



GOVERNMENT

*Liberty
Equality
Fraternity*



**HEALTH
INNOVATION
AGENCY**

Biomedicines and bioproduction



2023 OVERVIEW
IN FRANCE
AND EUROPE

“ France on the way to becoming a major player in biomedicines and biomanufacturing! ”

Through France 2030 and the Health Innovation 2030 plan, the French government is investing massively to make France the most innovative and sovereign nation in Europe when it comes to healthcare. At the heart of this approach, biomedicines and biomanufacturing in advanced therapies are the focus of an acceleration strategy coordinated by the French Health Innovation Agency working with various government ministries.

This strategy mobilises all players in the sector around a number of major challenges: maintaining France's leading position by ensuring a constant flow of innovations from academic research, accelerating development projects while at the same time promoting local industrialisation, guaranteeing the quantity and quality of biomedical products at controlled costs for the healthcare system, and lastly, to actively support the industry by creating and funding dedicated organisations.

A joint commitment by France BioLead¹, France Biotech² and the French Health Innovation Agency bears witness to this vision. Mabdesign has been commissioned to carry out an in-depth study to better identify the strengths and weaknesses of the biomedical sector, provide effective support for the players involved and target the aid and action required. It explores existing biomedicines and those under development, as well as biomanufacturing capacities in France and Europe (UK, Germany, Belgium, Spain, Italy, Ireland and Switzerland).

The findings of this study, two years ahead of the launch of the Biotherapies and Biomanufacturing Acceleration Strategy, reveal that France occupies a prime position in global competition, with 584 biomedicines under development, making it Europe's second-largest pipeline, just behind the UK. What's more, the country has a comprehensive industrial biomanufacturing infrastructure, covering the entire value chain from research and development to the production of commercial batches. It is vital to continue the policy of structuring the sector in order to make it increasingly competitive and attractive internationally, and thus guarantee patient access to optimum treatments.

Lise ALTER,
CEO Health
Innovation Agency

Laurent Laffèrère,
CEO France BioLead

Franck Mouthon,
Chairman of France Biotech

▶▶▶ **Summary based on *Study and characterisation of the biomedicine sector in France*, a study carried out in 2023 by Mabdesign for France 2030, the French Health Innovation Agency and its acceleration strategy *Biomedicines and Biomanufacturing in Advanced Therapies, France Biotech and France Biolead*.**

This study was carried out in 8 countries: France, United Kingdom, Switzerland, Portugal, Italy, Belgium, Ireland and Germany. The data used goes up to July 2023.

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1. Association representing the bioproduction sector
2. Association federating and leading the health innovation entrepreneurial sector

What are Biotherapies?

Biomedicines, also known as biotherapies, are derived from living organisms, unlike drugs which are chemically synthesised. These include medicines whose active substances are derived from a biological source or produced using bioproduction and bioengineering tools.

THERAPEUTIC PROTEINS, PEPTIDES AND BIOPOLYMERS*

▽▽▽

ANTIBODIES

MONOCLONAL ANTIBODIES

CONJUGATED MONOCLONAL ANTIBODIES

ANTIBODIES (OTHER)

OTHER THERAPEUTIC PROTEINS, PEPTIDES AND BIOPOLYMERS

RECOMBINANT PROTEIN

PROTEIN

FUSION PROTEIN

PEPTIDE

RECOMBINANT PEPTIDE

ENZYME

RECOMBINANT ENZYME

BIOPOLYMER (POLYSACCHARIDE)

* All synthetic peptides have been excluded from the scope

ADVANCED THERAPY MEDICINAL PRODUCTS (ATMP)

▽▽▽

CELL THERAPIES

GENE THERAPIES

BY RNAi

GENETICALLY MODIFIED CELL THERAPIES

CAR-T

TCR-T

NK

VACCINES

▽▽▽

USING mRNA

USING DNA

RECOMBINANT VECTORS

TOXOIDS

CONJUGATED

LIVE ATTENUATED

INACTIVATED

OTHER

ONCOLYTIC VIRUS

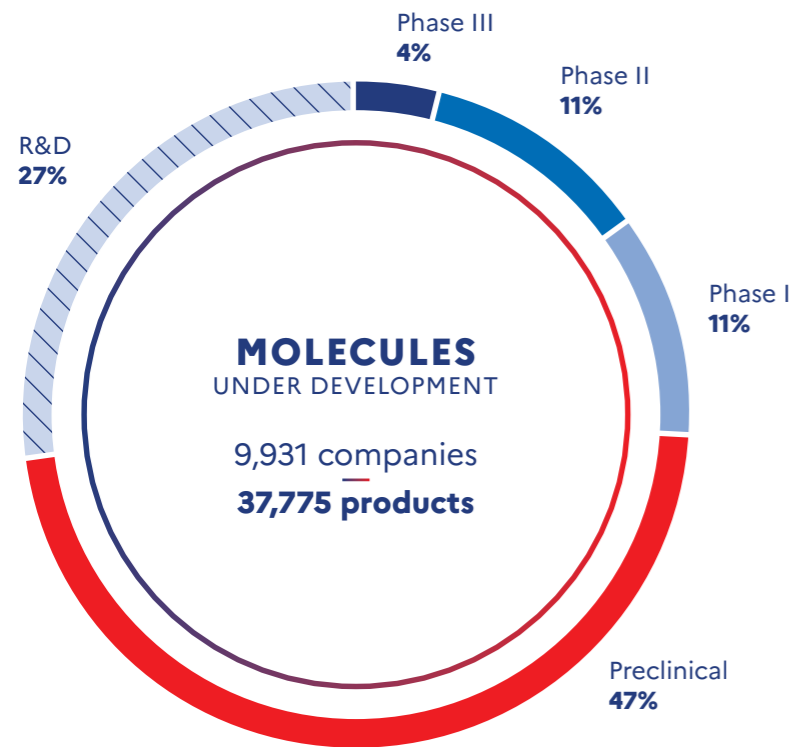
SUBUNIT



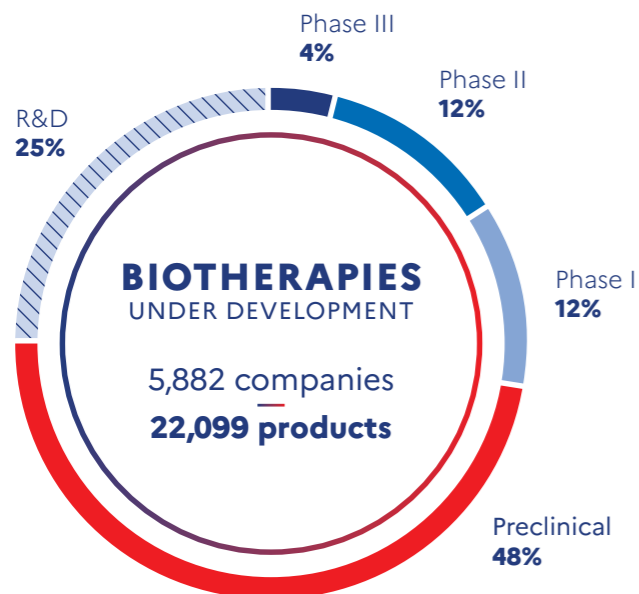
In the rest of this summary, a unique biomedicine is defined as the biomedicine as an active substance, whereas a product is defined as an active substance in a specific indication in a marketing authorisation.

Current situation in the biomedicines market

In the world



59% of molecules under development are biomedicines



In Europe

TOP

3

TREATMENT AREAS



INFECTIOUS DISEASES



ONCOLOGY



METABOLIC DISORDERS

1. MARKETED

2. UNDER DEVELOPMENT



ONCOLOGY



INFECTIOUS DISEASES



METABOLIC DISORDERS

TODAY,
690 UNIQUE BIOMEDICINES
ARE MARKETED IN EUROPE



511 therapeutic proteins, peptides and biopolymers

Therapeutic antibodies account for 44% of marketed products in this product family.



158 vaccines

96% of marketed products are prophylactic vaccines.



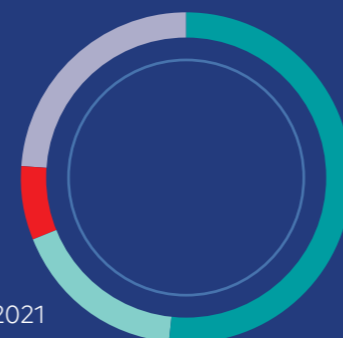
21 advanced therapy medicinal products

Within the ATMP family, 45% of products marketed are CAR-T cell therapies.

These 690 "unique" biomedicines actually correspond to **4,316 products** in a specific indication, with marketing authorisation and marketed in Europe. **419 major groups** and **159 ISE** alone market **95% of biomedicines**, with very few VSE/SME (14 and 64 respectively) bringing their products to market.

110

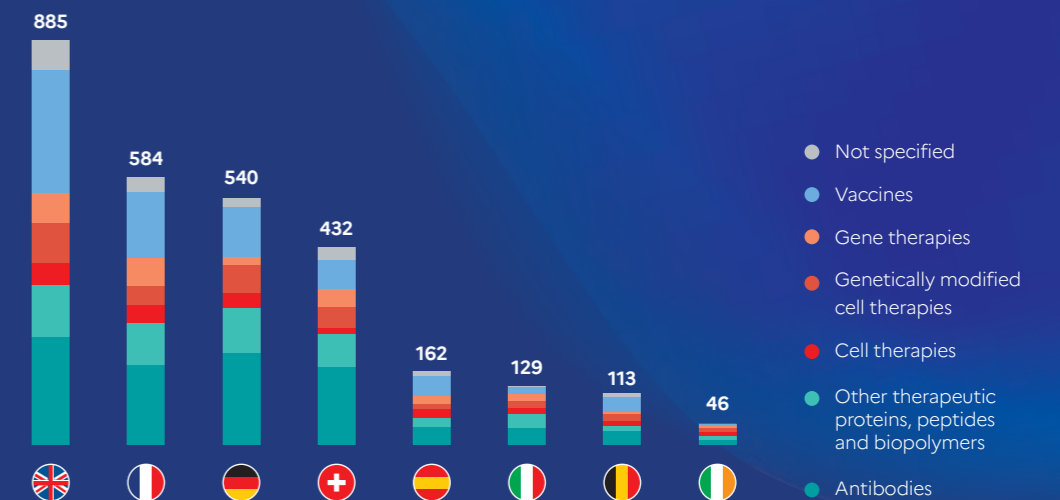
NEW BIOMEDICINES FOR 132 NEW PRODUCTS HAVE OBTAINED AN MA SINCE MARCH 2021



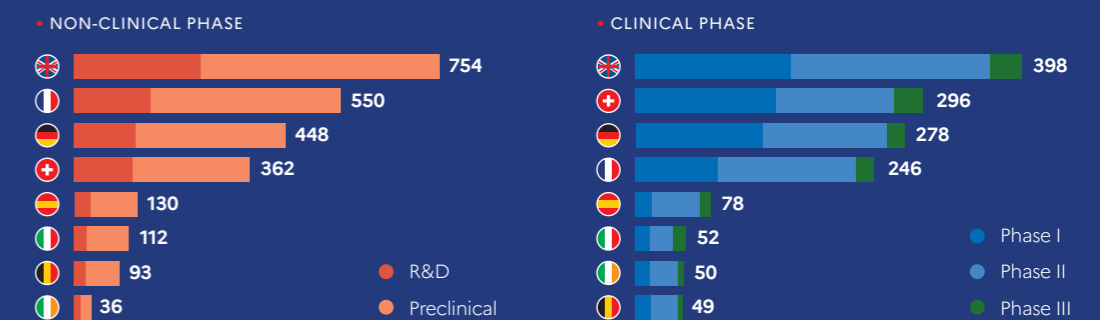
2,886 BIOMEDICINES

UNDER DEVELOPMENT IN EUROPE

▼ BREAKDOWN OF UNIQUE BIOMEDICINES BY TYPE AND COUNTRY ▼



▼ BREAKDOWN OF UNIQUE BIOMEDICINES BY TYPE AND COUNTRY ▼



Europe has a large and growing number of biomedicines under development: **679 vaccines, 701 ATMP and 1,335 therapeutic proteins, peptides and biopolymers**. The majority of products under development in the latter group are antibodies (67%).

France ranks 2nd in Europe in the development of biomedicines

ANTIBODIES AND PROTEINS

ANTIBODIES



OTHER THERAPEUTIC PROTEINS, PEPTIDES AND BIOPOLYMERS



ATMP

CELL THERAPY



GENE THERAPY



GENETICALLY MODIFIED CELL THERAPY



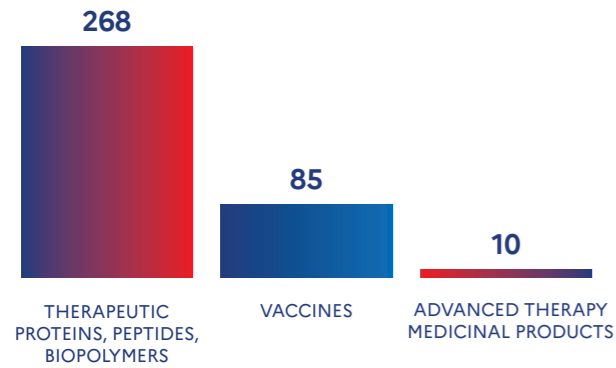
VACCINES



363

UNIQUE BIOMEDICINES

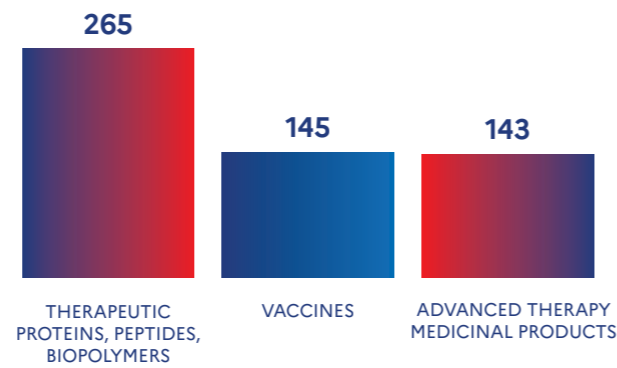
MARKETED BY 88 COMPANIES IN FRANCE



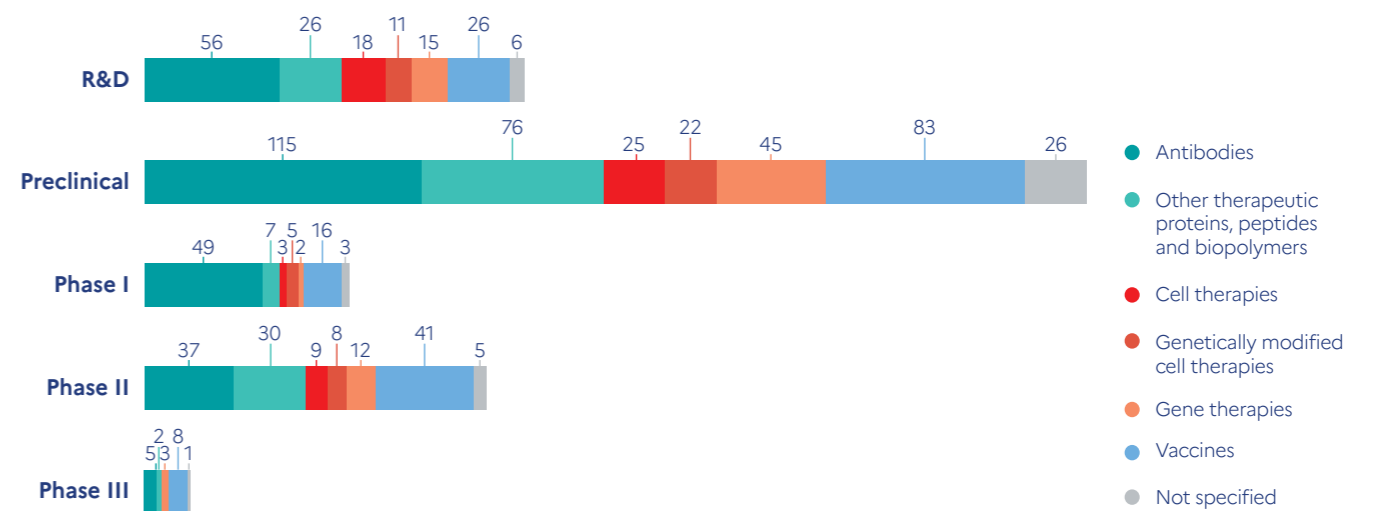
584

UNIQUE BIOMEDICINES

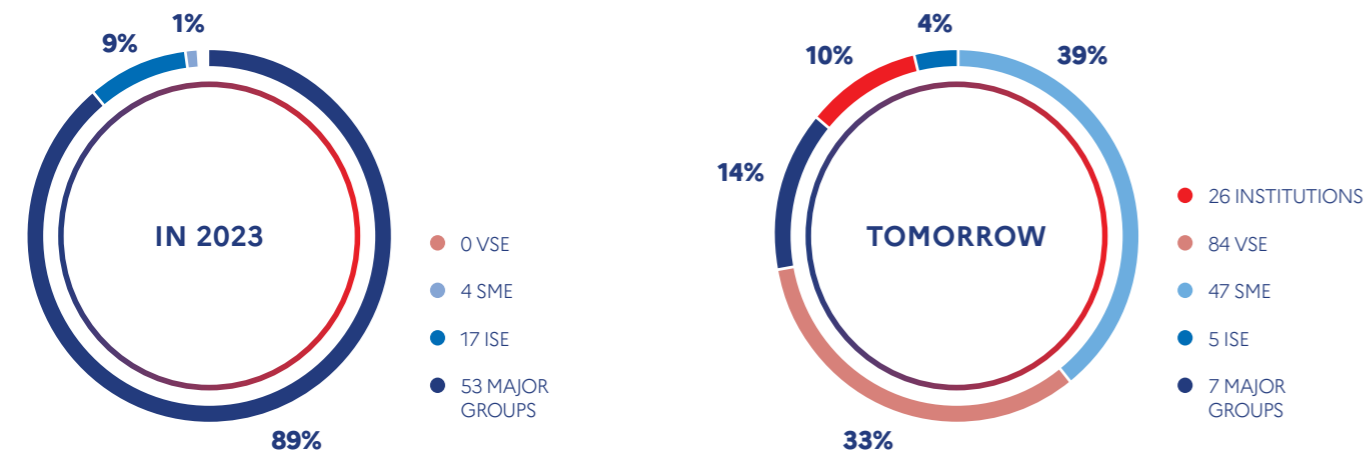
UNDER DEVELOPMENT IN FRANCE



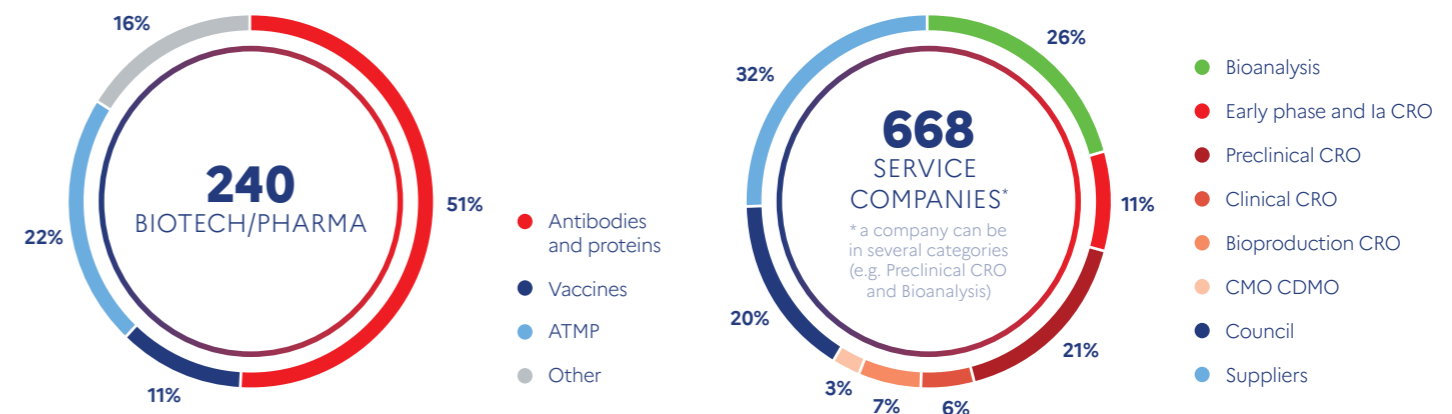
PRODUCTS BY PHASE OF DEVELOPMENT AND TYPE OF BIOMEDICINE



BREAKDOWN OF PRODUCTS BY TYPE OF COMPANY



SNAPSHOT OF THE STRUCTURES CONTRIBUTING TO BIOMEDICINE DEVELOPMENT



France ranks 2nd behind the UK, with over 580 unique biomedicines under development. The French ecosystem includes over one thousand structures: institutions (research institutes, universities, hospitals, foundations, local or national structures), biotechnology companies, service companies and training organisations. Two regions have historically led the way here: Ile-de-France and Auvergne-Rhône-Alpes.

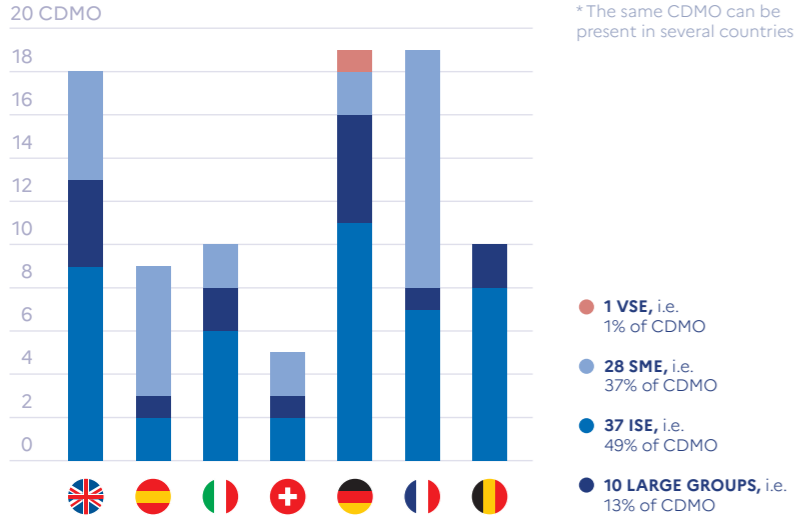
70% of biomedicines under development are in the non-clinical phase, whilst 30% are in the clinical phase. France accounts for 20% of European biomedicines under development. It has the 2nd largest pipeline of products in non-clinical phase and the 4th largest pipeline of products in clinical phase. Main treatment areas: oncology, infectious diseases, immunology.

Biomanufacturing

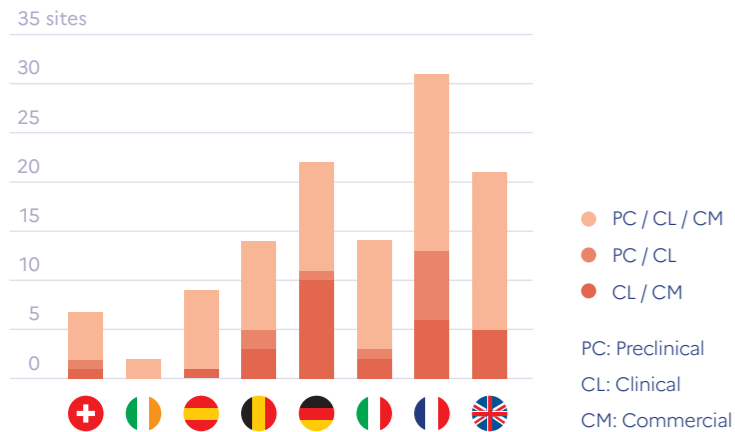
in Europe and France

CDMO LANDSCAPE IN EUROPE*

The majority of CDMO in the UK, Germany and Belgium are large groups and ISE. By contrast, France is characterised by a fragmented landscape, with a majority of SME.

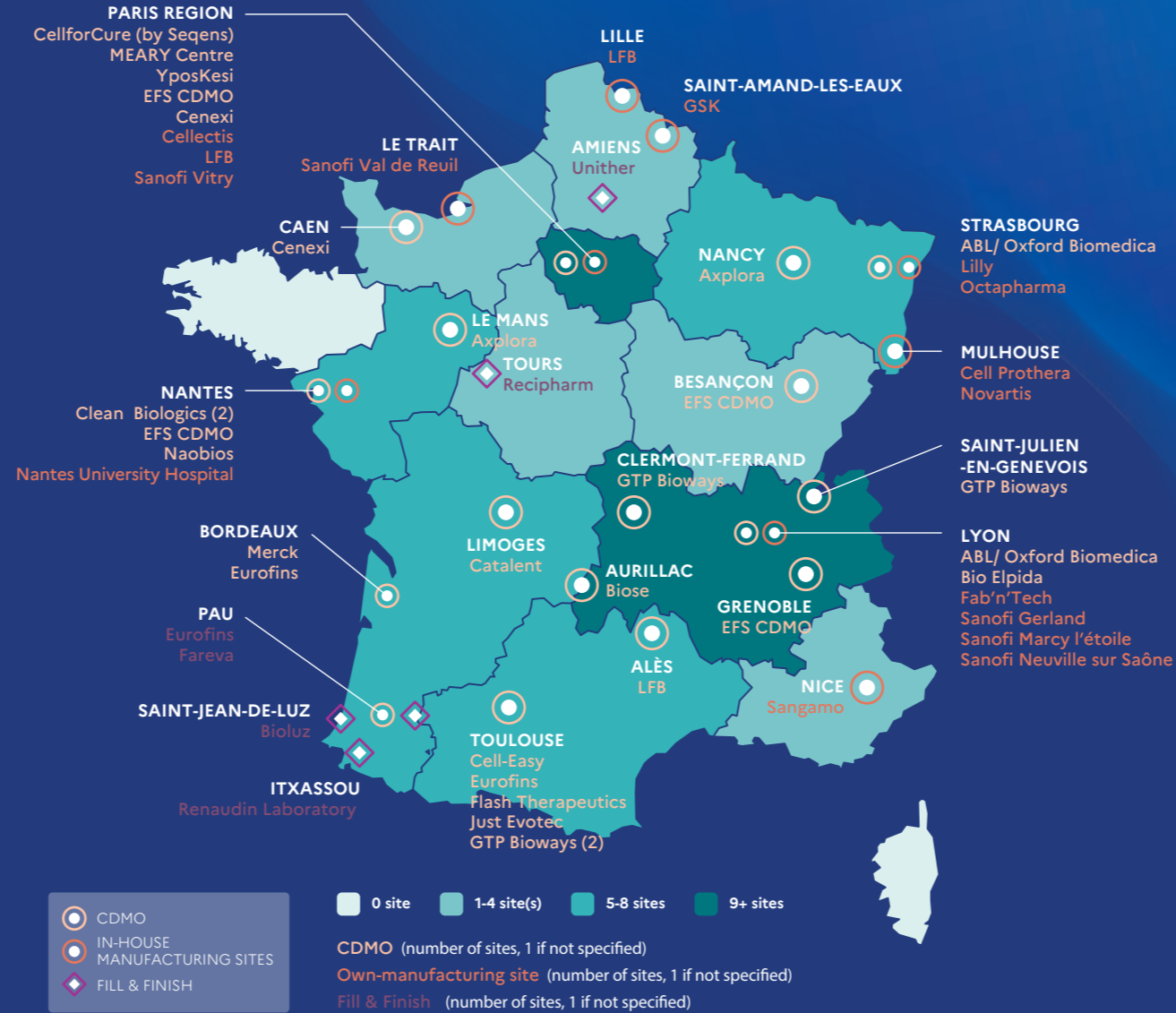


BATCH TYPES THAT CAN BE PRODUCED BY CDMO IN EUROPE



BIOMANUFACTURING SITES IN FRANCE

This map provides a comprehensive overview of biomanufacturing sites in France, including CDMO (Contract Development Manufacturing Organisations), in-house manufacturing sites and fill & finish sites (which cover the filling, finishing and packaging stages of biological products intended for the market).



NUMBER OF GMP BIOPRODUCTION SITES

52 SITES / **35 COMPANIES**

CDMO

31 SITES / **19 COMPANIES**

IN-HOUSE BIOMANUFACTURING

16 SITES / **11 COMPANIES**

FILL & FINISH

5 SITES / **5 COMPANIES**

THE INTERNATIONAL DIMENSION OF CDMO IN FRANCE

IS SMALLER COMPARED TO ITS EUROPEAN NEIGHBOURS

85% of CDMO in France are of French origin and their sites are located only in France. Only **15%** of CDMO in France have an international dimension.

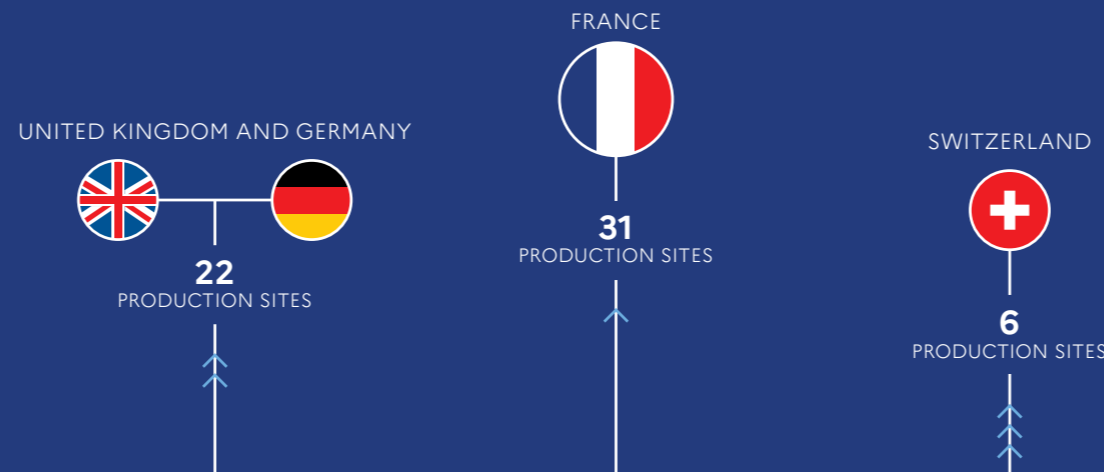
47% of CDMO in Germany are of German origin. **53%** of CDMO in the country have an international dimension, including 30% from the USA.

30% of CDMO in Belgium are of Belgian origin. **70%** of CDMO in the country have an international dimension, including 30% from the USA.

63% of CDMO in the UK are of UK origin. **37%** of CDMO in the country have an international dimension, including 25% from the USA.

80% of CDMO in Switzerland are of Swiss origin. Major player: Lonza. **20%** of CDMO in the country have an international dimension.

FRANCE HAS THE LARGEST NUMBER OF PRODUCTION SITES IN EUROPE



Spotlight on:

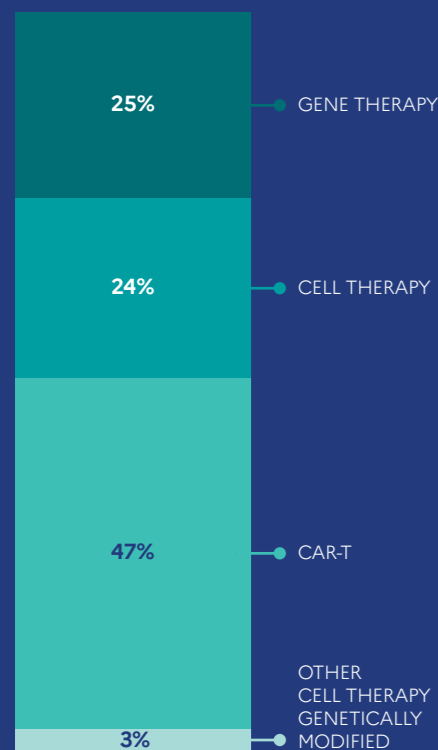
Advanced therapy medicinal products (ATMP) in Europe

TODAY

21 UNIQUE ATMP MARKETED IN EUROPE

I.E. 87 PRODUCTS

BREAKDOWN OF MARKETED ATMP BY DRUG SUB-TYPE



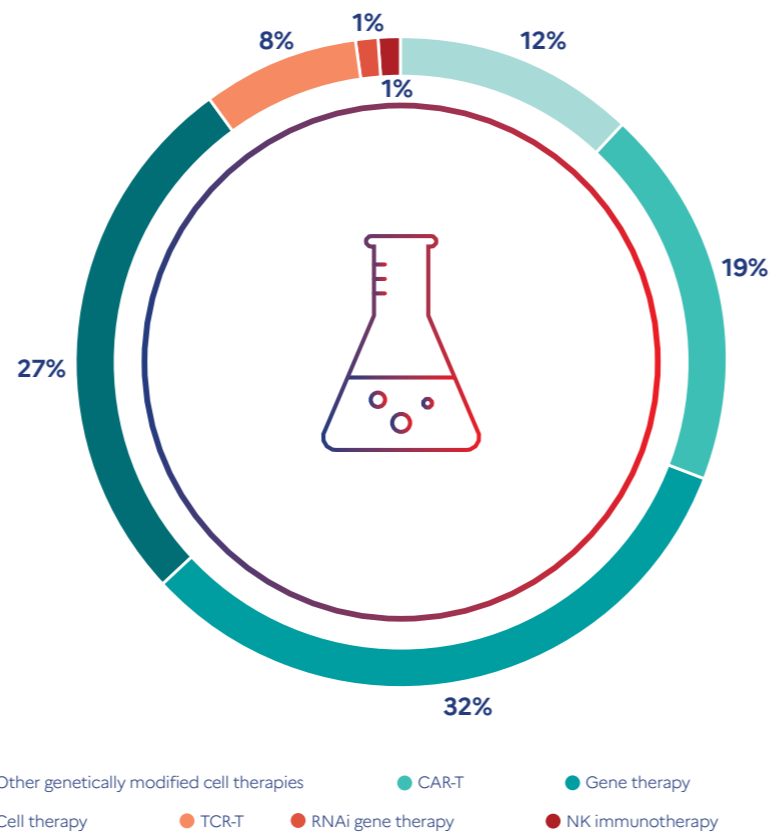
There are currently 7 cell therapies, 5 gene therapies and 9 genetically modified cell therapies (including 6 CAR-T) on the market.

TREATMENT AREAS

- ONCOLOGY
- OPHTHALMOLOGY
- CENTRAL NERVOUS SYSTEM
- HAEMATOLOGY

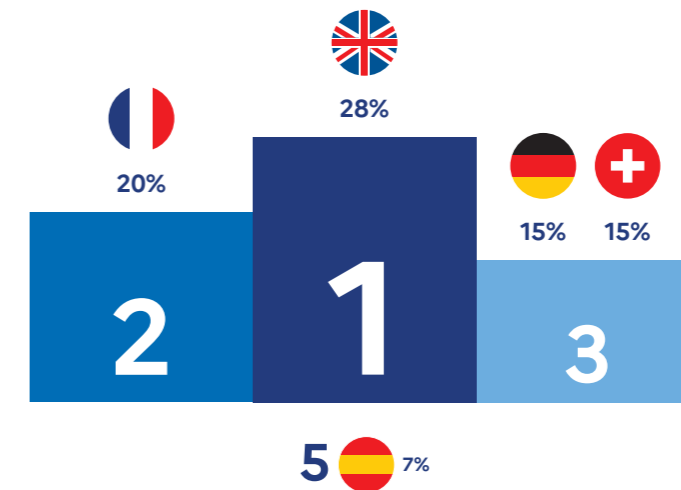
701 UNIQUE ATMP FOR 880 PRODUCTS UNDER DEVELOPMENT IN EUROPE

ATMP FAMILIES UNDER DEVELOPMENT BY ATMP SUB-TYPE



PROGRESS IN THE DEVELOPMENT OF ATMP IN EUROPE

PRODUCTS UNDER DEVELOPMENT



TOP 3

TREATMENT AREAS

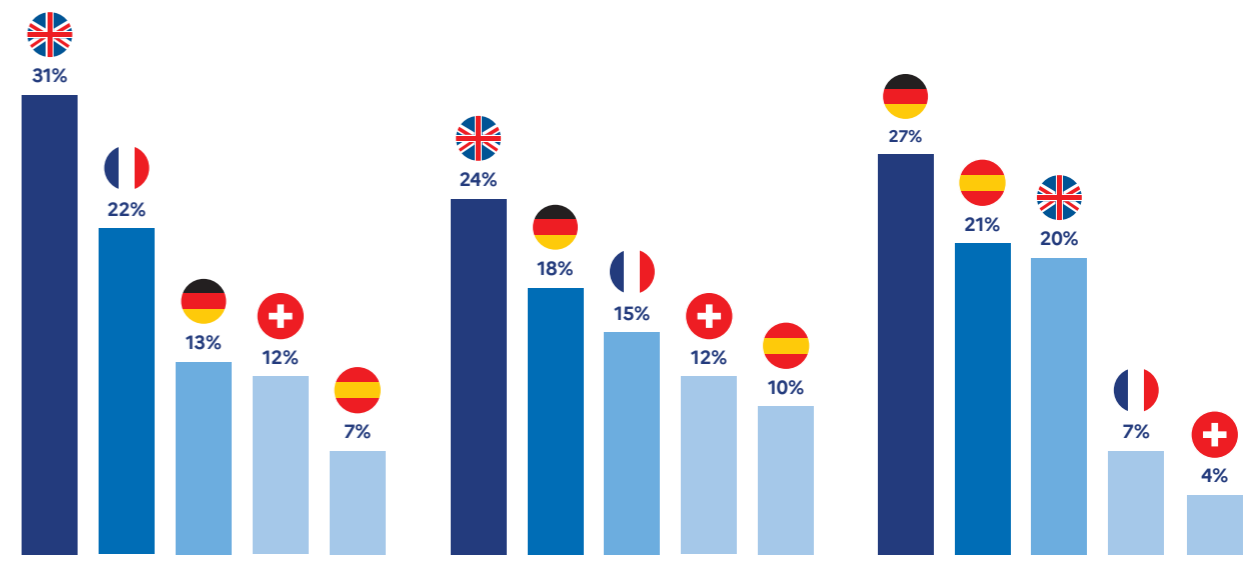
- ONCOLOGY
- OPHTHALMOLOGY
- CENTRAL NERVOUS SYSTEM

INDUSTRIAL FABRIC

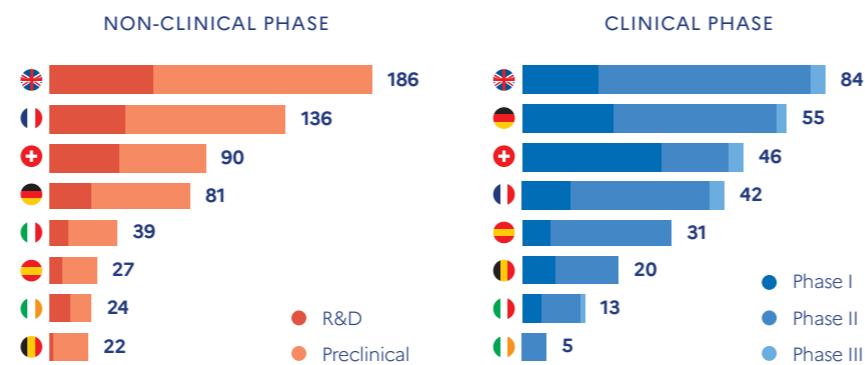
VSE / SME
% of total by country

ISE / LE
% of total by country

INSTITUTIONS
% of total by country



ATMP DEVELOPMENT PHASES BY COUNTRY



The number of ATMP under development is far higher than the number of ATMP currently available. Within this group, **genetically modified cell therapies are the most promising**, with CAR-T as well as CR-T and NK cells.

In Europe, each country has its own ATMP sector with specific characteristics. **France is based on its VSE/SME industrial fabric**, with an ATMP pipeline that is still in a very early stage (the majority of products are in the non-clinical phase). In terms of ATMP development by VSE and SME, **31% takes place in the UK, compared with 22% in France.**

Spotlight on:

Advanced therapy medicinal products (ATMP) in France

TOP
3

TREATMENT AREAS

CELL THERAPY

ONCOLOGY

IMMUNOLOGY

METABOLIC DISORDERS

GENE THERAPY

OPHTHALMOLOGY

CENTRAL NERVOUS SYSTEM

GENETIC DISORDERS

GENETICALLY MODIFIED CELL THERAPY

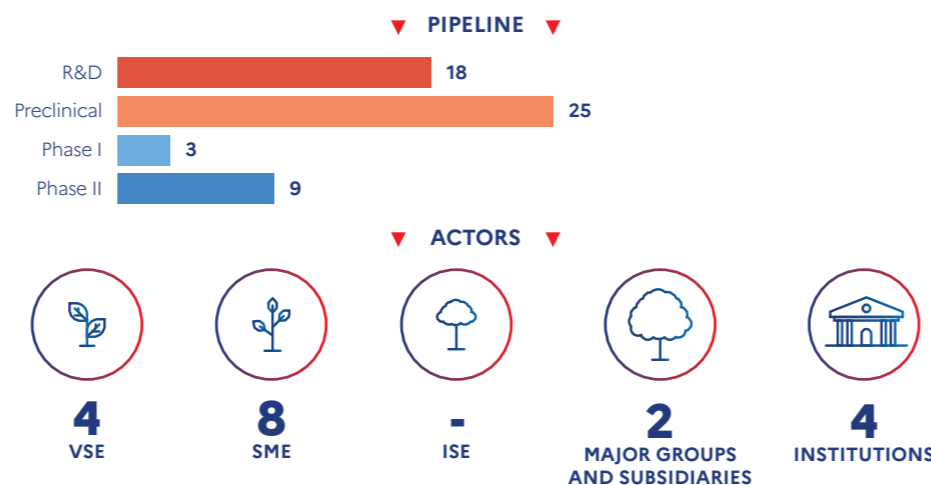
ONCOLOGY

IMMUNOLOGY

HAEMATOLOGY

41 CELL THERAPIES UNDER DEVELOPMENT

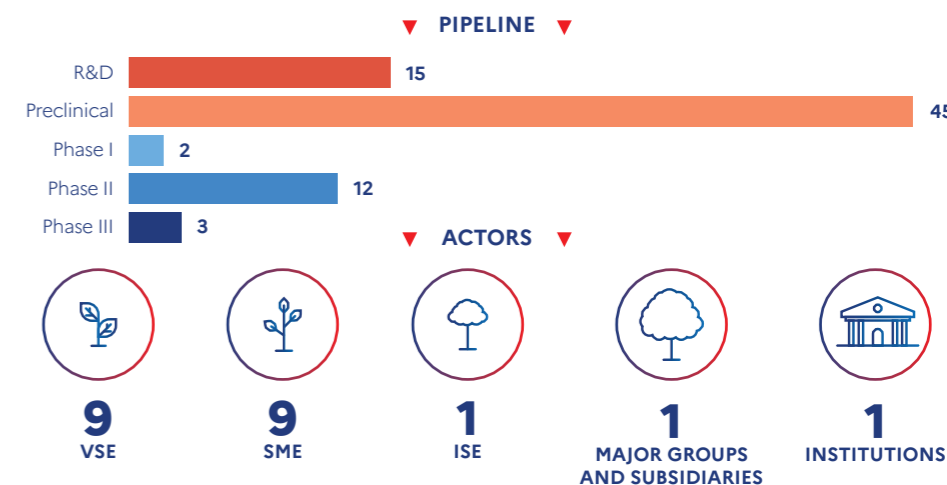
in 55 products being developed in France.



Of the cell therapies under development in France, 44% are allogeneic and 12% autologous. In 44% of cases, the strategy was not specified by the project sponsors.

61 GENE THERAPIES UNDER DEVELOPMENT

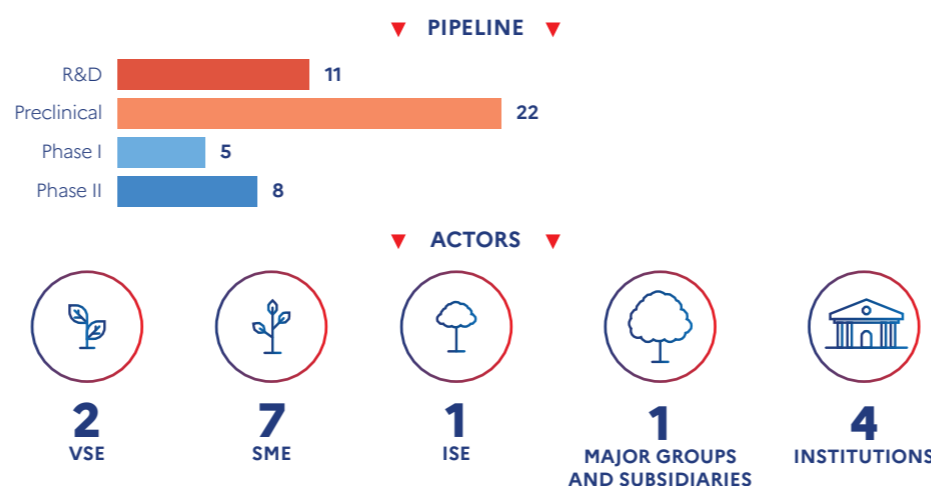
in 77 products being developed in France.



Of these gene therapies under development, 40 are described as using an Adenovirus or Adeno Associated Virus.

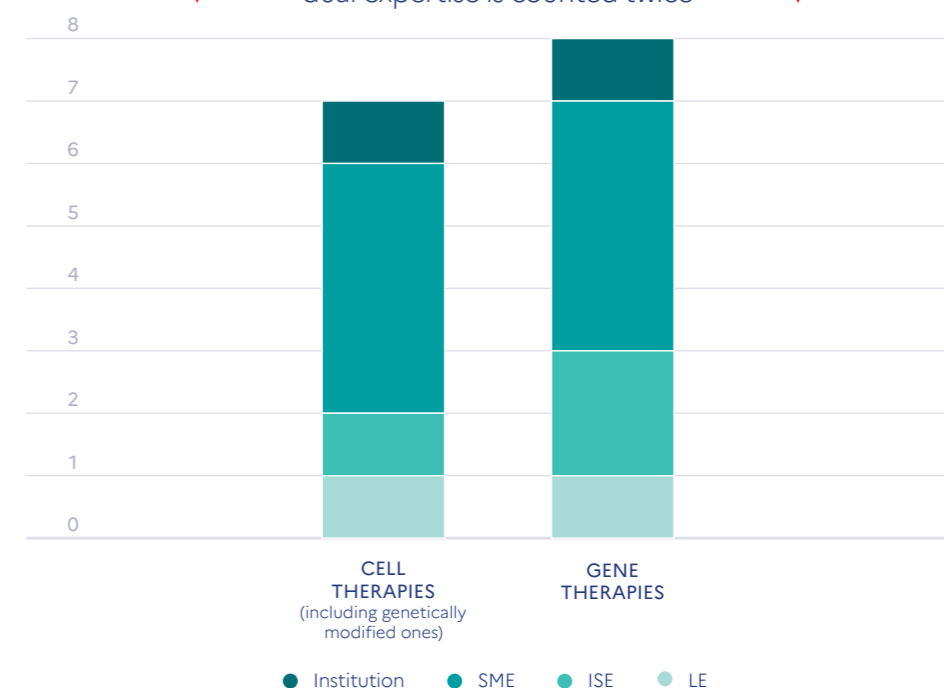
41 GENETICALLY MODIFIED CELL THERAPIES UNDER DEVELOPMENT

in 46 products being developed in France. Including 18 CAR-T, 5 TCR-T and 2 NK cell therapies.



Of the genetically modified cell therapies under development in France, 27% are allogeneic therapies and 22% are autologous therapies. In 51% of cases, the strategy was not specified by the project sponsors.

France has 11 CDMO specialising in ATMP, and any single CDMO with dual expertise is counted twice



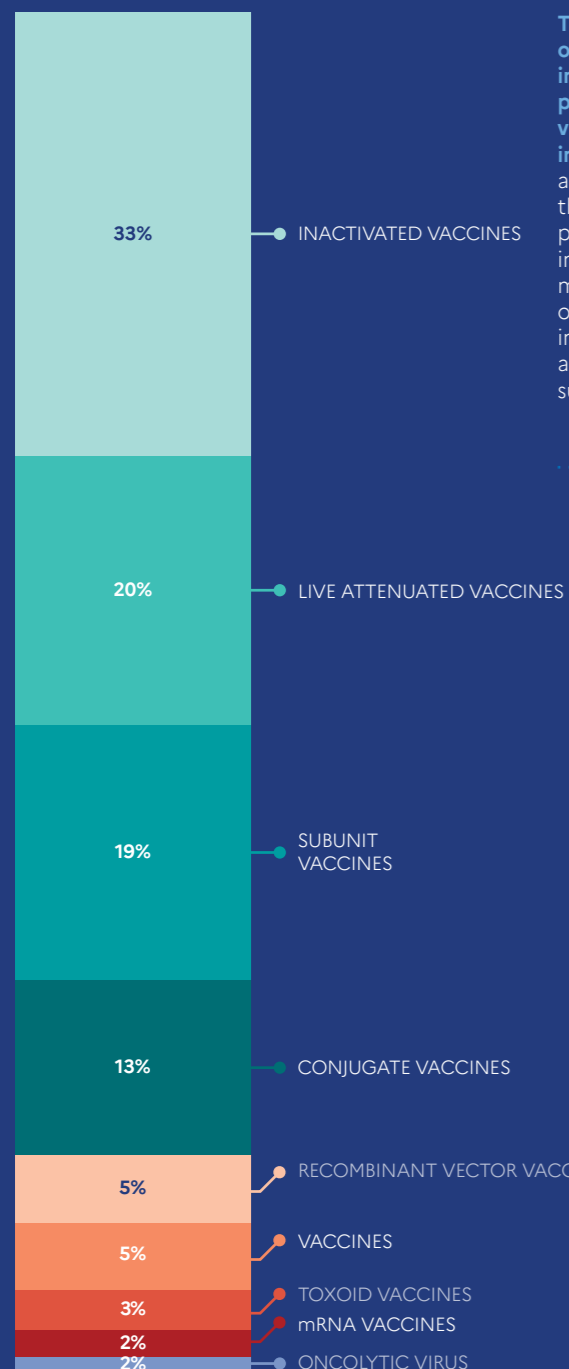
Spotlight on:

Vaccines under development in Europe

TODAY

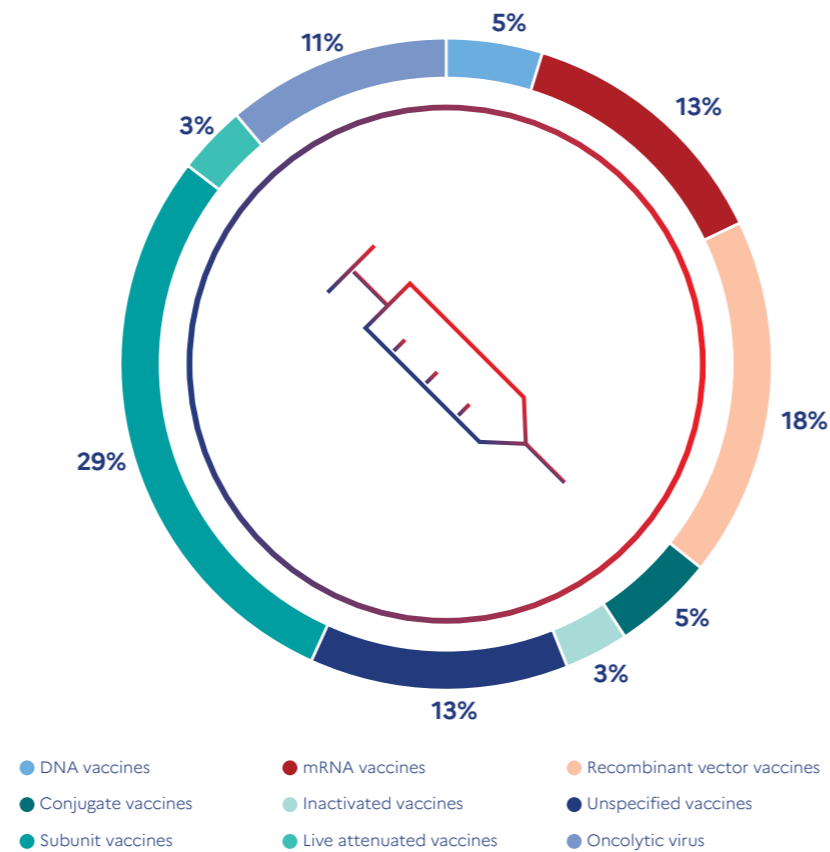
158 UNIQUE VACCINES MARKETED IN EUROPE
I.E. 651 PRODUCTS

BREAKDOWN OF MARKETED ATMP BY DRUG SUB-TYPE

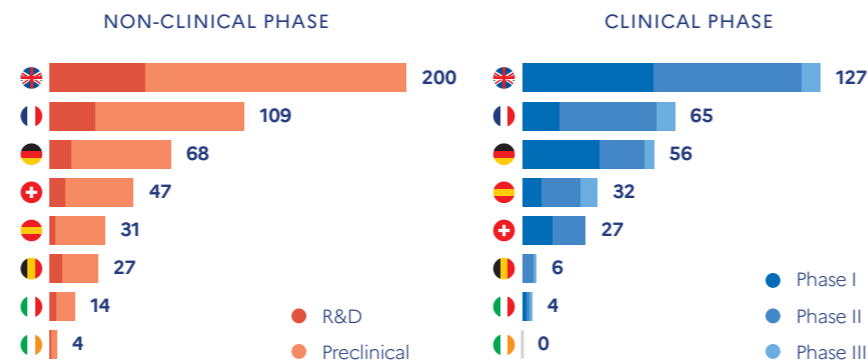


The vast majority of vaccines marketed in Europe are prophylactic vaccines for infectious diseases, and use technologies that are not particularly innovative. The majority of vaccines on the market are inactivated, live attenuated or subunit vaccines.

FAMILIES OF VACCINES UNDER DEVELOPMENT BY SUBTYPE OF BIOMEDICINE



VACCINE DEVELOPMENT PHASES BY COUNTRY

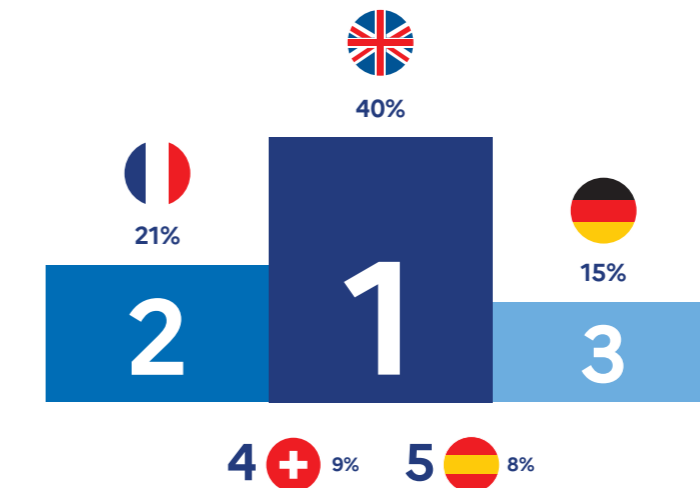


The number of vaccines under development is almost identical to the number of vaccines currently on the market, although the proportion of mRNA vaccines is higher.

679 UNIQUE VACCINES FOR 817 PRODUCTS UNDER DEVELOPMENT IN EUROPE

PROGRESS IN VACCINE DEVELOPMENT IN EUROPE

PRODUCTS UNDER DEVELOPMENT



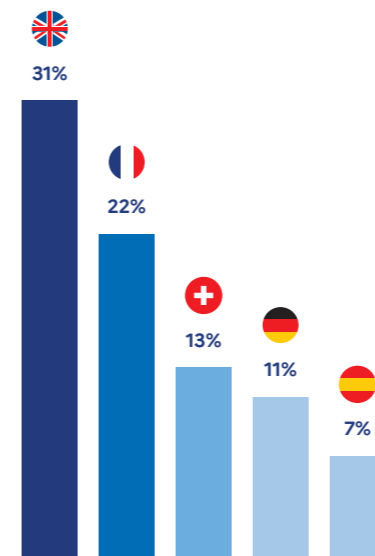
TOP 3

TREATMENT AREAS

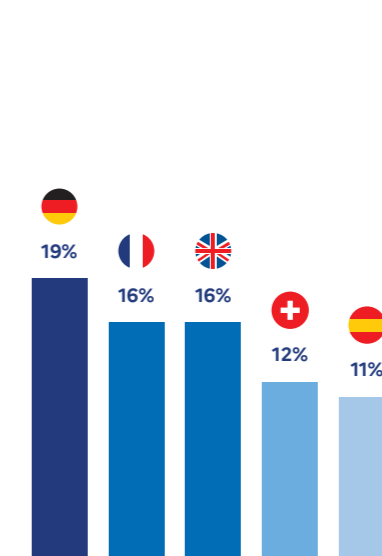
- INFECTIOUS DISEASES
- ONCOLOGY
- IMMUNOLOGY

INDUSTRIAL FABRIC

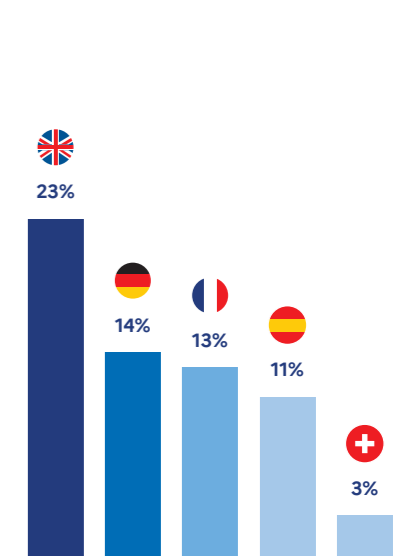
VSE / SME % of total by country



ISE / LE % of total by country



INSTITUTIONS % of total by country



The UK is the European leader in vaccines, followed by France and Germany. France is a major player, with an extensive industrial network developing 21% of European vaccines. It matches the UK in terms of marketing vaccines, but is lagging behind in terms of involving its institutions in vaccine development. Vaccine development by VSE and SME is 31% in the UK, compared with 22% in France.

Spotlight on:

TOP
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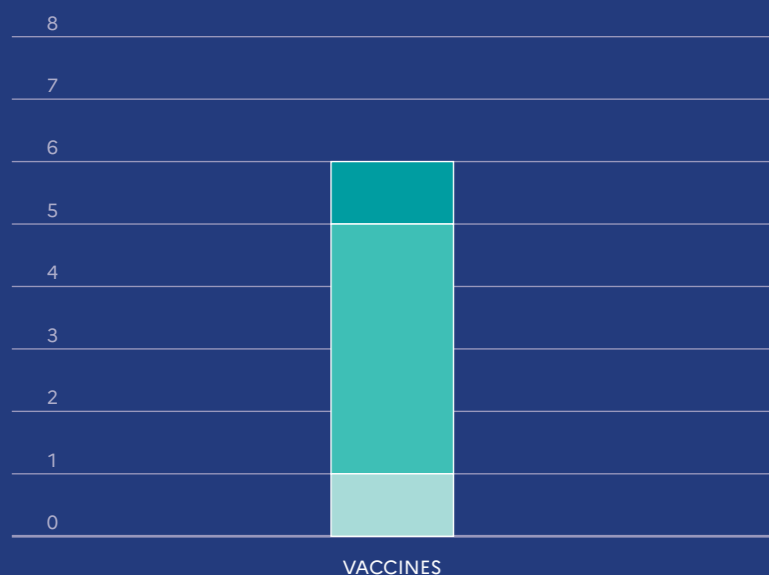
TREATMENT AREAS

INFECTIOUS DISEASES

ONCOLOGY

IMMUNOLOGY

France has 6 CDMO with expertise in vaccines

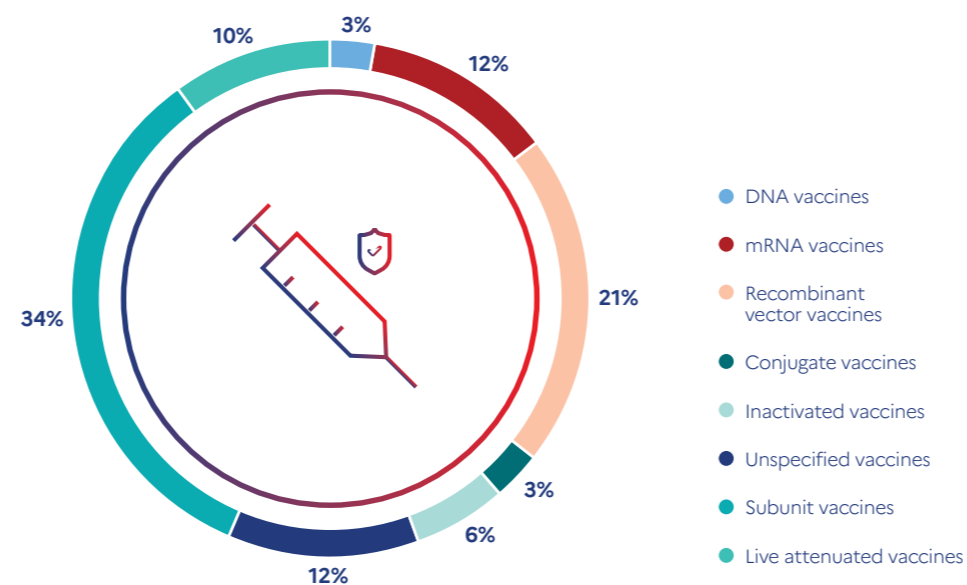


● SME ● ISE ● LE

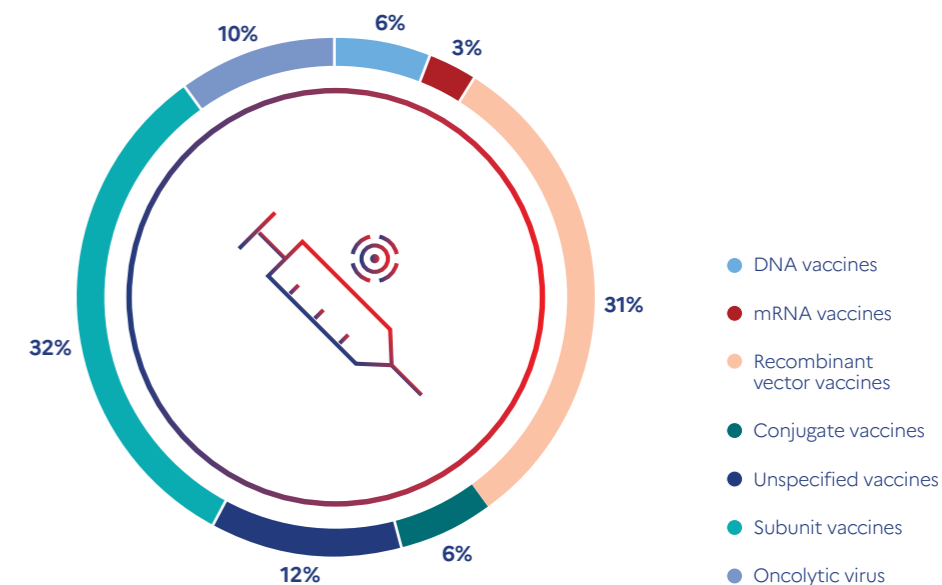
Vaccines under development in France

145 VACCINES IN 174 PRODUCTS UNDER DEVELOPMENT IN FRANCE

PROPHYLACTIC VACCINES

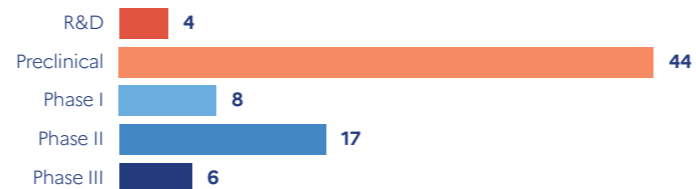


THERAPEUTIC VACCINES

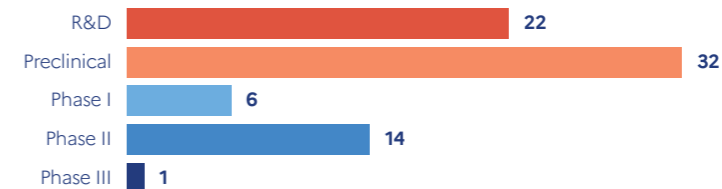


53% of vaccines under development are prophylactic vaccines, 47% of therapeutic vaccines.

PIPELINE



PIPELINE



Historically, France has focused heavily on the prophylaxis of infectious diseases and is well positioned in this market.

The momentum generated by COVID-19 continues, thanks to new technologies.

ACTORS



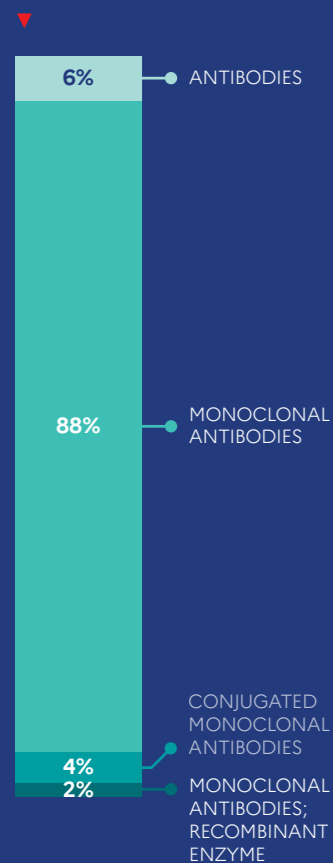
Spotlight on:

TODAY

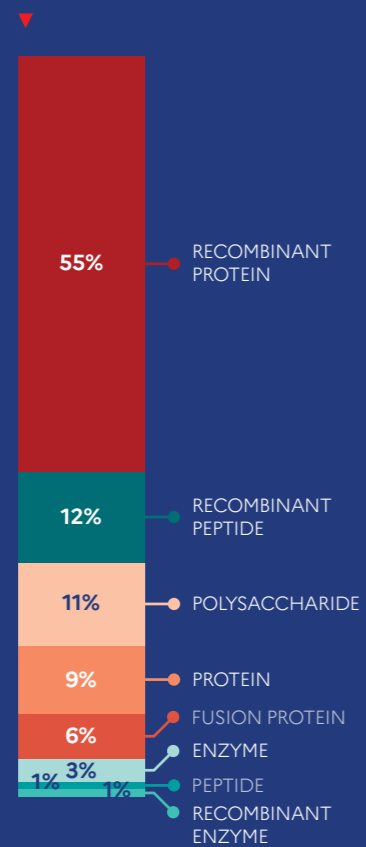
180 UNIQUE ANTIBODIES MARKETED, I.E. 1577 PRODUCTS

331 THERAPEUTIC PROTEINS, PEPTIDES AND BIOPOLYMERS MARKETED, I.E. 2001 PRODUCTS

DISTRIBUTION BY DRUG SUB-TYPE



DISTRIBUTION BY DRUG SUB-TYPE



TOP 3 TREATMENT AREAS

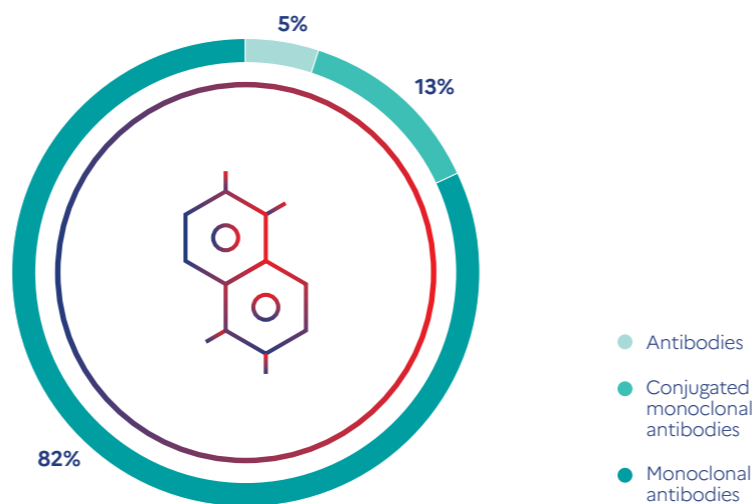


Antibodies and other proteins in Europe

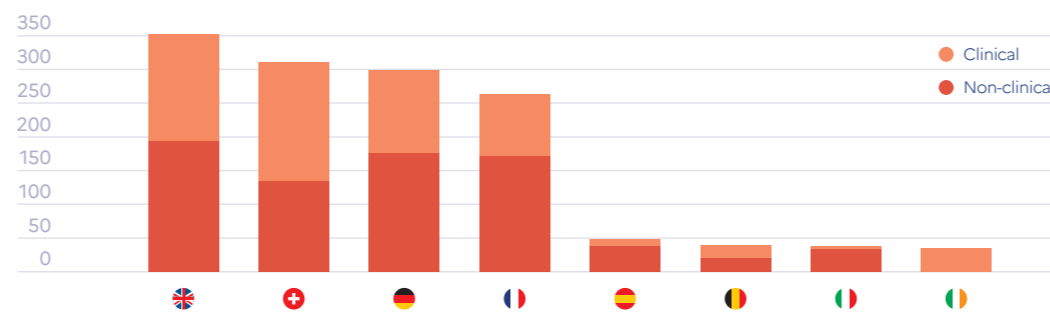
ANTIBODIES



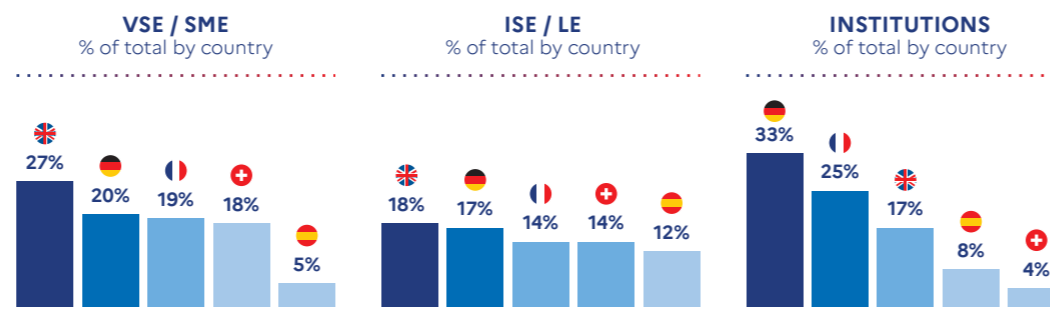
883 ANTIBODIES / 1377 PRODUCTS UNDER DEVELOPMENT



ANTIBODIES UNDER DEVELOPMENT BY COUNTRY



INDUSTRIAL FABRIC

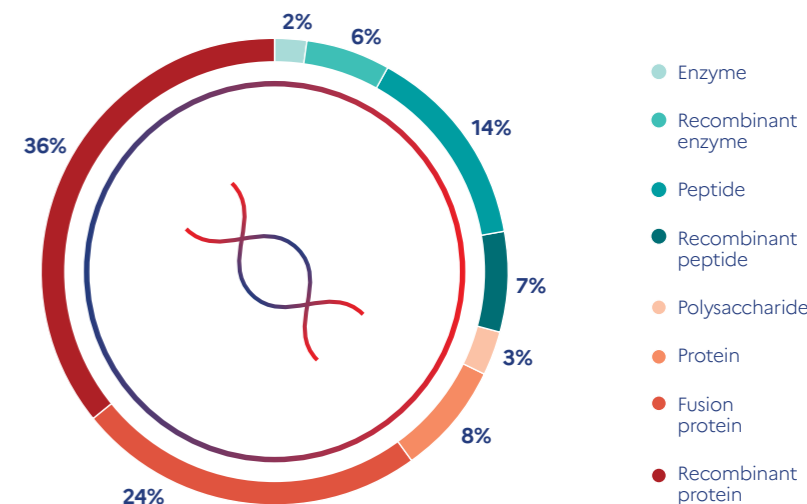


In Europe, antibodies represent the second largest category of biomedicines marketed in terms of number of products, after therapeutic proteins, peptides and biopolymers. Monoclonal antibodies are the most marketed antibody sub-type and the most represented in the development pipeline. **Four European countries are leading the development of antibodies:** the UK, Switzerland, Germany and France. Among the unique antibodies under development, 678 monoclonal antibodies and 141 conjugated monoclonal antibodies were developed

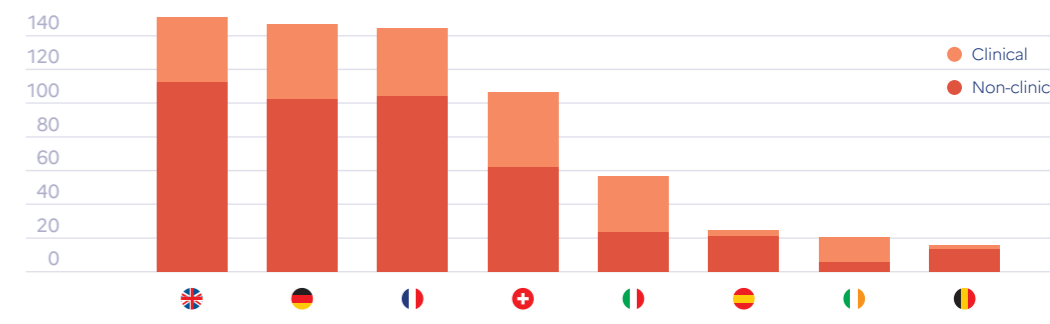
OTHER PROTEINS



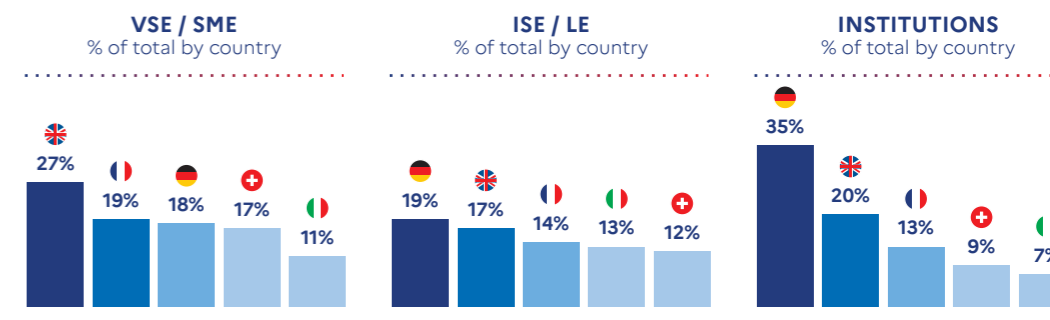
452 PROTEINS UNDER DEVELOPMENT



OTHER PROTEINS UNDER DEVELOPMENT BY COUNTRY



INDUSTRIAL FABRIC

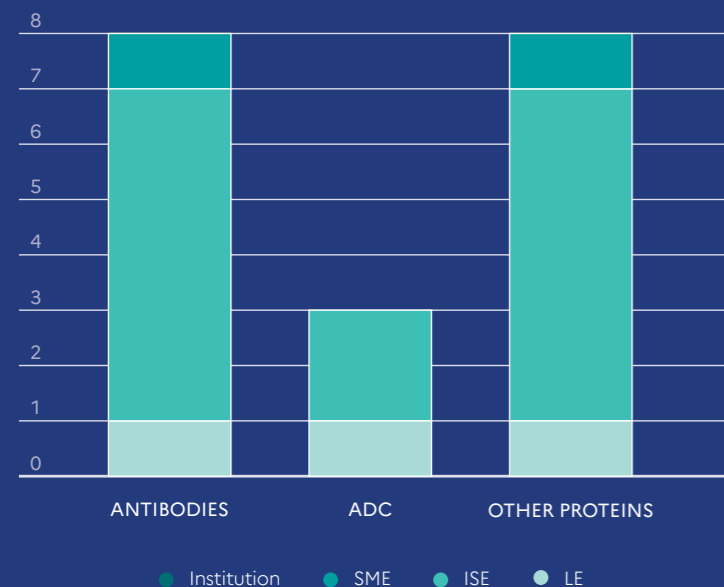


649 therapeutic products are under development, i.e. 452 unique therapeutic proteins, peptides and biopolymers. The majority of products marketed are recombinant proteins, whilst they account for **36% of products under development**, followed by fusion proteins. The UK, Germany and France are leading the way in Europe in the latter.

Spotlight on:

France has a total of 8 CDMO with expertise in antibodies, conjugated antibodies and other proteins.

The same CDMO can have several areas of expertise. ▼



GOOD TO KNOW

*The "antibody" biomedicine sub-type is a default sub-category. This sub-type groups together antibodies that are neither monoclonal antibodies nor conjugated monoclonal antibodies. For marketed products, this biomedicine sub-type includes polyclonal antibodies. For products under development, this biomedicine sub-type includes polyclonal antibodies and antibodies whose specificities have not yet been made public

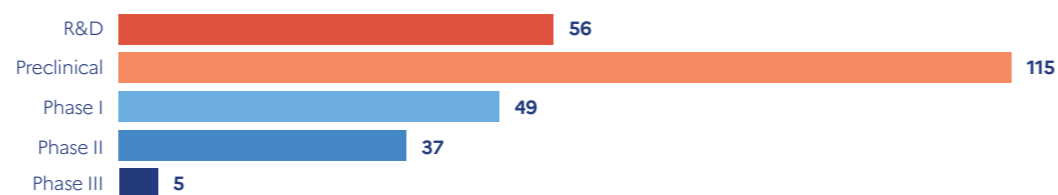
Antibodies and other proteins in France

ANTIBODIES ▼

173 ANTIBODIES UNDER DEVELOPMENT

in 262 products being developed by companies based in France.

PIPELINE ▼



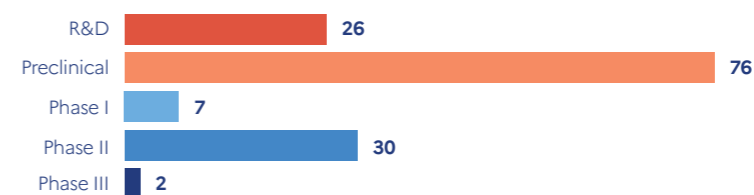
Antibodies are used to treat a wide range of diseases that have a high negative impact on society, so having access to them is vital for all countries. In France, they are the biomedicines with the highest market share in terms of sales (86%). They also have the largest pipeline.

OTHER PROTEINS ▼

92 OTHER PROTEINS UNDER DEVELOPMENT

in 141 products being developed by companies based in France.

PIPELINE ▼



Although the marketed molecules market is mature, it remains promising, with molecules under development and a desire for innovation.

ACTORS ▼



ACTEURS ▼



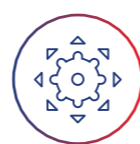
TOP

3

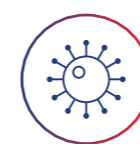
TREATMENT AREAS



ONCOLOGY



IMMUNOLOGY



INFECTIOUS DISEASES

TOP

3

TREATMENT AREAS



OPHTHALMOLOGY



CENTRAL NERVOUS SYSTEM



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