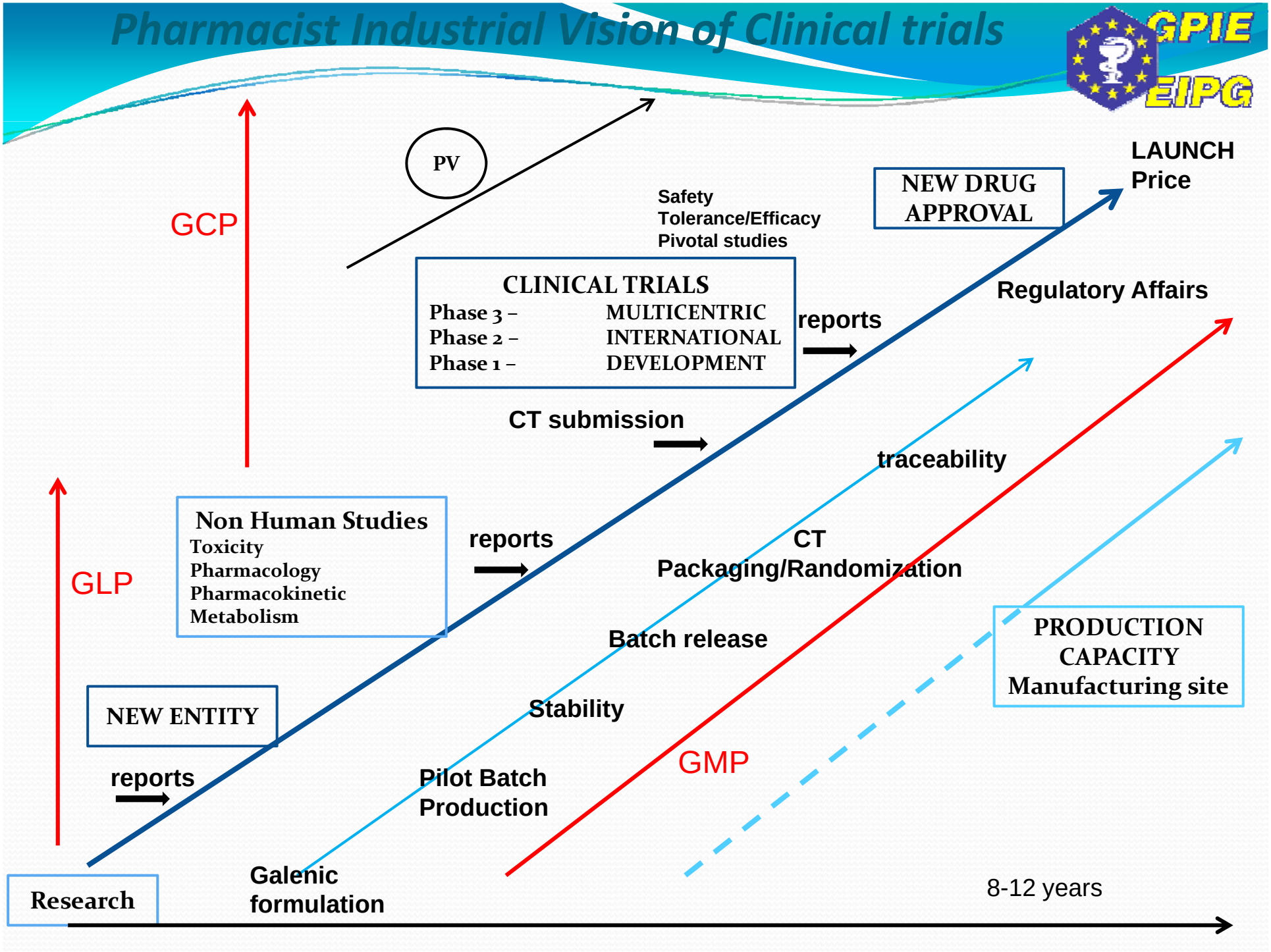
Pharmacist
Industrial Vision of Clinical trials

Vision of International Clinical Research
(Leem Study)

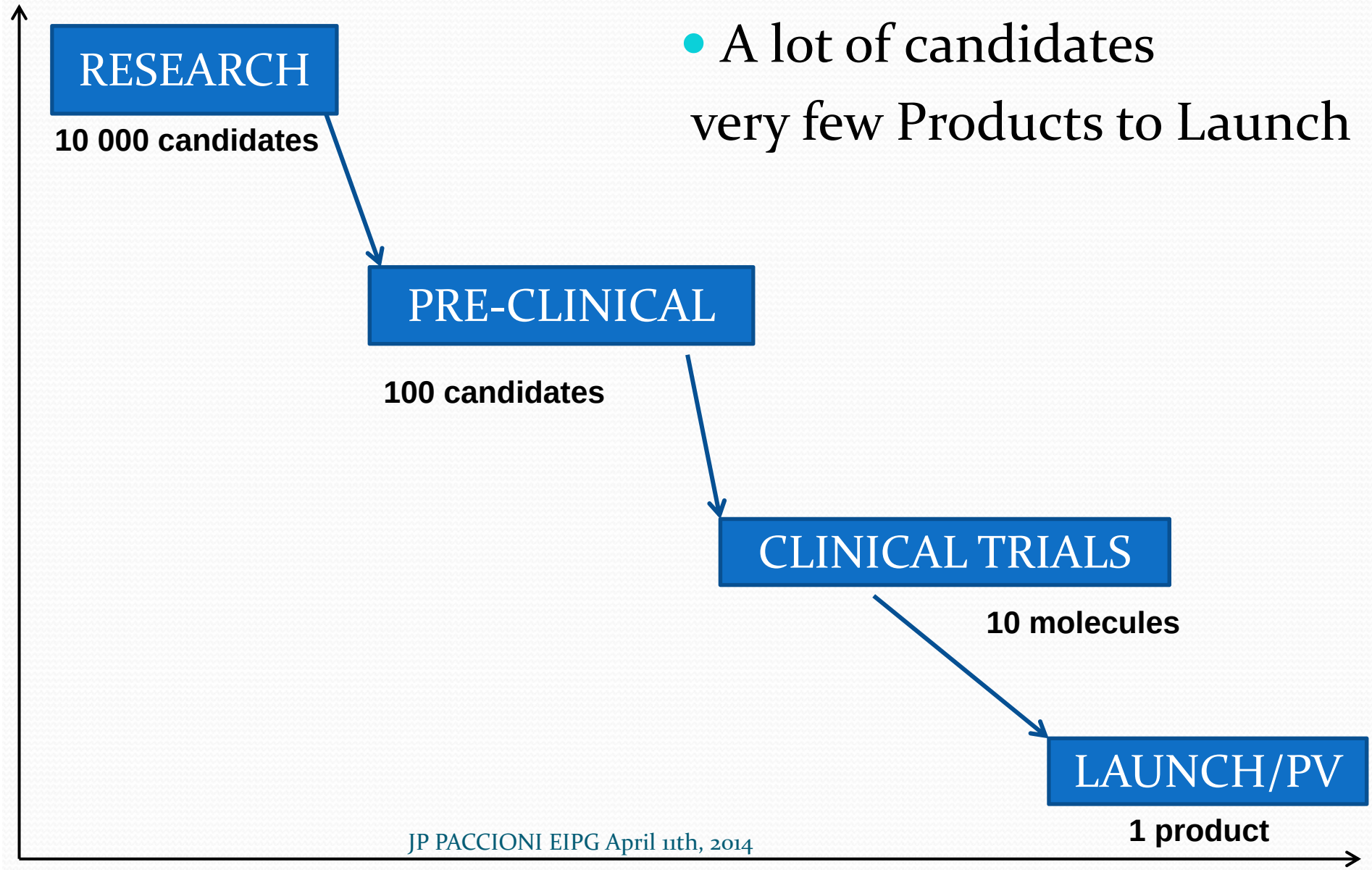
Pharmacist Industrial Vision of Clinical trials

- Clinical Trials are by definition the only way to get Marketing Authorization Approval of a new Medecine
- But Clinical Trials are a part of a long Pharmaceutical Process from Research and Development… to approval and launch
  - 8 to 12 years process
  - A very complex process – 1 molecule on 10 000
  - A costly process : 1 to 1,5B$ for a new Entity
  - A risky process : how to finance R&D with a limited number of marketed medecines

Pharmacist Industrial Vision of Clinical trials



Pharmacist Industrial Vision of Clinical trials



- A lot of candidates

very few Products to Launch

INTERNATIONAL CLINICAL RESEARCH

Synthesis of 6 surveys conducted by Leem since 2002 and 2012

Clinical Research: a major issue for French attractiveness within an increasingly competitive environment

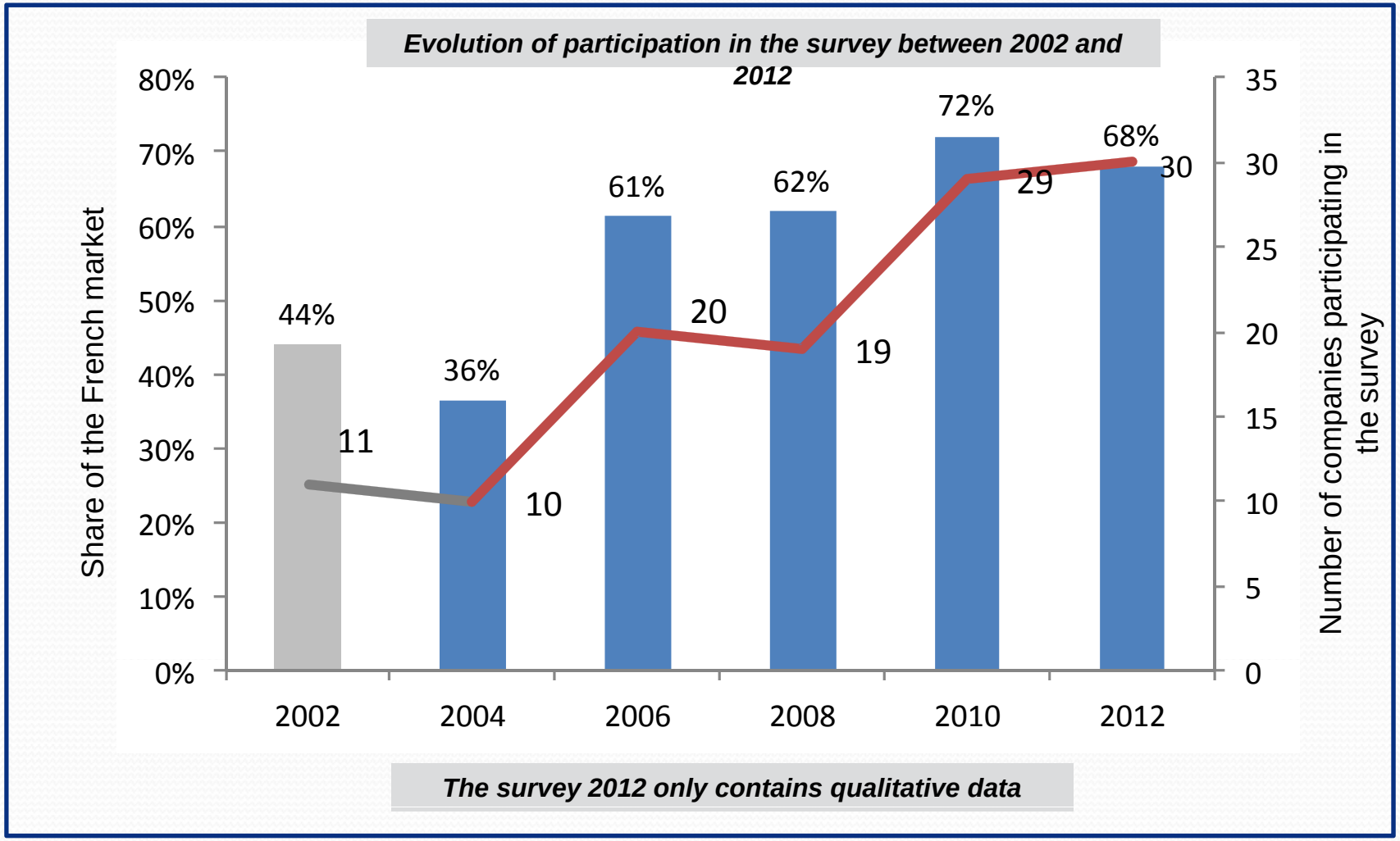
- **Survey performed by the Leem every 2 years in association with Publicis Healthcare Consulting to conduct a situation analysis of France's position in international clinical research (quantitative aspects and qualitative perception)**

- **Exceptional and unique scope of available data in Europe thanks to 6 surveys conducted since 2002**
  - International studies of development (Phase II et III) with French participation

Since 2004, nearly 500 studies, over 1 million patients included

Synthesis of 6 surveys conducted by Leem since 2002 and 2012

The survey representativeness increased steadily between 2002 and 2012 to reach 30 laboratories



Synthesis of 6 surveys conducted by Leem since 2002 and 2012

2012 survey: a significant sample

30 pharmaceutical companies involved in the 2012 survey

- Abbott
- Actelion
- Amgen
- Astellas
- AstraZeneca
- Bayer
- Biogen
- BMS
- Boehringer Ingelheim
- Celgene
- Daiichi-Sankyo
- Gilead
- GlaxoSmithKline
- Ipsen
- Janssen
- Léo Pharma
- LFB
- Lilly
- Lundbeck
- Merck Serono
- MSD
- Novartis
- NovoNordisk
- Pfizer
- Pierre Fabre
- Roche
- Sanofi
- Sanofi Pasteur
- SPMSD
- Takeda

New participants : Companies that have not participated to the previous surveys

For France

- 559 studies (vs 415 en 2010) Of which 110 studies de phases I et I/II
- 22 114 patients (vs 22 095 en 2010)
- 3 152 centers (vs 2 433 en 2010)

For international comparison

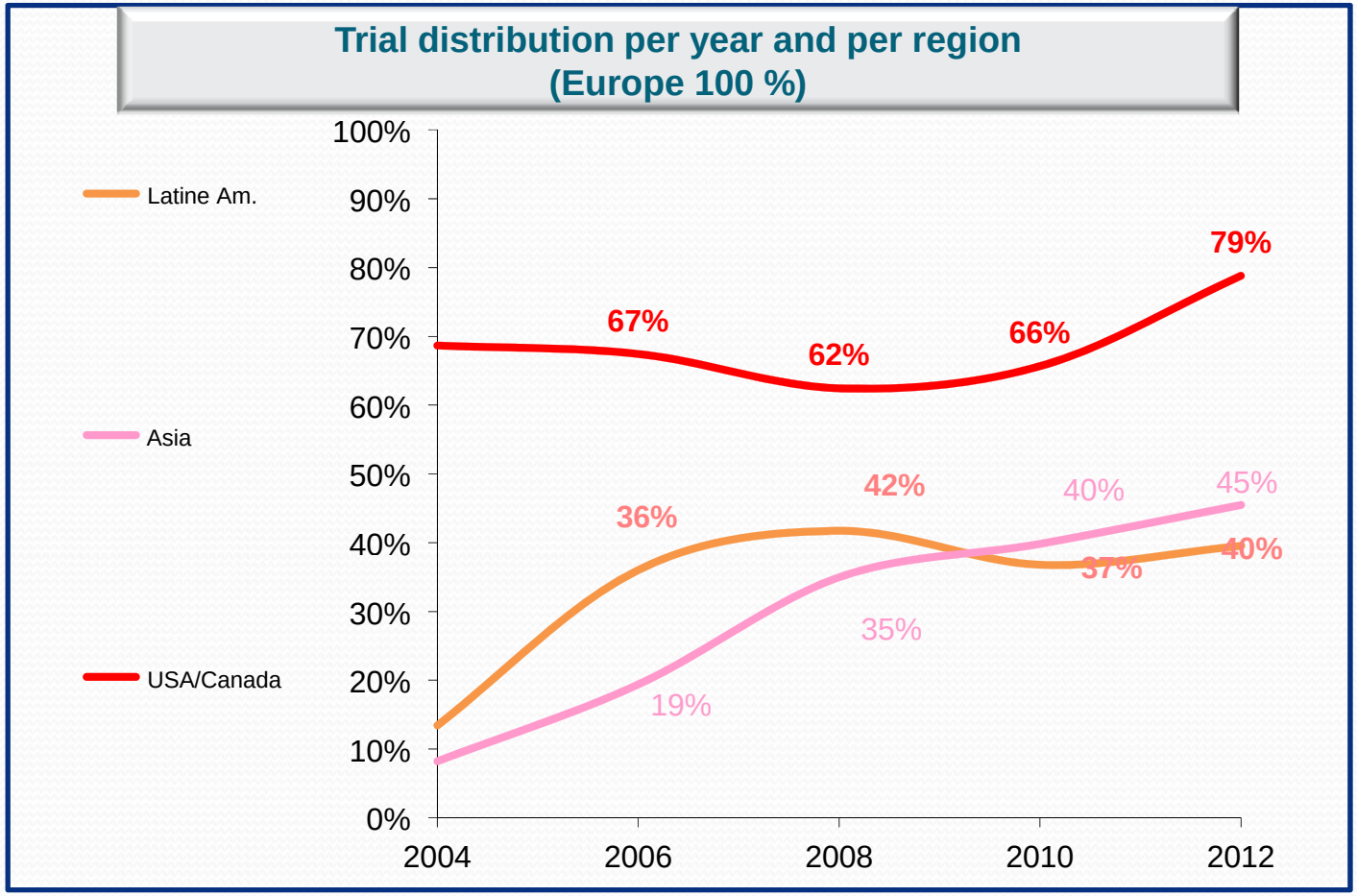
- 420 studies (vs 328 en 2010)
- 246 895 patients (vs 249 704 en 2010)
- 32 965 centers (vs 24 337 en 2010)

Note : Loss of 3 laboratories : Cephalon, Cytheris, Servier
and merger between Pfizer-Wyeth / MSD-Schering Plough / Takeda-Nycomed

Synthesis of 6 surveys conducted by Leem since 2002 and 2012

US-Canada has increased significantly as they are now involved in nearly 4 studies out of 5

World

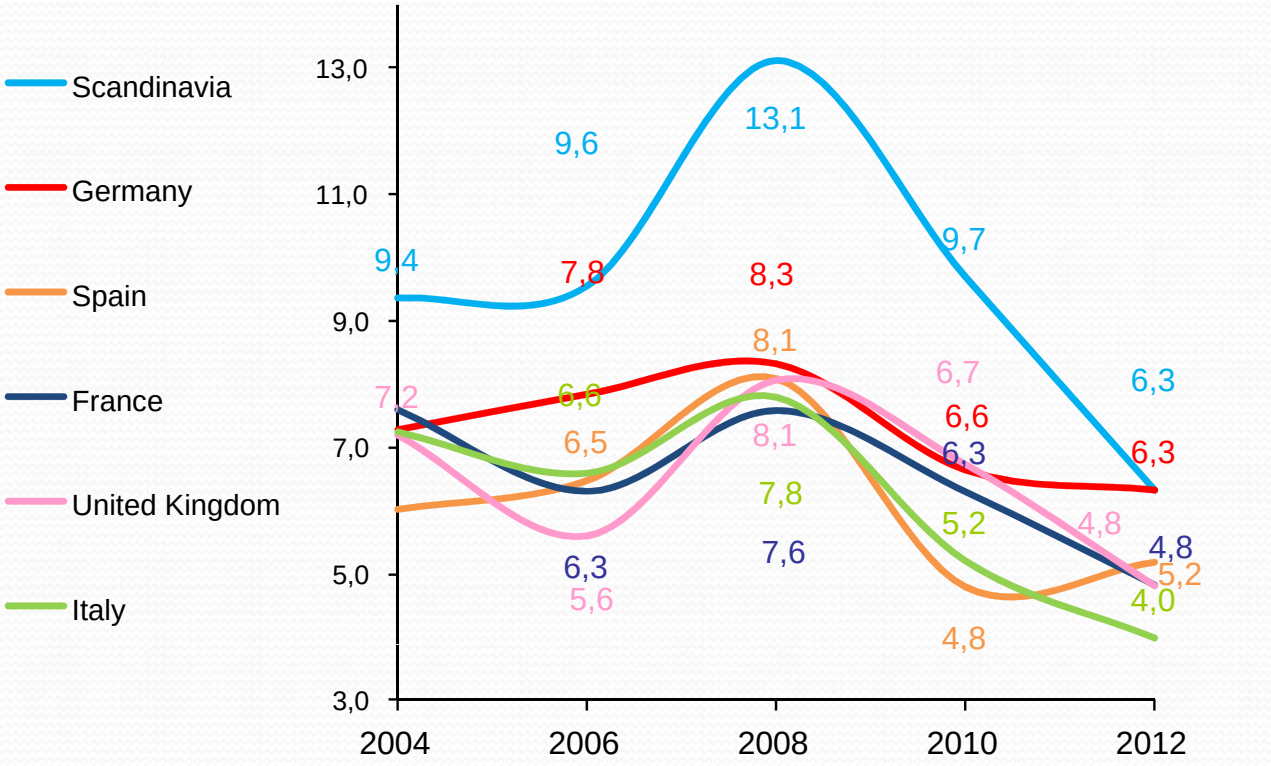


Synthesis of 6 surveys conducted by Leem since 2002 and 2012

In Europe, participation of Western European countries is quite close, in overall decrease

Europe

Average Number of patients per center and per year



Only studies involving France have been included

Synthesis of 6 surveys conducted by Leem since 2002 and 2012

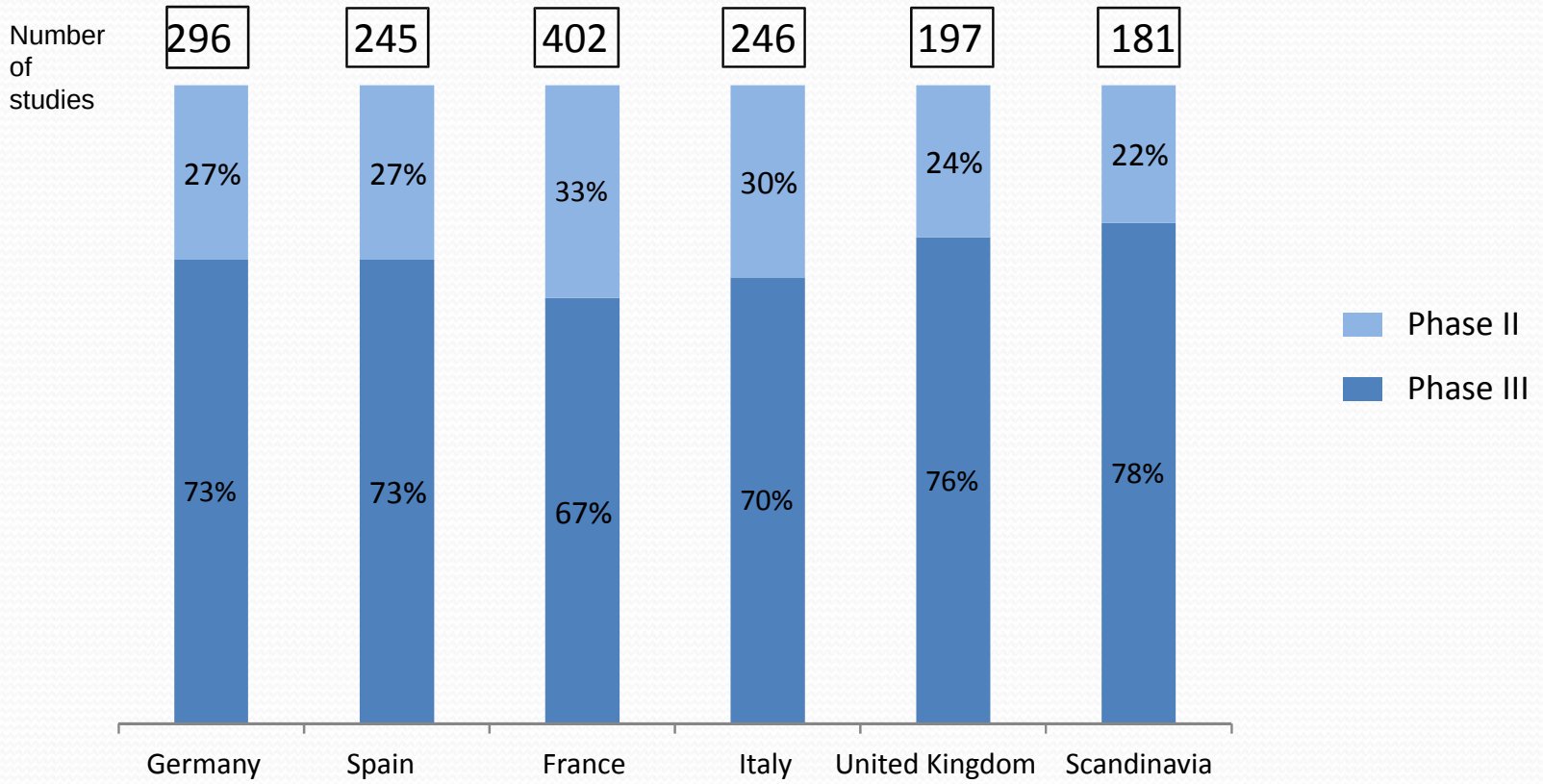
Only studies involving France were included

At the European level, the analysis per phase revealed a higher rate of phase II studies in France

Europe

Phases II/III

Phase II and III distribution (2012)

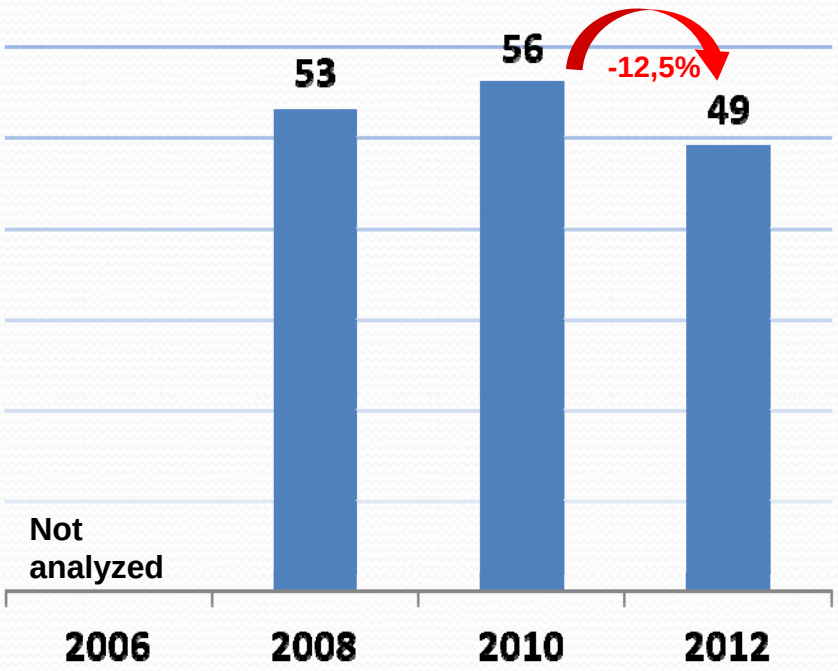


- But with a higher proportion of phase III studies in each country
- Involvement of France in Oncology and Rare Diseases Phase II

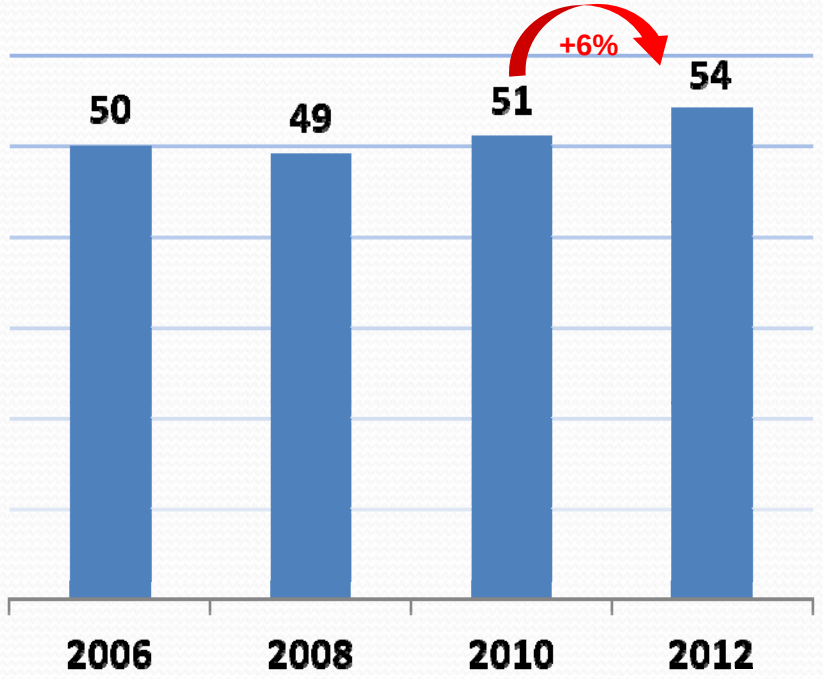
Synthesis of 6 surveys conducted by Leem since 2002 and 2012

Variations in timelines approval from the different authorities are different

Median timelines to obtain the approval by ANSM (in days)



Median timelines to obtain the approval by EC (in days)

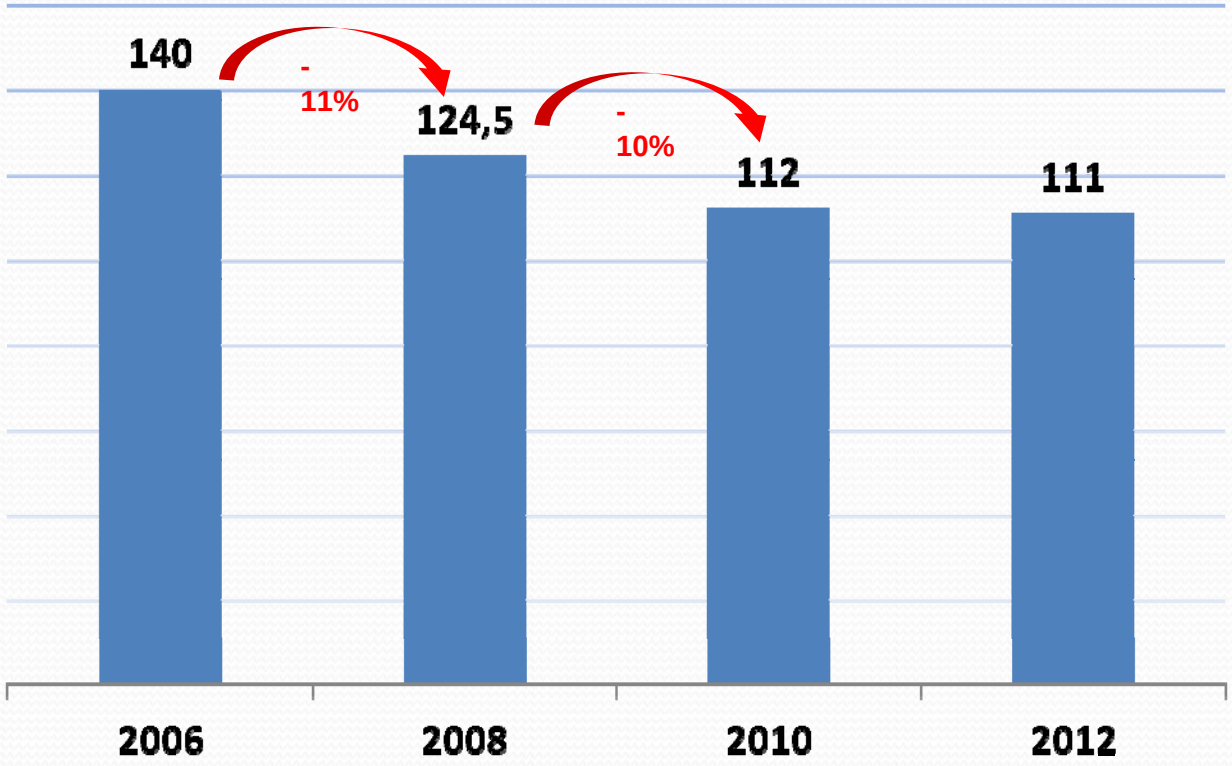


Phase I, II, III and IV for regulatory purpose

Synthesis of 6 surveys conducted by Leem since 2002 and 2012

Hospital contracts (first contract) timelines dropped significantly from 2006 to 2010 and have since remained stable

Median deadline to obtain the signature of the first hospital contract (in days)



Synthesis of 6 surveys conducted by Leem since 2002 and 2012

France recruited 6.5 % of total patients and ranks behind USA, Eastern Europe, Asia, Latin America but also Germany

	Number of studies
France	420
Germany	310
Other West. Eur	301
US	293
Est Europe	280
Italy	258
Spain	257
Canada	237
Australasia	215
United Kingdom	207
Asia	191
Scandinavia	188
Latin Am.	166
Africa and Mid.East.	119

	Number of patients		Ratio recruited patients/ 1 000 000 hab
	Number	%	
US ↗	47 333	19,2%	153
Est Europe ↘	36 970	15,0%	113
Asia ↗	25 368	10,3%	7
Germany =	22 047	8,9%	270
Latin Am.	20 743	8,4%	293
Other West. Eur	19 930	8,1%	39
France ↘	16 092	6,5%	246
Canada	10 847	4,4%	317
Scandinavia	10 770	4,4%	423
Spain	9 672	3,9%	206
Australasia	8 761	3,5%	114
Italy	8 029	3,3%	133
United Kingdom	7 048	2,9%	17
Afr. Moyen Or.	3 285	1,3%	55

Europe	420	130 558	52,9%	177
World	420	246 895	100%	45

- As only studies involving France were included, the number of studies France took part in is the highest by definition

In comparison with the 2010 survey

- **An increase for:**
  - The USA : 19,2% vs 15,4%
  - Asia: 10,3% vs 7,8%
- **A decrease for Europe:** 52,9% vs 60,8%
- **No variation for Germany :** 8,9% vs 9%
- **Also a decrease for:**
  - Eastern Europe: 15,0% vs 21,6%
  - France : 6,5% vs 7,6%

Synthesis of 6 surveys conducted by Leem since 2002 and 2012

Conclusion of the 2012 survey

- Global decrease of Europe in international competition
- France remains in the average of the European countries at a growing distance from Germany, but still with some advantages
- Some alarming signals which calls for the mobilization of all stakeholders
  - Collapse of some therapeutic areas
  - EC and Hospital contracts timelines
  - Deterioration of the perception of administrative simplicity

Synthesis of 6 surveys conducted by Leem since 2002 and 2012

Reinforce our mobilization efforts at all levels

- **A mobilization of all Member States and of the European Commission**
  - To adopt an European Regulation which really simplifies processes and shortens timelines
  - To set up a positive environment for clinical research, in particular a reflection on a European certified training for investigators
- **A better focus in France**
  - Hospitals for a simplification of hospitals contractualization and the setting up of efficient organizations (CenGeps actions)
  - Regulatory Authorities (ANSM, EC) to keep competitive timelines
  - Investigators to improve feasibility studies and GCP training
  - Patients to favor their inclusion in clinical trials

Synthesis of 6 surveys conducted by Leem since 2002 and 2012

- Thanks for your attention