

**APPROVAL BY THE RESEARCH ETHICS COMMITTEE FOR
BIOMEDICAL RESEARCH PROJECTS**

The Research Ethics Committee of the Hospital Universitari de Bellvitge, by means of the fast procedure of revision of the documentation contemplated in their Standard Operating Procedures, has revised all the documentation concerning the research project with our Ref **PR019/24**, entitled:

“DATACOM. A NEW EU FRAMEWORK FOR AN ETHICAL RE-USE OF HEALTH DATA”, sponsor’s identifier: **101108151**

Documents with versions:

Protocol	DataCom_Proposta
Spanish- Patient information sheet	version approved on date of 06/02/24
Spanish- Consent informed	version approved on date of 06/02/24
Interview summary protocol	Protocol_Interviews

Presented as main applicant by Dr Víctor Moreno Aguado, from the Oncology Analytics Program (ODAP) at Institut Català d’Oncologia de L’Hospitalet (ICO-L’Hospitalet), and promoted by Dr Chiara Gallese, from Department of Law at University of Turin Lungo Dora Siena, the Committee has definitively approved the project. This approval will be included in the meeting of February 15th 2024 (Act 05/24).

That the current composition of the Research Ethics Committee is as follows:

President	Dr Francesc Esteve Urbano	MD - Intensive Care
Vice president	Dr Pilar Hereu Boher	MD - Clinical Pharmacology
Secretary	Dr Enric Sospedra Martínez	Pharmacist - Hospital Pharmacy
Members-at-large	Dr Jordi Adamuz Tomás	Nurse
	Mrs. Anna Boix Traserra	Lawyer – DPO
	Dra. Nuria Calaf Figueras	Pharmacist – Primary Care
	Dr Concepción Cañete Ramos	MD- Pneumology
	Dr Sara Cobo Sacristán	Pharmacist - Hospital Pharmacy
	Dr Ana María Ferrer Artola	Pharmacist
	Mrs. Esther Ferrer Canals	Patient representative
	Dr Xavier Fulladosa Oliveras	MD - Nephrology
	Mrs. Sara Hidalgo Durán	Philosophy – Non-health member
	Dr Carles Lladó i Carbonell	MD- Urology
	Dr Sara Larriba Bartolomé	Pharmacist

Mrs. Sonia López Ortega	Social Graduate
Dr Antoni Lorente Martínez	Engineering
Dr Juan Jesús Martín Liberal	MD - Medical Oncology
Dr Sergio Morchón Ramos	MD - Preventive Medicine
Dr Miguel Ángel Pavón Ribas	Biologist - Non-health member
Dr José Carlos Sánchez Salado	MD - Cardiology
Dr Joan Josep Queralt Jiménez	Lawyer
Dr María Teresa Terán Virtus	MD - Clinical Pharmacology

This Committee is organized and operates in compliance with applicable regulatory requirements and ICH GCP (International Conference on Harmonization Guidelines on Good Clinical Practice).

The required quorum for the meeting was achieved.

Dr Enric Sospedra Martínez

L'Hospitalet de Llobregat, 6th February, 2024