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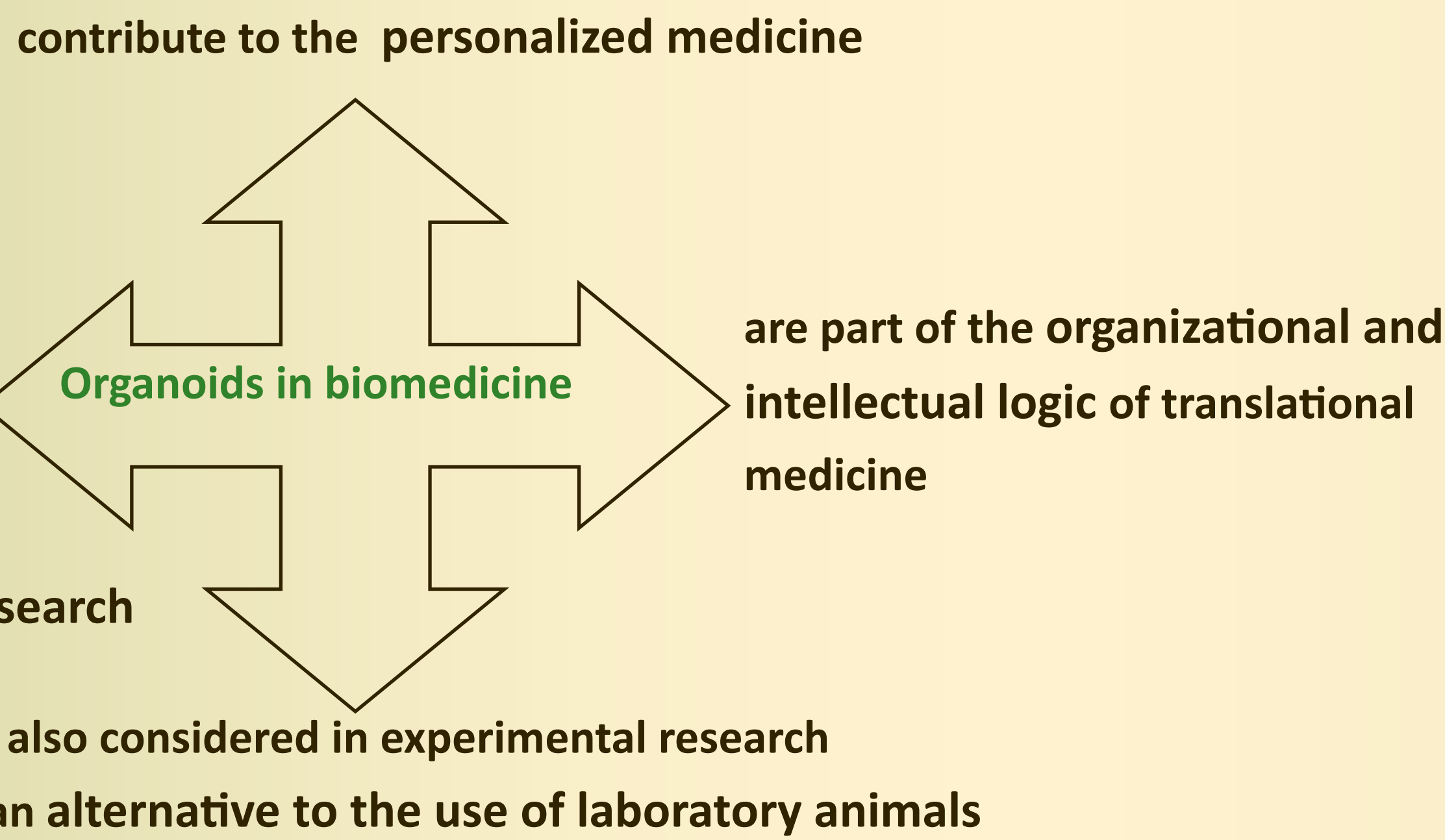
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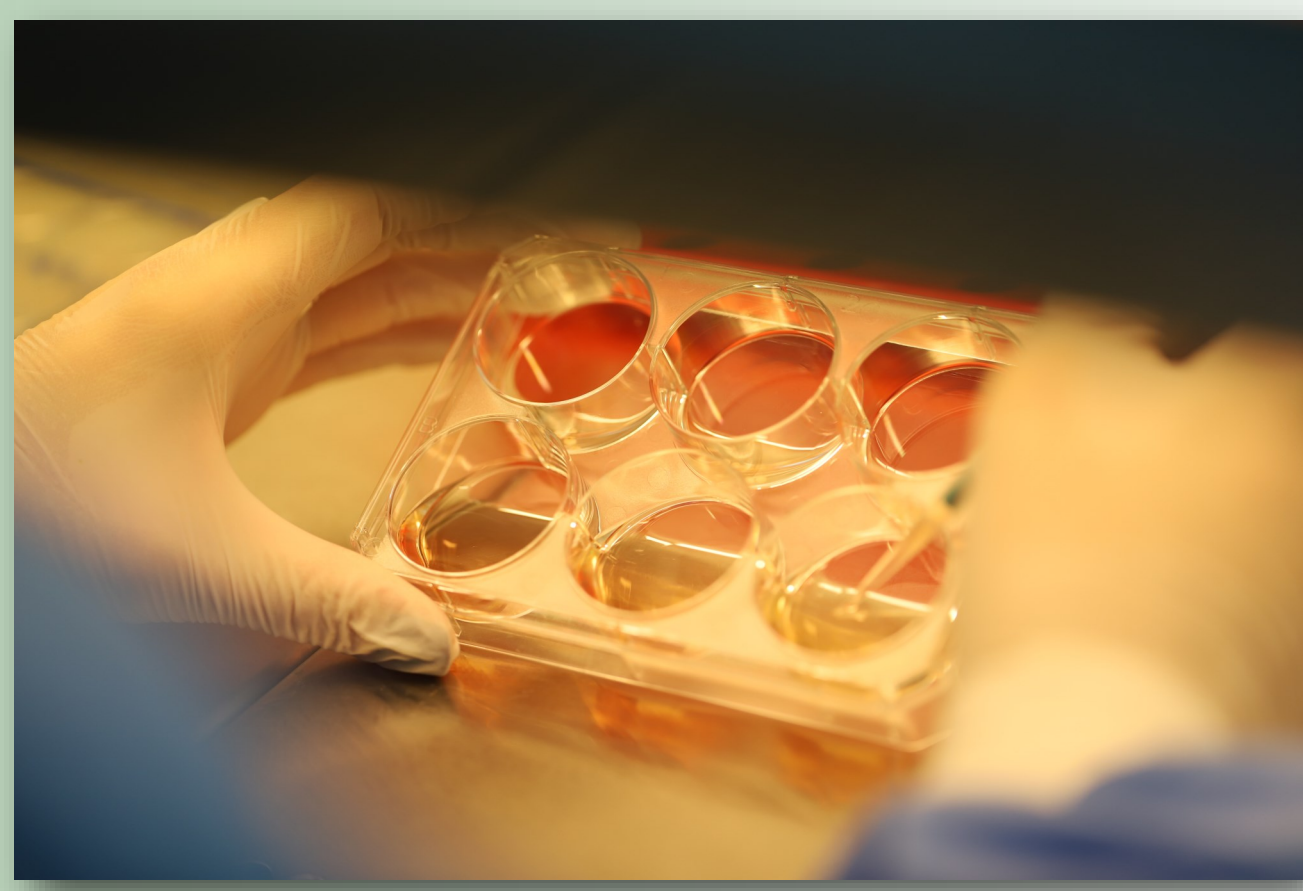
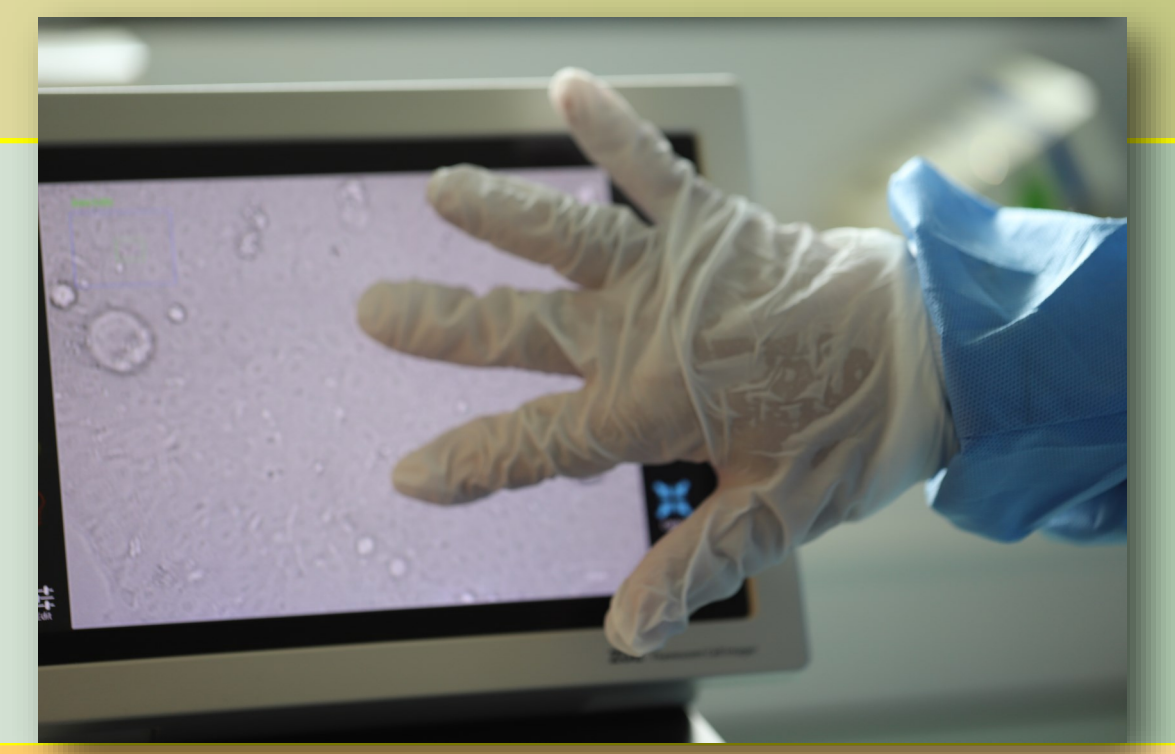
Organact takes an **interdisciplinary** approach, combining sociology, anthropology and law, to **human organoids** and the issues they raise in their **production, circulation and use**. These little-known entities blur the usual categories and qualifications, but remain little studied in SHS outside 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



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.



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.

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

Socio-anthropological approach

- This approach is based on a *detailed comparative ethnography* of organoid production and use in France
- Comparison of the *constitution of organoids* (type of cells used, status and manipulation), their banking and the regulation of the resulting bio-banks.
 - Comparison of the *horizons of personalized (or precision) medicine*, and the logics of industrial appropriation and patentability of living organisms.
 - Comparison of the *epistemic, sociological and regulatory issues* involved in integrating organoids into biomedical research.

Legal approach

- Identification and relevance of the status and legal regime** applicable to organoids: no legal definition of organoids, no single legal regime applicable, several legal criterias for various legal regimes
- General legal issues**: complementarity between different fields of law, distinction between hard-law and soft-law, obtention of human cells, quality and security of organoids, uses of organoids etc.
- Specific legal issues**: distinctions between various types of organoids and their respective status, specific rules for stem cell research generating organoids?

Cross-cutting analysis / comparative analysis



ORGNOID STATUS: laboratory products vs. attached to persons, moral value of these new living entities, qualification of organoids

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

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