



HYBRIDA



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1. HYBRIDA Project

An organoid is an organised three-dimensional aggregate of cells produced *in vitro* from stem cells. Organoids have the potential to serve as three-dimensional culture models simulating some micro-anatomical features and properties of different organs, like the heart, the brain, the intestine, the kidney, the liver or the skin. HYBRIDA is a three-year Horizon 2020 project that has initiated in February of 2021 and aims at developing a conceptual and regulatory framework by addressing three kinds of uncertainties present in organoid research: (a) *Conceptual uncertainty* that relates to the open questions about the nature of organoids, the way people conceive entities that cannot be categorised as either persons or things, and the knowledge of the characteristics of organoids. (b) *Epistemological and methodological uncertainty* that relates to the open questions about how to address forms of uncertainty that cannot be evaluated through the use of statistical methods. This is particularly pertinent to the cases that organoids are intended for personalized or precision medicine. (c) *Regulatory uncertainty* that emerges due to the fact that parts of regulatory frameworks concerning the rights and duties of persons have been merged with elements of regulation dealing with the stewardship of objects or things.

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2. Basic Objectives

- **To ensure a comprehensive development process:**
 - ◆ Identification of different forms of uncertainty.
 - ◆ Mapping exercise and comparative analysis of relevant regulatory frameworks.
 - ◆ Identification of conceptual gaps, HTA-related gaps, and regulatory overlaps and regulatory gaps.
 - ◆ Provision of a comprehensive overview of ethical and normative aspects of organoid research and related technologies.

- **To involve key stakeholders:**
 - 1st stage**
 - ◆ Three deliberative workshops with a wide variety of stakeholders such as representatives of the general public, vulnerable groups, patients, donors and civil society organizations with a view to: Understanding the worries, fears, and expectations of the general public, vulnerable groups, patients, and donors.
 - 2nd stage**
 - ◆ Deep interaction through expert interviews and co-creation workshops.
 - 3rd stage**
 - ◆ Expert and professional stakeholder assessment of the guidelines, CoC and ethical framework produced via six focus group interviews.

- **To build on knowledge from other EU- and national projects**

HYBRIDA partners will make good use of the strong links with past and present research and innovation activities and projects, pertaining to organoid research and organoid-related technologies, RE and RI, in order to successfully perform the planned activities.



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3. Project partners

The project brings together a consortium of 8 partners, research performing organizations, of 8 countries (Norway, Greece, United Kingdom, Belgium, Denmark, Netherlands, France, Italy). The research fields covered within the partners are medical and health science, humanities, philosophy, law, policy research and data protection/management. These complementarities allow the consortium to perform work at an individual level.



No.	Name	Short Name	Country
1	Universitetet I Oslo	UiO	Norway
2	National Technical University of Athens	NTUA	Greece
3	The University of Manchester	MAN	United Kingdom
4	Universite Catholique de Louvain	UCL	Belgium
5	Aarhus Universitet	AU	Denmark
6	Academisch Ziekenhuis Leiden	LUMK	Netherlands
7	Institut national de la santé et de la recherche médicale	INSERM	France
8	'Università degli Studi dell'Insubria	UNINS	Italy

4. Kick-off meeting



The project's kick-off meeting was successfully held on March 16, 2021 with the participation of consortium partners, Advisory Board members and EC Project Officers. During the KOM, project contents were examined into details, and next activities were scheduled.

5. Deliverables Achieved

In the first 12 months (M1-M12) of the HYBRIDA project, the following deliverables were successfully uploaded to the participant portal, for the European Commission's evaluation.



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D1.2 Different forms of conceptual uncertainty relating to organoids, chimeric entities and hybrids in philosophical, ethical, and legal literature (UCL)

D1.3 Different forms of conceptual uncertainty relating to organoids, chimeric entities and hybrids in scientific literature (UCL)

D3.1 Map report of normative, RE and RI frameworks (NTUA)

D3.2 Comparative analysis (NTUA)

D4.1 Protocol for WP4 (AU)

D4.2 Report on participant selection (AU)

D4.3 Report on the public attitudes, understandings and perspectives on organoid research (AU)

D8.1 Dissemination and communication plan (NTUA)

D8.2 Newsletters and leaflets (NTUA)

D8.5 Events (NTUA)

D9.1 Quality Assurance Plan (UiO)

D9.2 Data Management Plan (UiO)





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6. Mini-public workshops

Three deliberative (mini-public) workshops were organised at the end of November 2021 in Denmark, Italy and Greece, with the purpose to understand the attitudes of the general public, patients, donors and CSOs towards organoid research. The participation of all stakeholders was active and fruitful, expressing a positive attitude towards organoid research irrespective of participant category and background characteristics such as gender, religious affiliation and age.



The participants found the prospects of progress as well as both current and future benefits of organoid research promising and attached positive expectations to their application and contribution within biomedical research. While they broadly supported the use of organoids, they also expressed a number of key concerns and worries related to their current and future derivation and use. More details on the workshops' methodology and results will be available in the respective reports which will become publicly available on the project's website soon.



7. Upcoming Events



HYBRIDA will participate in the **5th European Technology Assessment Conference 2022** (Karlsruhe, 25-27 July 2022) with an oral presentation regarding the results of a scoping review study on the debates pertaining to organoid research. The central focus of the conference, organized within the global TA network, is on existing and potential impacts of digital technologies within societies and socio-technical systems (such as power grids, medical treatments, mobility, logistics and production) as well as on individuals.