





Research Program (PEPR) Biotherapies and Bioproduction of Innovative Therapies

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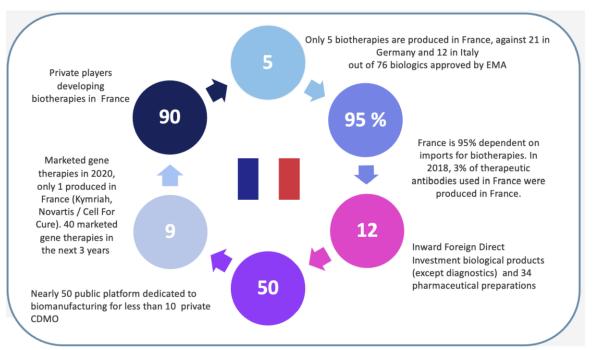








The need to foster the development of biotherapies in France



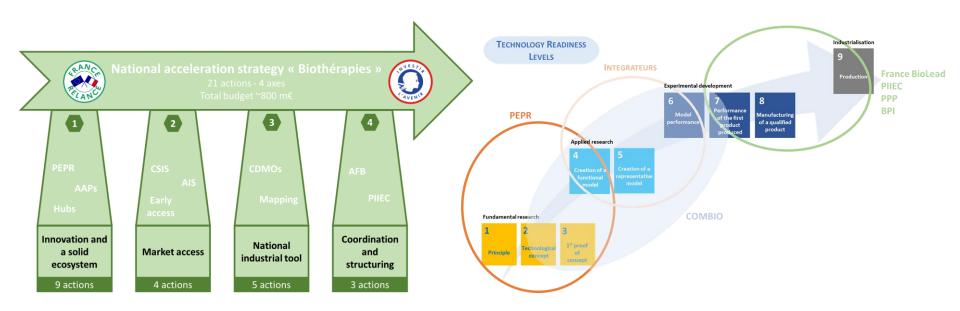
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Comprehensive overview of the French BBTI Acceleration Strategy





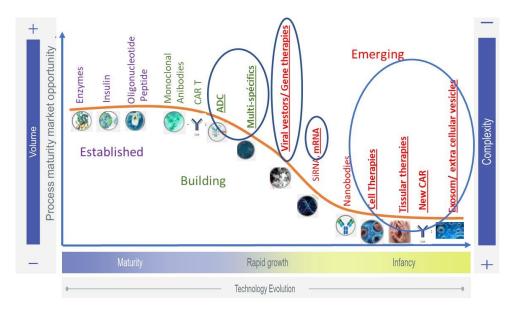






Objectives:

- Launch scientific challenges
- Structure research communities to foster breakthrough
- Consolidate the excellence of French research
- Bring innovative approaches within the international competition



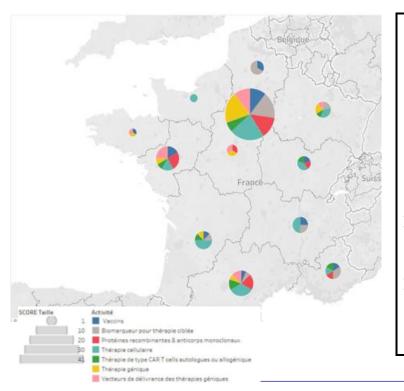








4 main axes and 2 cross-cutting objectives



Anticipate the Accelerate the Develop Support an scale-up of cell deployment of engineering to emerging therapies and gene therapies benefit industrial the emergence biotherapies sector of tissue and centered around the use therapies bioprocesses of extracellular (oncology) vesicles Address the technological challenges associated with the production and deployment of current biotherapies Prepare the future innovative biotherapies and jointly develop their modes of production



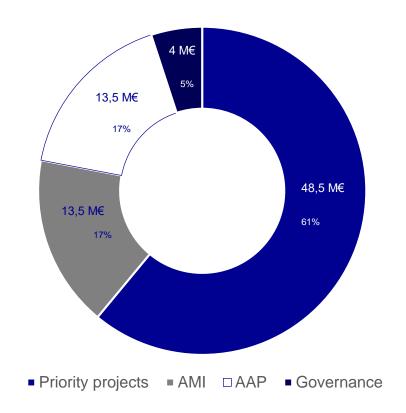




Actions and budget

Budget of **80 millions €** over **7 years** for three main types of actions:

- 74M € dedicated to call for projects to found disruptive proposals focused on the main scientific axes;
- Foster <u>education and training</u> of students and young scientists in the community
- Promote <u>international</u> <u>visibility</u> of the French academic community



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The governance programme focus on 4 main actions



Call for projects



and projects follow up

Foster education and training



Support Communication and dissemination



Promote European visibility

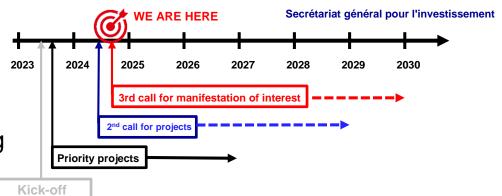






Three calls for projects

Support projects at low TRL (1-4), funding dedicated to French academic groups:



Priority projects

- √ 12 projects launched in 2023
- √ 3 for each axes: cell therapies, gene therapies, biomanufacturing and EVs
- ✓ 4 years duration, average 4M € each
 ✓ 3 to 11 academic partners

https://pepr-biotherapies.fr/projets/

2nd call for projects

- ✓ Focus on the 4 scientific axes opening to emerging therapeutics
- ✓ Aim to found groups that could not profit from the first call
 - √ 54 proposals under evaluation
- Results available in January 2025

3rd call (expression of interest)

- ✓ multidiscipinary projects integrating new expertises and approaches for innovative biotherapeutics and/or their manufacturing (4 scientific axes)
- ✓ Look for the expression of interest of experts in data science, engineering, chemistry, social science and ethics

Call to be launched in December 2024







12 targeted projects already started

Axis 3: Axis 4: Axis 1: Axis 2: **Engineering for** Extracellular **Cell therapies Gene Therapies** biotherapies and vesicles bioprocesses **IPSC France** Bioscale ACCREDIA **STROMAEV** AL. Bennaceur (Cithera) O. Adjali (TaRGeT) B. Maillere (CEA) D. Noël (IRMB) Bioengineered QualAAV RNAvac **Bacter-EV-Booster Skin France** P. Hantraye (MIRCen) C. Pichon (Univ. Orléans) JM. Chatel (Micalis) N. Fortunel (LGRK, CEA) **iChondro EDITO** THERA-B CARN F. Djouad (IRMB) T. Cronin (Univ. Nantes) A. Galy (ART-TG) F. Gazeau (LMSC)







1st call for projects published in 2024

Open between April and September 2024 to support innovative and disruptive research projects around the PEPR's 4 scientific axes

Targeted topics:

- Large-scale manufacturing of cell therapies and the emergence of tissue therapies
- **Gene therapies:** preclinical development of new non-viral vectors, synthetic biology, automation of production processes, etc.
- **Developing engineering for biotherapies and bioprocesses:** continuous bioproduction, large-scale purification, PAT, microfluidic technologies, AI, AQbD, etc.
- **Emerging fields in biotherapies:** extracellular vesicles, therapeutic antibodies, microbiota-based biotherapies, phagotherapy, etc.

Evaluation on going

Evaluation jury selected by ANR (54 application)

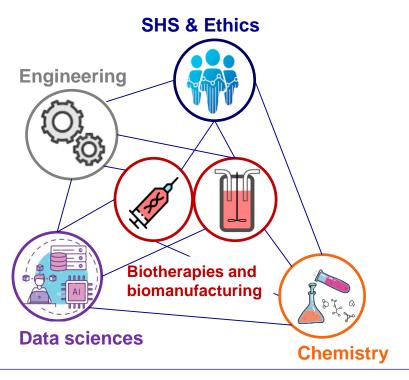








2nd calls for projects to be published in 2024



Build multidisciplinary project, integrating new expertise and approaches for designing their innovative biotherapeutics and/or manufacturing

Specifically look for the **expression of interest** of experts in complementary domains



Launching of the 3rd call for projects by the end of 2024







Scientific axes of the 2nd call for projects

Field 1: Design of new biotherapies

Bioconjugation, bioorthogonal chemistry, vectorization, nucleic acid analogues, artificial biomolecules, design of pro-drugs associated with biotherapeutic products

Field 2: Improving process reproducibility and efficiency

- **1. Improve bioproduction conditions:** process optimization, reproducibility, efficiency, automation, characterization, stability, artificial intelligence, machine learning, deep learning
- **2. Modeling tools for the automation of bioproduction processes:** Modeling biological and physical systems in bioreactors, multiscale modeling to simulate bioproduction processes

Field 3: Improving the perception and acceptability of biotherapies

Acceptability of new biotherapies, economic models to analyze the cost of biotherapies and their biomanufacturing, simplification and harmonization of consents

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Timing of the 2nd call for projects

Focus on multidisciplinarity and integration of new stakeholders

Call launching: December 2024-January 2025

Estimated start of projects: Q4 2025

Minimum 4 academic partners

Maximum project duration: 4 years

Topics: Data science

Engineering Chemistry

Social sciences and ethics

CONSTRUCTION OF THE CALL

Workshop with a panel of experts and PEPR pilots

LAUNCH OF THE CALL

Opening of the 1st phase open by the end of 2024

BUILDING OF CONSORTIA

Selection of letters of intent by the PEPR SAB and pilots

WRITTING OF FULL PROJECTS

EVALUATION OF PROJECTS BY ANR



FRANCE

biolead









