

# Financing and Structuring the Organoid and Organ-on-Chip Sector in France

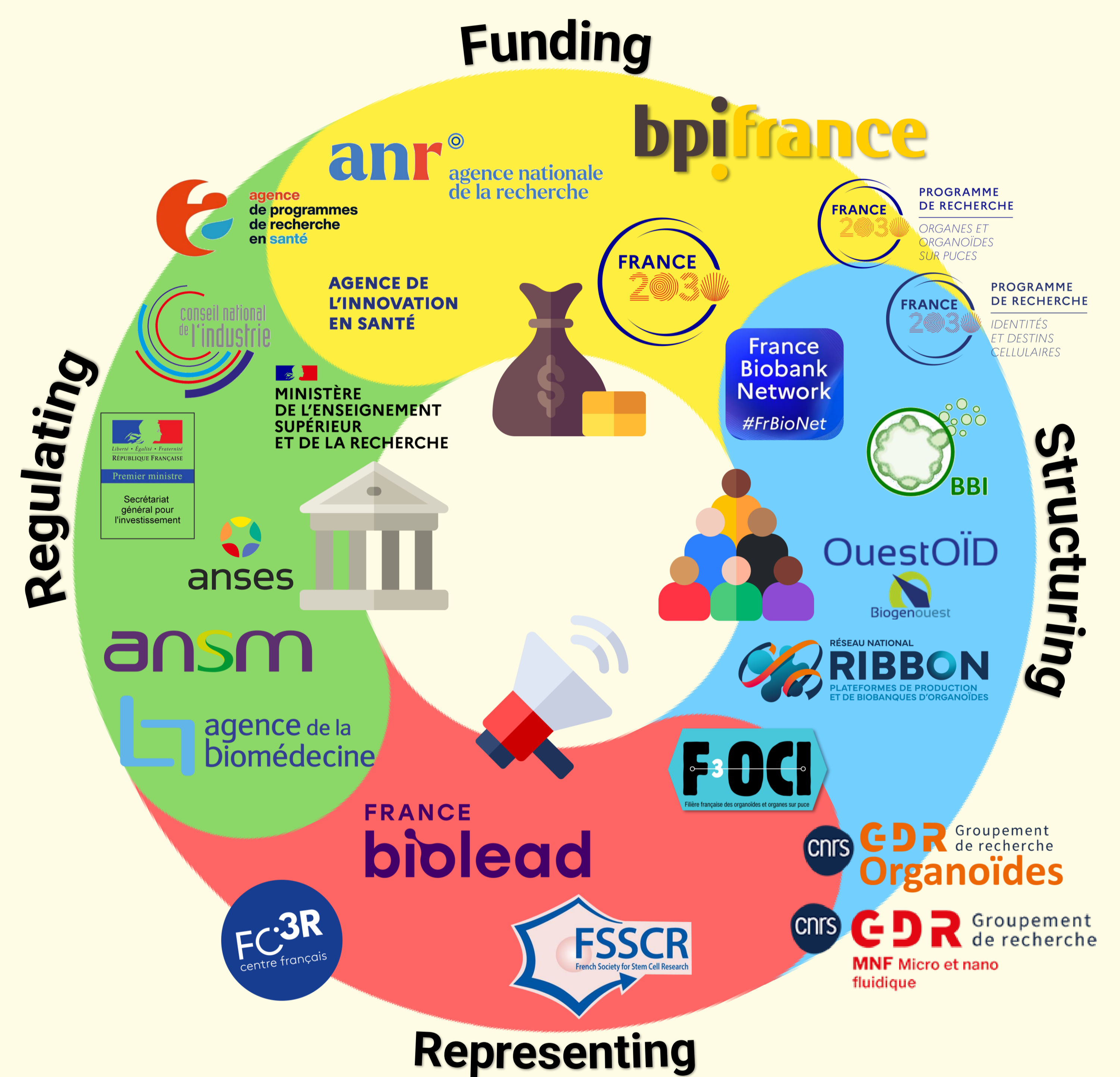
Adrien Bottacci<sup>1</sup>, Guylène Nicolas<sup>2</sup>, Aurélie Mahalatchimy<sup>3</sup>

<sup>1</sup>PhD Student, UMR 7268 ADES, CDSA Health Law Centre - UMR 7318 DICE CERIC International, Comparative and European Laws, Aix-Marseille Université – CNRS, Aix-en-Provence, France ; <sup>2</sup> Professor, UMR 7268 ADES, CDSA Health Law Centre, Aix-Marseille Université, Aix-en-Provence, France ; <sup>3</sup> CNRS Researcher in law, UMR 7318 DICE, CERIC International, Comparative and European Laws, Aix-Marseille Université – CNRS, Aix-en-Provence, France

## Introduction

- **Organoids and Organs-On-Chip (O&OOCs) technologies** are emerging tools that hold great potential to lastingly transform health research.
- **Strong international competition** in this field requires effective national innovation policies.
- In focus: **funding and structuring** of the emerging O&OOCs ecosystem.
- Overview of the **established and emerging actors** (their role and their competence) and the Sectorial Strategic Contract. Analysis of the interactions between actors.

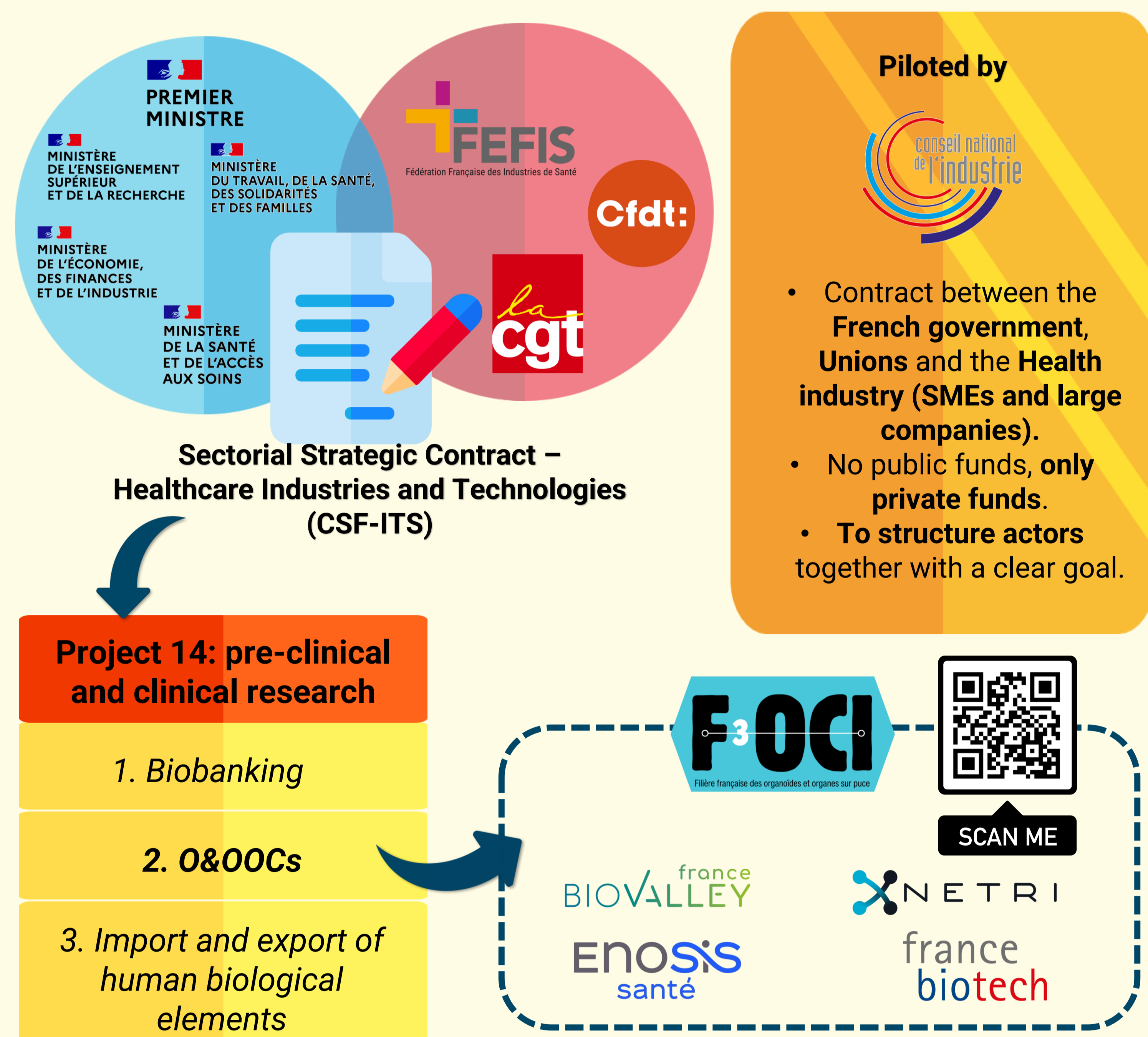
## Main Actors of the Emergent French O&OOC Ecosystem



Note that this representation is a model used for analytical purposes. In fact, some of these actors may accumulate several of these activities.

- **Core Activities of Involved Actors**
  - **Regulating**: ministries, agencies (ANSM, ABM, AIS...)
  - **Funding**: mainly public investment bank, public-private, private... national research agency...
  - **Representing**: advocacy groups (learned societies...).
  - **Structuring**: national research centres (CNRS, INSERM, INRIA, CEA, INRAE, l'Institut Pasteur, France universités, Udice), start-up consortia, competitiveness clusters, academic labs and platforms...
- **Links Between Actors**
  - **Orientations**: descending (government oversight), ascending (e.g. advocacy), and horizontal exchanges (sharing of resources)
  - **Forms**: contractual or informal and interpersonal links...

## The Sectorial Strategic Contract (2023-2026)



- **Sectorial Strategic Contract of Healthcare Industries and Technologies (CSF-ITS)**
  - Piloted by the *Conseil National de l'Industrie* (CNI)
  - Aims to build an **integrated industrial sector** (cell cultures, microfluidics, sensors...)
  - Based on **reciprocal commitments** between government and industry (w/o budget)
- **O&OOCs in Project 14**
  - **Demand** raised by Biovalley France (bottom-up), officialised under the CSF-ITS by FEFIS and the Ministry of Research. Lead to the creation of F3OCI.
  - **Purpose**: enter the international race as a unified industrial sector.
  - **Objectives**:
    - coordinate initiatives ;
    - develop standards and qualification processes ;
    - strengthen expertise and international visibility ;
    - ensure national health sovereignty.
  - **Key actions**: cartography of actors and projects, white paper, training, TRL (Technology Readiness Level) assessments, coordinate with regulatory bodies

## Conclusion

Significant progress in structuring the O&OOC sector but major challenges remain.

- **Challenges**:
  - **Industrial Translation**
    - Technological maturity (validation and standardization of models, reproducibility, reliability)
    - Industrial scale-up and market access
  - **Knowledge sharing, Consensus Building and Stakeholder Integration**
    - Standardization, regulatory validation and acceptance,
    - Industry-academia partnerships, visibility of platforms
    - Public acceptability, donors and patient associations engagement

The French O&OOC sector is in rapid transformation, with **strong potential to position itself internationally**, as long as **coordination and consensus** are achieved.

- **Coordinating Public and Private Actors**
  - **Private actors**: ambiguous context of competition and cooperation.
  - **Public actors**: who's competent to act? (i.e. standardised consent forms). Central authorities reluctant or slow to take positions, reliance on informal contacts.
- **Quickly Evolving Ecosystem**
  - New actors and structures (e.g. F3OCI)
  - **GDR organoïdes** to take the form of a *thematic network* (CNRS, INSERM).
  - Risk of **redundant initiatives** when lack of knowledge or communication or coordination. Amplified by the current circular structure.
- **Regulatory Scope**
  - Grouping organoids, organ-on-chip and organoid-on-chip technologies? **Grouping O&OOCs** with other **New Alternative Methods** (NAMs)? What are the specific issues, the commonalities?