Becoming European leader in clinical research: our proposals

The 13th 'Attractiveness of France for Clinical Research' survey

Executive Summary

The Attractiveness of France for Clinical Research survey

Industry-led clinical trials of medicines initiated between 1 January 2022 and 30 June 2023. Analysis of international competition (using the Trialtrove database) and French results (using the Oscar database), accompanied by identification of good practices in Spain

Pharma companies committed to clinical research

- Sponsoring the majority of therapeutic trials, early-stage patient access to innovative therapies
- Partners of all national stakeholders in clinical research
- Investing in innovative developments

The European leadership set out in the France 2030 national investment plan is under threat from strong international competition

- The US leads the way in the most dynamic areas of research, while regulatory changes across the EU are negatively impacting European attractiveness
- France remains the EU No. 3
- Spain continues to pull away from Germany, France, the UK and Italy

The Leem's action plan

Pharma company targets: to increase France's involvement in international trials (by 25%), contribute to reducing trial startup lead times to 120 days

Shared principles: full commitment from all stakeholders, integration of trials into the care pathway, and joint public/private oversight of all actions implemented

Priority actions for 2024:

- Remove the need for biological sample export-import permits for trial startups
- Simplify the single agreement & introduce fast track pathways '120 days to startup' for innovative therapy trials
- Make decentralisation and digitalisation integral components of clinical research

leem

Pharma companies are committed to clinical research in France

→ *they are sponsoring most clinical trials of medicines*

684 trials in France are initiated by pharma companies

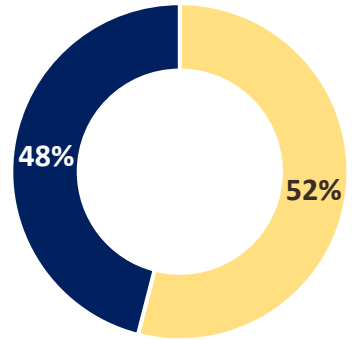
72% of trials are greenlighted

224 pharma companies are clinical trial promoters

52% of these trials are promoted by Top20* pharma companies

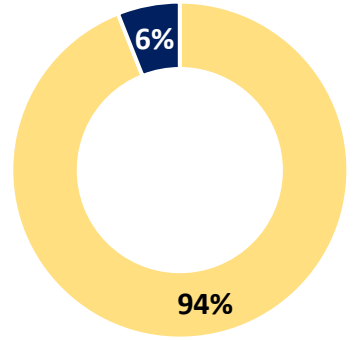
94% of trials have an international dimension

*by global revenue



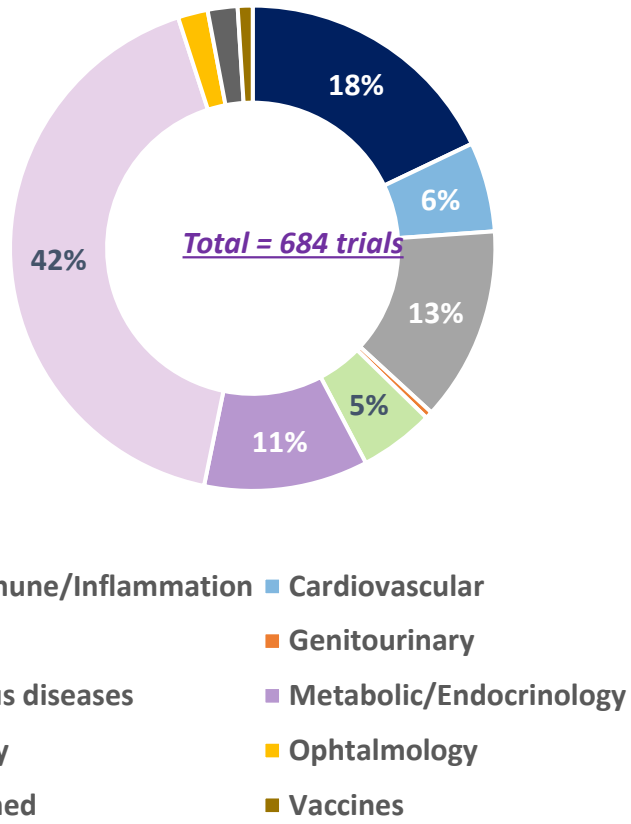
Total = 684 trials Startup 2022 – S1 2023

With other pharma companies
With Top 20 pharma companies



Single country
Multinational

Clinical trials provide patients with early access to innovative therapies



Trials involving patients with:

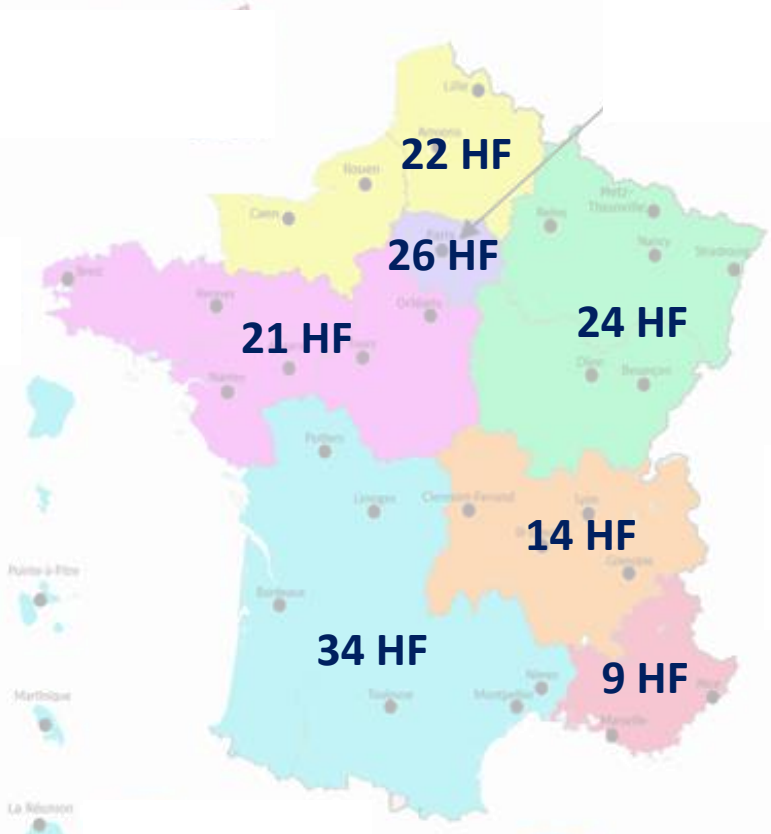
- cancers (42%)
- autoimmune diseases (18%)
- central nervous system disorders (13%)

At European level, France is involved in:

49% of early-stage cancer trials
50% of rare cancer trials
43% of rare disease trials
43% of paediatric trials

Pharma companies partner with all French clinical research stakeholders

Number of healthcare facilities (HF) by inter-region



Industry-led trials in France are conducted in conjunction with 150 healthcare facilities: CHU, CH, CLCC, EBNL, clinics and SSAs*

Pharma companies have supported 112 academic trials with hospitals, cooperative groups and civil society groups

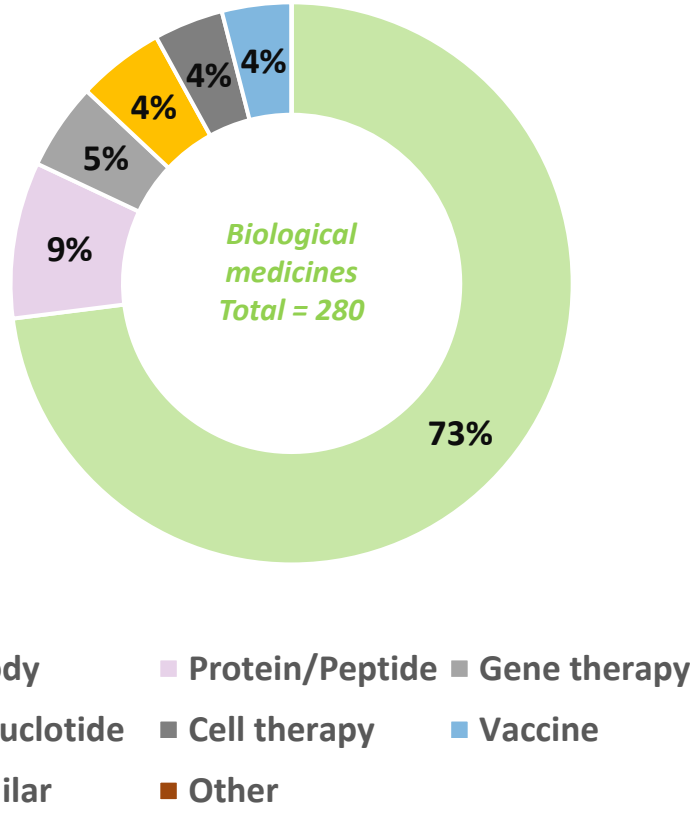
*University Hospitals, Hospital Centres, Cancer Centres, Non-Profit Institutions, Clinics and the Military Health Service

leem

Pharma companies invest in innovative clinical developments

41% of trials evaluate biological medicines
- 73% of which are antibodies
- 9% are proteins or peptides
- and 9% are gene or cell therapies

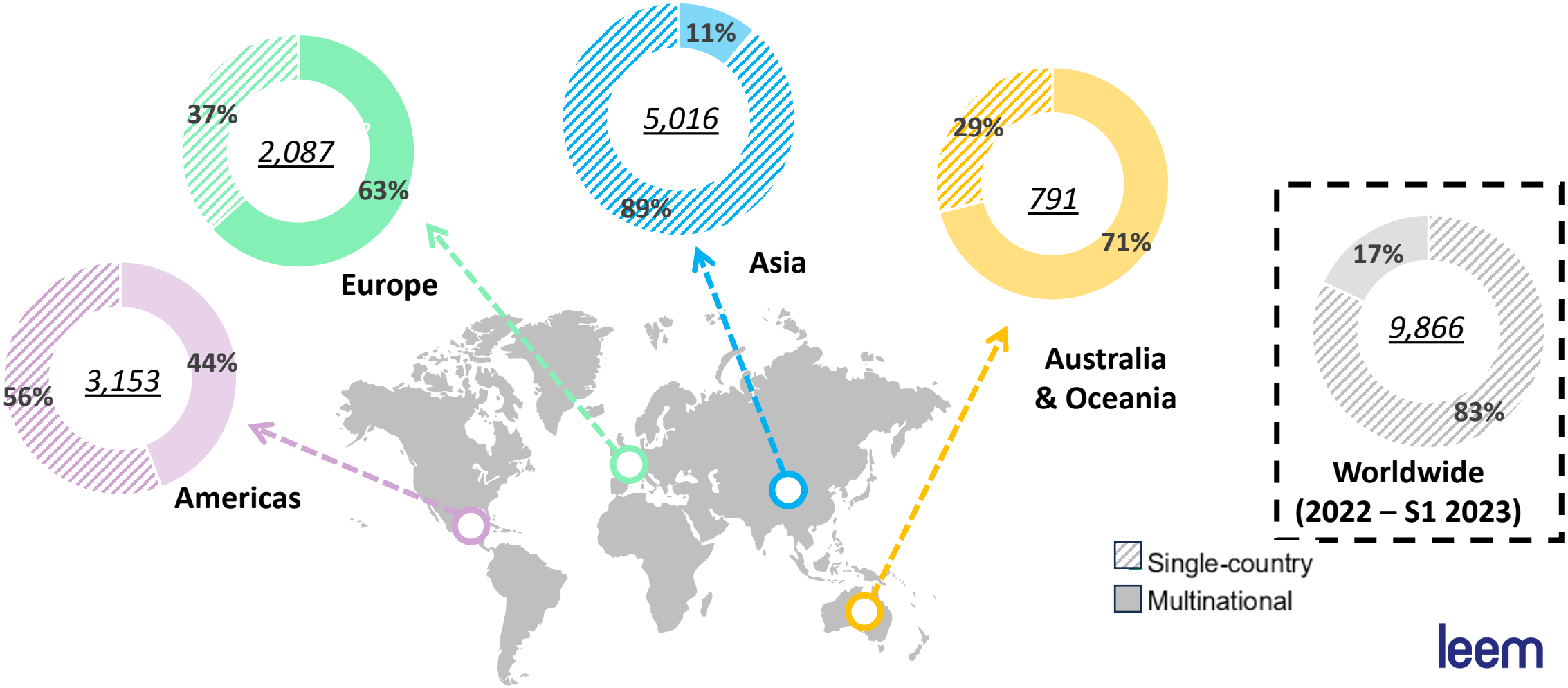
77% of trials use biomarkers
13% are innately innovative
(in terms of design, methodology and decentralisation)



leem

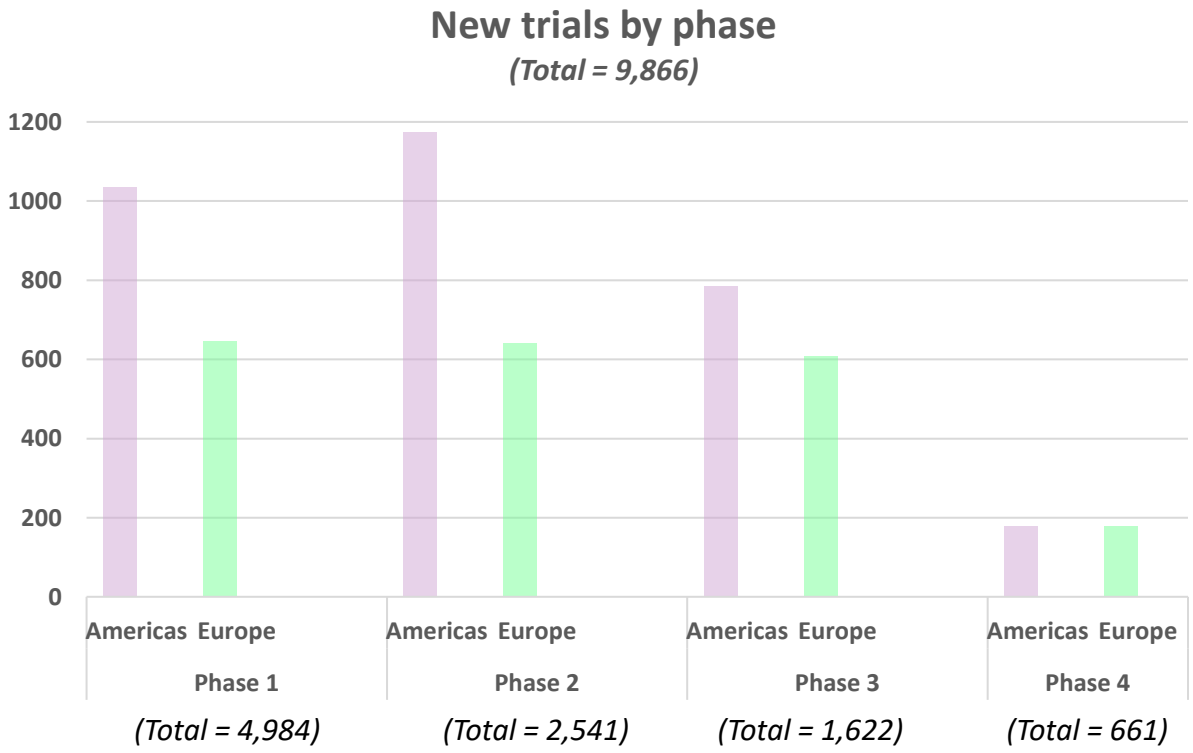
Europe competes directly with other major regions

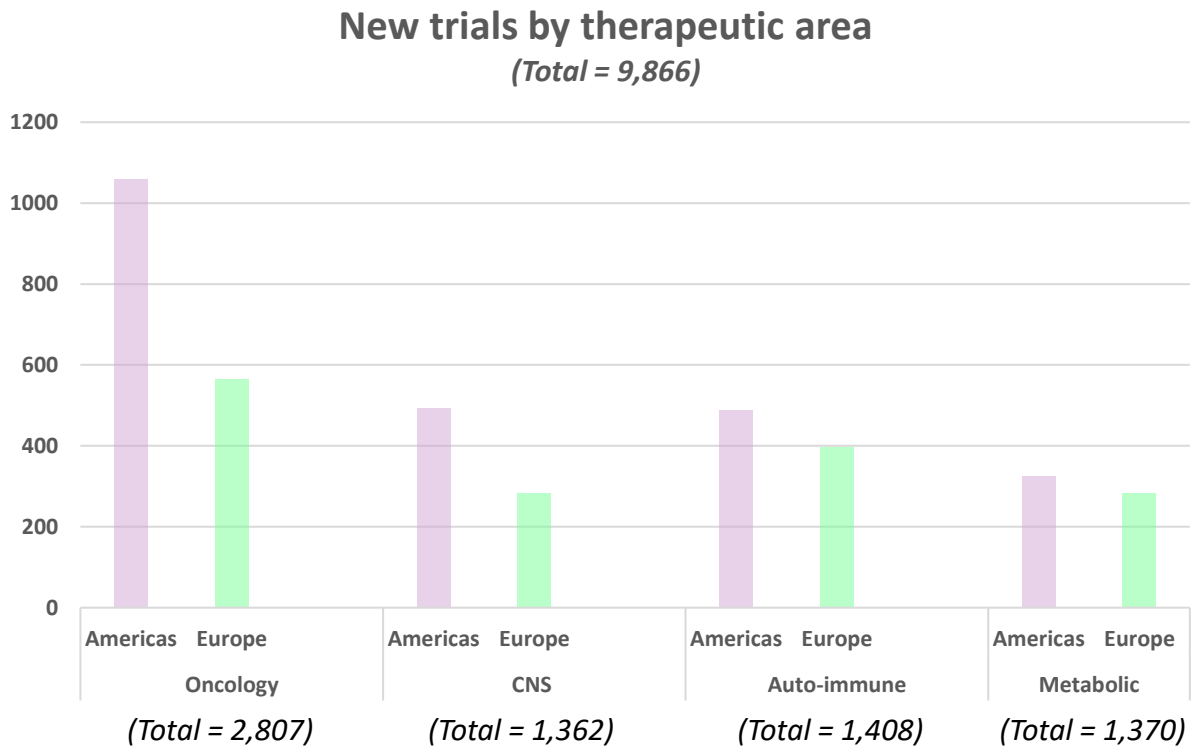
→ *Europe is No. 3 worldwide and No. 2 for multinational trials*



Europe is lagging behind the Americas across all the most dynamic therapeutic areas

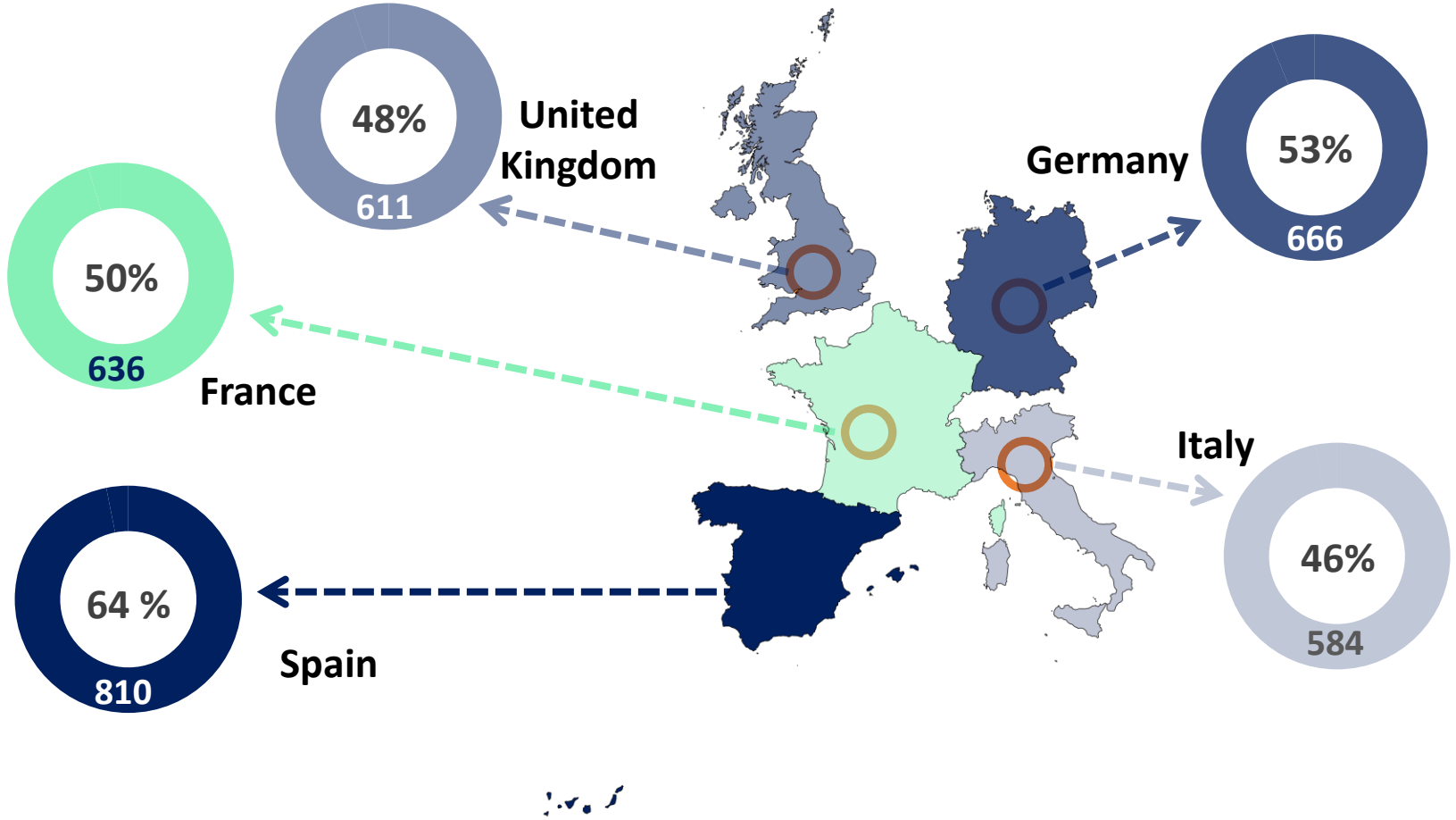
- *in phases 1&2 (76% of trials)*
- *in oncology (28%), CNS disorders (14%), metabolic disorders (14%) and autoimmune diseases (14%)*





Spain continues to stand out distinctively, while France maintains its No. 3 ranking in the EU

→ *France contributes to half of all clinical trials initiated in Europe*



The attractiveness of France is being challenged by this threatening situation

→ *France retains its ranking as No. 2 in Europe for oncology research, but trails behind Germany and the United Kingdom for phase 1&2 clinical trials*

European % (by no. of trials)	*Phase 1*	*Phase 2*	*Phase 3*	*Phase 4*
France	**37% (57)**	**47% (238)**	59% (303)	46% (37)
Germany	32% (50)	46% (234)	65% (334)	58% (46)
Italy	25% (38)	41% (208)	60% (308)	36% (29)
Spain	**58% (89)**	**61% (310)**	**73% (375)**	44% (35)
United Kingdom	31% (47)	46% (235)	57% (291)	45% (36)
Europe	100% (154)	100% (510)	100% (514)	100% (80)

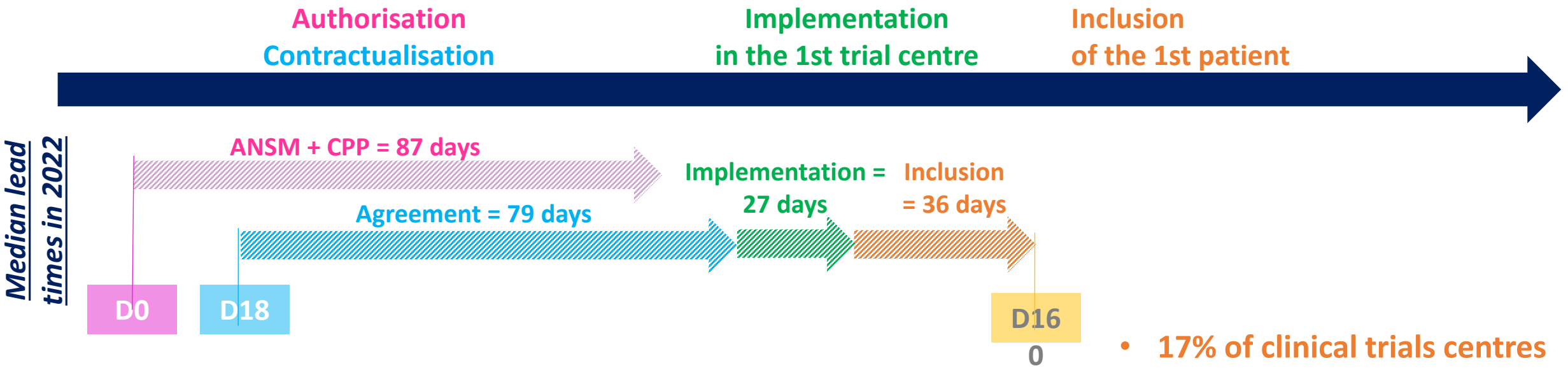
Oncology	*CNS*	*Autoimmune*	*Metabolic*
60% (263)	52% (85)	27% (119)	45% (62)
48% (212)	56% (90)	**38% (168)**	**52% (72)**
49% (217)	59% (95)	24% (107)	47% (66)
75% (332)	**61% (99)**	35% (156)	45% (62)
48% (211)	54% (88)	28% (122)	49% (68)
100% (442)	100% (162)	100% (265)	100% (139)

Multinational trials excluding healthy volunteers

leem

In 2022, 1st patient inclusion took an average of 160 days in France

→ *trial initiation lead times must now comply with European regulations (CTR & IVDR) and there is room to improve inclusion performance*



- **17% of clinical trials centres with no inclusion**
- **86% of inclusion targets achieved**

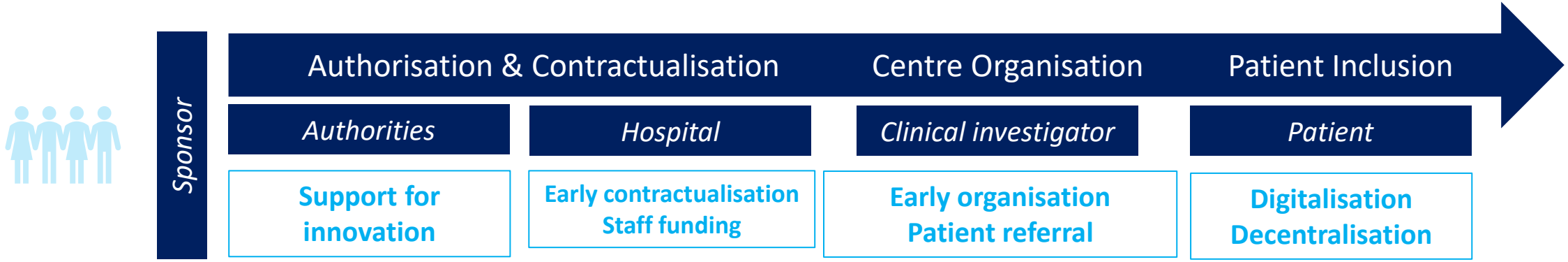
Identification of good practices in Spain

Three stages 2015-2022

- No. 1 for early stage cancer trials
- No. 1 for all cancer trials
- No. 1 or 2 for other therapeutic areas

Operational performance

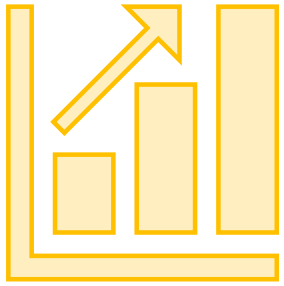
- Authorisation within 53 days since 2016
- 60-day contractualisation for early stage & cancer trials since 2019
- 94% inclusion rate



Becoming European leader in clinical research

Shared principles

- Stakeholder involvement
- Clinical research integrated into the care pathway
- Joint public/private oversight



Pharma company goals

- To boost French involvement in multinational trials (by 25%)
- To reduce startup lead times (to 120 days)

Authorisation & Contractualisation → Centre Organisation → Patient Inclusion

Remove the need for biological sample export-import permits

Simplify the single agreement and introduce fast track pathways ‘120 days to startup’ for innovative therapy trials

Make decentralisation an integral component of clinical research practice & ensure the long-term future of the ECLAIRE platform

Ensure the presence of trained staff in dedicated research facilities

Work together to provide shared oversight of French clinical research performance using an effective tool for collecting and monitoring key indicators

leem