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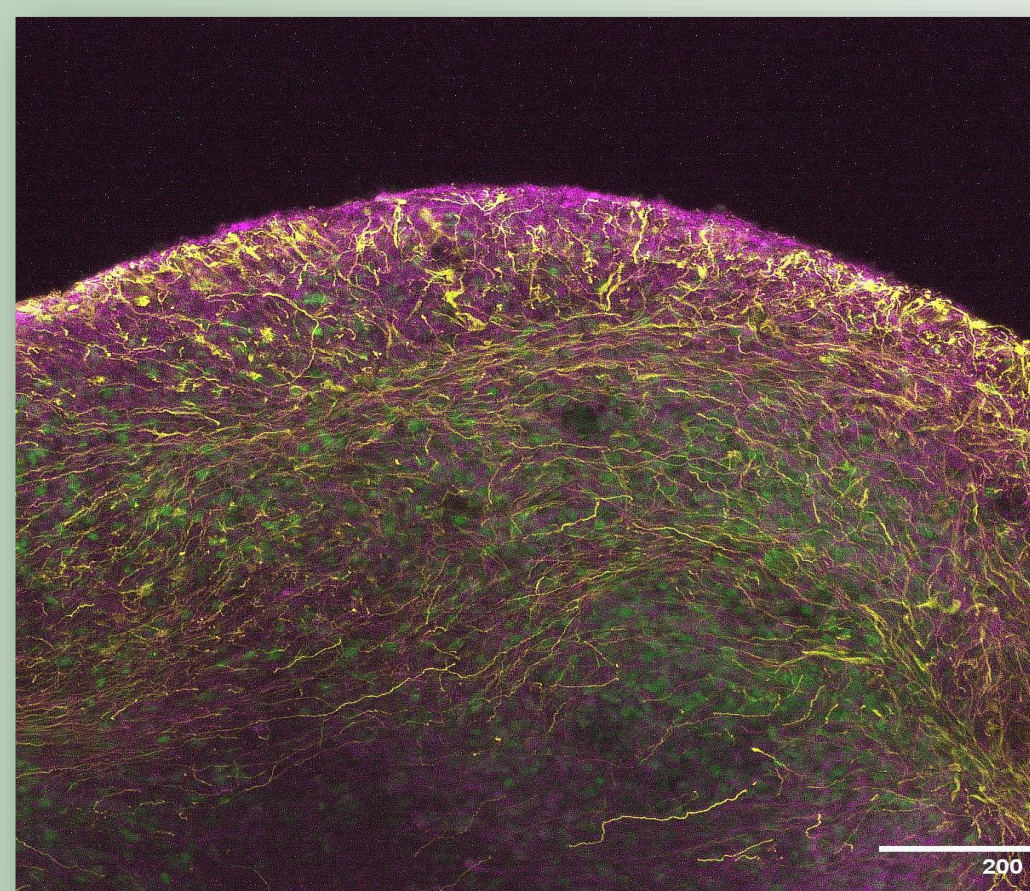
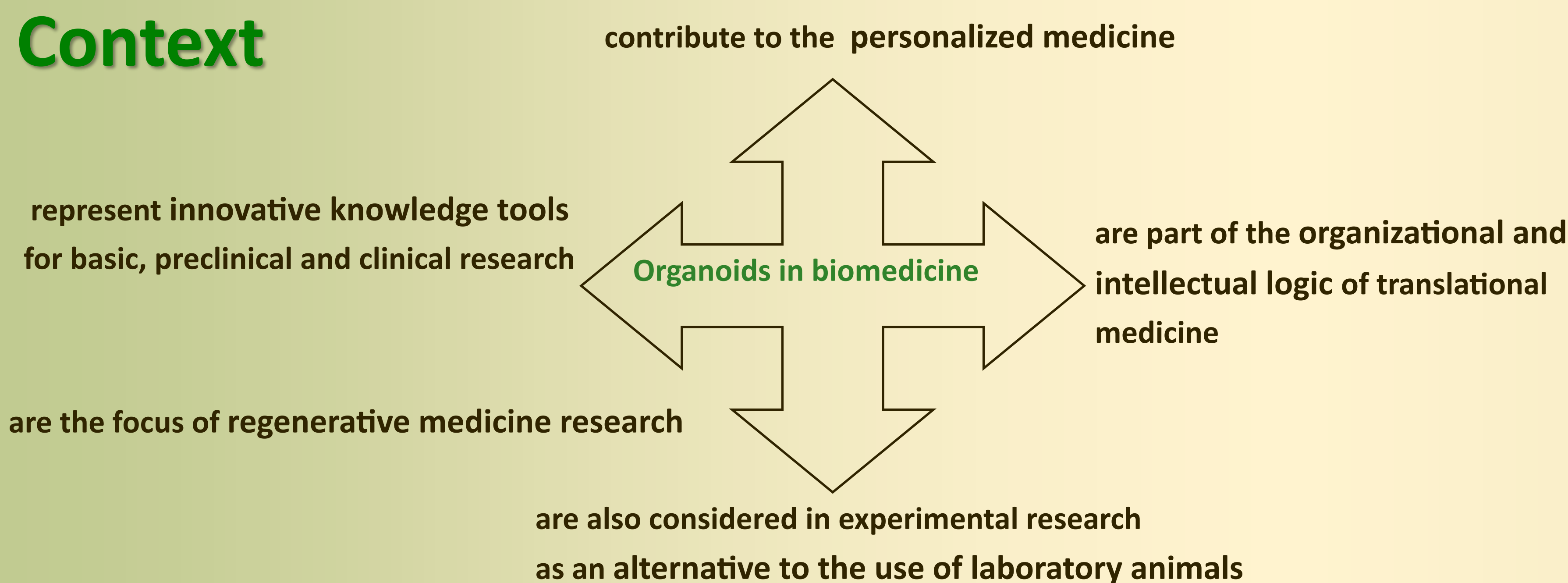
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Organact takes an **interdisciplinary** approach, combining sociology, anthropology and law, to **human organoids** and the issues they raise in their **production, circulation and use**. These little-known entities blur the usual categories and qualifications, but remain little studied in SHS outside of ethical aspects. Organact aims to shed light on **how these entities are regulated**. It aims to provide an account of the **many activities involved** in scheduling organoid-based practices, and to assess their impact on the **healthcare system**.

## Context



Cortical organoid (2 months)

## Hypothesis

**H1**: The specificities and uncertainties of organoids challenge existing frameworks in biomedical research and the healthcare system: some of the practices that mobilize them are well-defined, while others go beyond them.

**H2**: Organoids elicit distributed regulatory activities which our project aims to shed light on.

## Socio-anthropological approach to cerebroid

The **ethnographic study** focuses on the various stages from the manufacture of cerebroids to their disposal.

These **manufacturing and conservation activities** are meticulously studied, as are the **uses** to which they give rise (from "fundamental" research to more "applied" activities).

The **"controversial" or contentious** aspects of cerebroids are also examined: questions of sentience/consciousness, moral values, legal status, chimerism, organoid intelligence, etc.

Analysis of the **heterogeneous arrangements** in which the organoids take part and the reconfigurations they generate: negotiation issues (technical, etc.), relationship with cerebroids (care practices, etc.), qualifications ("wild" cerebroids, neuronal organoids, etc.), public/private links and stakes.

## Legal approach to cerebroid

**Legal definitions**: tissues and cells? Organs? Advanced Therapies Medicinal Products? "New approach methodologies"?

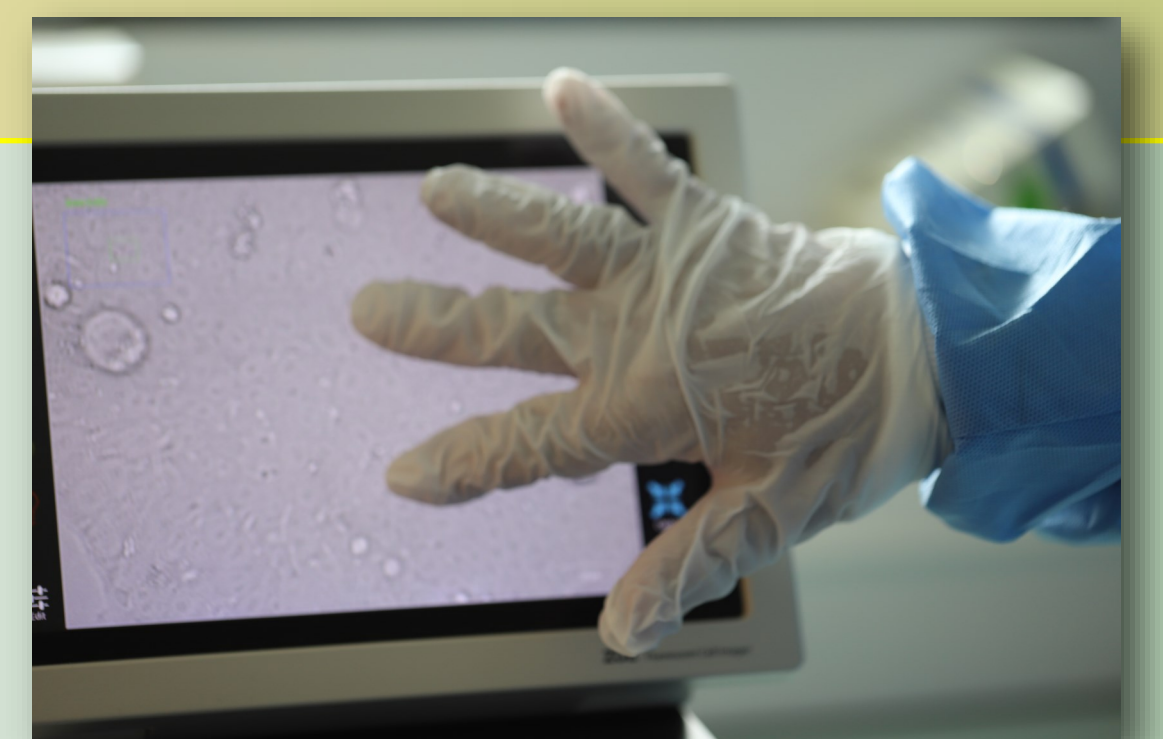
**No specific legal regime for brain organoids in French law**: basic research falls under the regime of stem cell research (articles L2151-1 to L2151-11 of the Public Health Code).

**Respecting donors' rights**: anonymity, bodily integrity, consent, free donation.

**Various soft law guidance**: International Society for Stem Cell Research, US National Academies, INSERM ethics committee, National ethics committee (CCNE).

## Objectives

- to explore biomedical practices (care and research) that rely on organoids
- to understand the impact of organoids on these practices, and how they are changing them.



## Questioning

To shed light on the **regulatory work** of these entities: how are they appointed? What powers are vested in them? In what arrangements are they employed? What regulations do they give rise to?

## Methodology

The **ethnographic fieldwork** involves the empirical study of complementary case studies in France (through situated observations, interviews and documentation), covering a continuum of practices from basic research to clinical application.

Anthropological and sociological analysis: aiming to take into account the diversity of organoid conditions (origins and stages of development) and their trajectories within the research practices or where they are manufactured and "cultivated".

The **legal analysis** will include these cases and will be complemented by an approach based on an exegesis of European and French legal texts.

## Empirical inquiry

Study 4 types of organoids **in laboratory and hospital settings**: describe the interweaving of conceptions of life, ethics and legal standards or normative frameworks with day-to-day practices:

- **Cerebroid** for modeling neurodegenerative diseases
- **Gastruloids** for studying morphogenesis of the cardiovascular system
- **Hepatic organoids** in preclinical research and health monitoring
- **Intestinal organoids** for cystic fibrosis research

## Cross-cutting analysis / comparative analysis



ORGNOID STATUS may vary according to several factors: types of organoids; stem cells used in their manufacture and the purposes for which they are used. Variations analyzed in the case studies identified above and in legal texts.

INDUSTRIALIZATION AND THE MARKET: from manufacturing to conservation: organization, actors, distribution, flows

PROMISES AND RESISTANCE /ORGANOIDS: Testing future scenarios, controversy study



