

Organoids and organs-on-chip in gene and cell therapy: which innovation strategies in France?

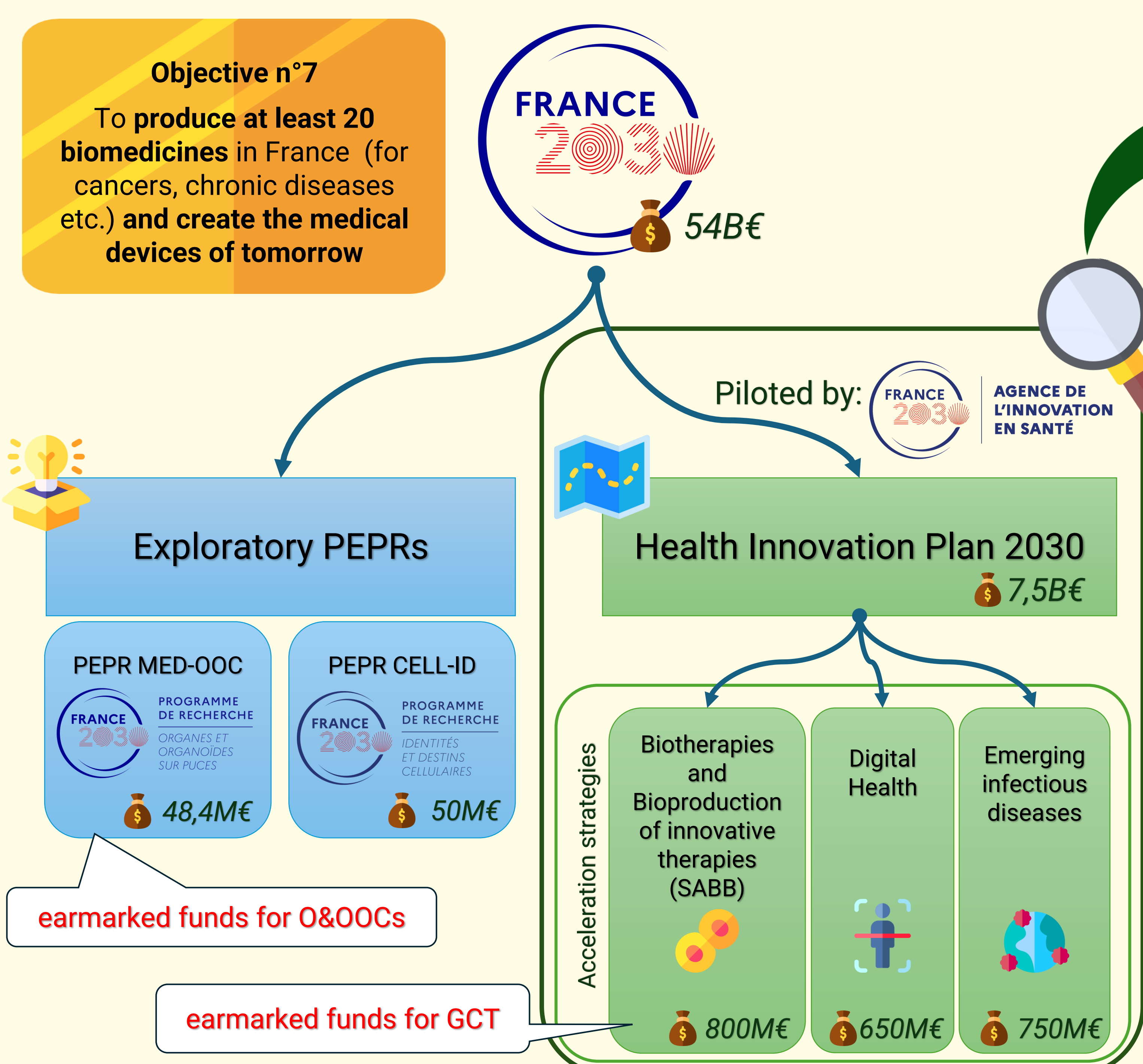
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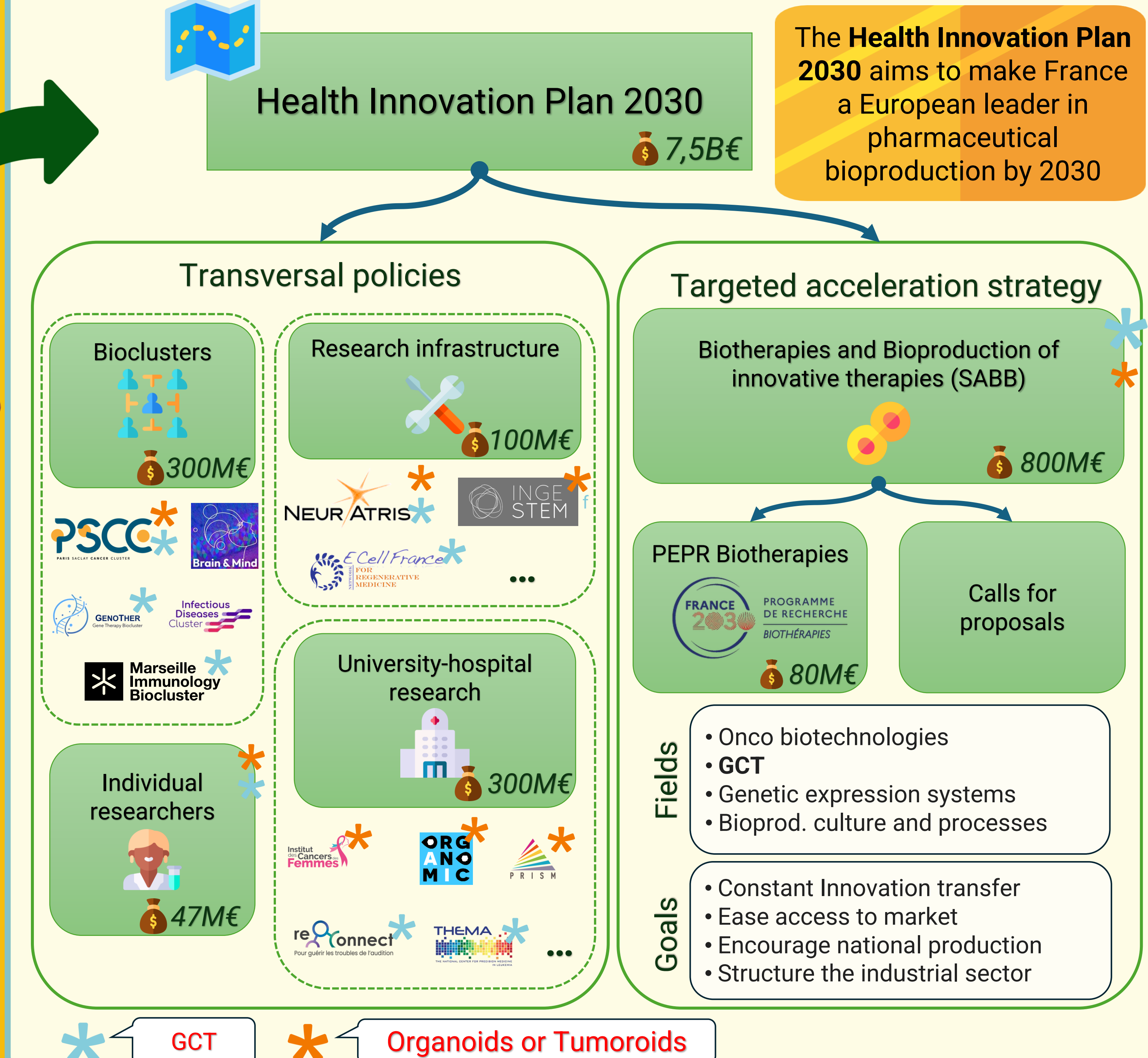
Introduction

- **Organoids and Organs-On-Chip (O&OOCs) technologies** are emerging tools in health research that are quickly becoming ubiquitous.
 - In the field of **Gene and Cell Therapy (GCT)**, they are mainly used in **pre-clinical development** for disease modelling, drug screening and toxicology.
 - If used one day as medicines, they would fall under the legal framework of **Advanced Therapy Medicinal Products (ATMPs)**.
- To harness their potential, combined efforts from researchers, start-ups, industrial manufacturers, investors and regulatory bodies are required to **structure the sector and secure funding**.
 - The main thrust of public funding comes from the national strategy **France 2030**, a multiannual, 54-billion-euros plan designed to massively invest in innovative technologies.
 - Part of it is the **Health Innovation Plan 2030** (*Plan Innovation Santé 2030*) designed to **ramp up the national production of biomedicines** in France.
- **How do these French funding policies contribute to the framing of the O&OOCs and GCT sectors?**

France 2030: exploratory and strategic policies



Health Innovation Plan: preparing the future of healthcare



- **Priority Research Programmes and Equipments (PEPRs): direct support for O&OOCs of low technological readiness.**
 - **PEPR MED-OOC** : creating a new generation of biological models on chips to reproduce the functioning of organs.
 - **PEPR CELL-ID** : deploy interception medicine in the field of paediatric brain cancer research.
- **Health Innovation Plan 2030:**
 - Piloted by the Health Innovation Agency (*Agence Innovation Santé*)
 - **Strategic and systemic approach** to health innovation:
 - **Address under-investment and de-industrialization** of the sector.
 - Develop a better health system: **more predictive, more preventive, more innovative** and more personalised.
 - National production of biomedicines to **control costs** of healthcare.
 - Subdivided in three **Acceleration Strategies**, with one providing **direct support for GCT**

The **Health Innovation Plan 2030** actually includes O&OOCs within its approach to GCT:

- **Transversal policies: indirect support for GCT and O&OOCs**
 - Fund **individual researchers**
 - Create **bioclusters**
 - Develop **research infrastructures**
 - Facilitate **university-hospital research**
- **SABB Acceleration policy: direct support for GCT and indirect support for O&OOCs**
 - From **basic research** (PEPR) to **industrialisation** (calls for proposals)
 - Cell quality & safety standards, Good Laboratory Practices, etc... are relevant for both O&OOCs and GCT.

Most of the ongoing and future funding calls are accessible from the website of the French National Agency for Research (<https://anr.fr/>)

Conclusion

- **O&OOCs are cross-cutting technologies**
 - Present **across many innovation strategies**.
 - Their **role is going to grow even more** in the future when they will be technologically mature.
 - O&OOCs can be used **throughout the GCT development pipeline**.
 - Most projects financed by the presented strategies already produce O&OOCs.
- **Direct and indirect funding for O&OOCs**
 - O&OOCs benefit from several French innovation funding policies including those related to **GCT**.
 - France has chosen to support O&OOCs directly, and indirectly as part of the development of biotherapies.

- Although organoids are **not explicitly part of the Health Innovation Plan** (they are not medicines as of today), **O&OOCs methodologies** can be included in ATMPs projects' applications in the PEPR Biotherapies.
- The fundings cover research programmes, infrastructures, individuals, equipment and the creation of bioclusters which are relevant for both O&OOCs and GCT.
- **Significance of the French strategies**
 - Overall approach recognising both the distinct and linked needs of O&OOCs and GCT.
 - Acknowledgement and support of the interest of O&OOCs both **in GCT development** and **as future GCT**.