

SORS: The Regulation on the European Health Data Space: An Introduction

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Abstract

In March 2025, the Regulation on the European Health Data Space was published in the Official Journal of the European Union (OJ). This is a regulatory tool of special relevance for various reasons. The first is that it aims to radically change the way we handle our health data, significantly strengthening concepts like interoperability and data access. Secondly, it represents a first step in the creation of the nine data spaces that European institutions intend to build in the coming years. But above all, the Regulation is important because it marks a significant advancement in a complex issue: the secondary use of health data for research purposes. This presentation will analyze its main features. To this end, I will begin by describing the current regime for handling health data in biomedical research. Next, I'll explain the changes introduced by the Regulation. Finally, I'll provide a critical review of the proposed new scenario, explaining some of its potential vulnerabilities.



Short Bio

Iñigo de Miguel Beriain holds a degree in Economics and Business, a degree and a European PhD in Law, and a PhD in Philosophy. He is a member of the Spanish Bioethics Committee and president of the CEIm of Euskadi. He has participated in multiple national and international research projects on data protection, new technologies law, bioethics, and biolaw. He has published seven books and over 150 articles and book chapters. He has delivered more than 100 presentations and lectures at conferences and seminars. He currently works as a Researcher at the University of the Basque Country/Euskal Herriko Unibertsitatea and as an Ikerbasque Research Professor (Ikerbasque, Basque Foundation for Science).

Speakers

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