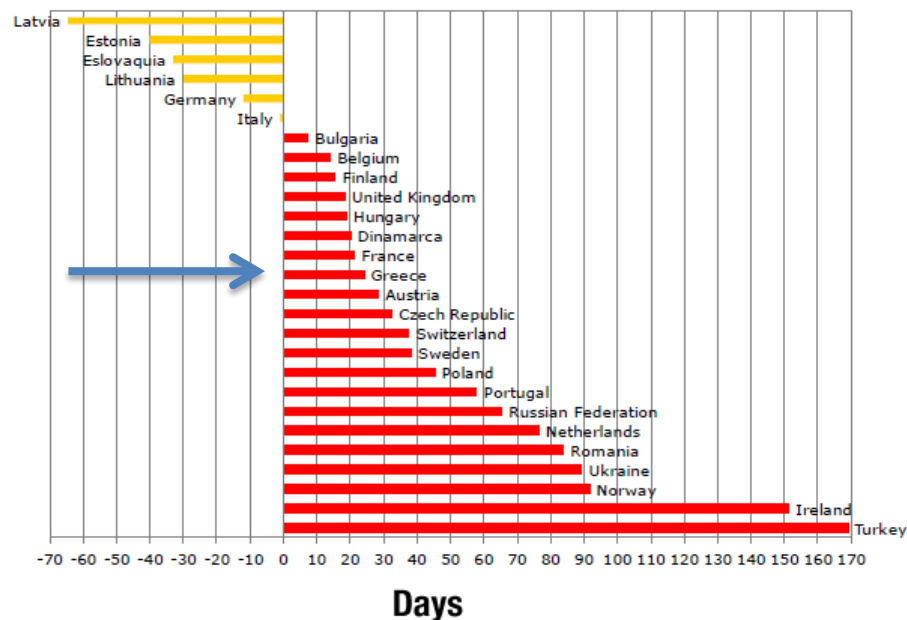
The **situation** is **improving**, in the period 2004-2009 **fourteen** countries began a trial before Spain, while in the period 2010-2014 the number of countries has been reduced to **six**.

Initiation time

2004-2009



2010-2014

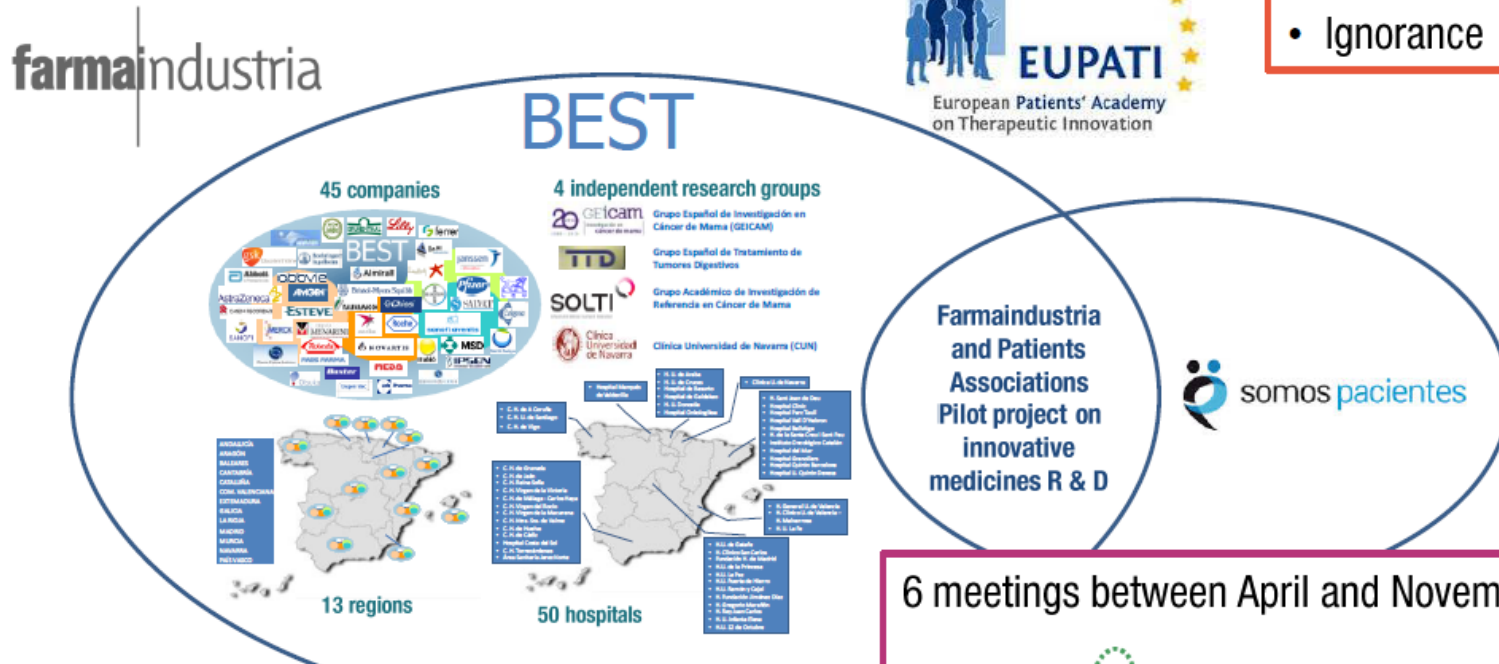


BEST Project and patient associations in CT

Change of model: Active Patient

Patient Centricity

- Need for information and training
- Ignorance



- ✓ Process of drug development
- ✓ What is a CT, who approves CTs, the role of the AEMPS, Ethical Committees, which law applies
- ✓ How and when to participate in a CT

6 meetings between April and November 2015

-Diabetes



-Rheumatology / Arthritis



-Oncology



BEST Project: excellence in clinical research

Spain: The First European Country to implement new legal framework on clinical trials

EU Clinical Trial Regulation
will come into effect by
October 2018 (CT Portal and
Database)

REGULATIONS

REGULATION (EU) No 536/2014 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL
of 16 April 2014
on clinical trials on medicinal products for human use, and repealing Directive 2001/20/EC

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I. GENERAL REGULATIONS

MINISTRY OF HEALTH, SOCIAL SERVICES AND EQUALITY

14082 *Royal Decree 1090/2015, of 4 December, regulating clinical trials with medicinal products, Ethics Committees for research with medicinal products and the Spanish Clinical Studies Registry.*

The main objectives:

- ✓ Shorter timelines (50-100d)
- ✓ Transparency (Public Register)
- ✓ Simplified procedures (authorization from SA & single and binding opinion from any Ethics Committee (EC))
- ✓ To reduce costs & red tape (contracts)
- ✓ More involvement of patients in EC

Entry into force: 13th/January/2016

BEST Project: excellence in clinical research

Conclusions: the importance of clinical research

- **Clinical research is key** for the pharmaceutical industry:
 - **Investment in clinical research** by the pharmaceutical industry has grown annually by 5% in recent years, from €299 million (2005) to €487 million (2014).
 - Rise in the number of clinical trials rolled out by the pharmaceutical industry in Spain, from 473 (2004) to 554 (2014). 95% of these clinical trials are international.
 - Results achieved thanks to the involvement of **public and private stakeholders: shorter timelines** (only 34 days later than the best European site of each trial; 93 days in 2004); **efficient recruitment**; units specialized in **early phases** (50% of CT in 2014).
- Excellence in clinical research is essential in a country's development:
 - **Industrial competitiveness.**
 - **Advantages for the national health service: access of patients to innovative drugs; motivation, know-how and development of its HCP**; prestige and image for its **institutions**; last but not least, **financial resources and savings in medication.**
- We are succeeding in making Spain an **attractive country** for clinical research. This needs to be maintained and, if possible, increased with the **new legal framework.**
WORKING TOGETHER!!!

Thank you!

www.farmaindustria.es

www.medicamentos-innovadores.org

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