



**SARDEGNA  
RICERCHE**



UNIONE EUROPEA  
Fondo europeo di sviluppo regionale



REPUBBLICA ITALIANA



REGIONE AUTÒNOMA DE SARDIGNA  
REGIONE AUTONOMA DELLA SARDEGNA



## ***I FAIR***

the Sardinian way to support and fund ***I***ndependent clinical studies that want to  
be ***F***indable, ***A***ccessible, ***I***nteroperable, and ***R***eusable

*to Zag*

***Authors (alphabetical order):*** E. d'Aloja<sup>1</sup>, **F. Cappai<sup>2</sup>**, C. G. Carboni<sup>2</sup>, G. Fotia<sup>3</sup>, F. Frexia<sup>3</sup>, G. Serra<sup>2</sup>, G. Sotgiu<sup>4</sup>, P. Uva<sup>3</sup>, G. Zanetti<sup>3,†</sup>.

***Authors' affiliations:***

1. University of Cagliari, Department of Medical Sciences and Public Health, Cagliari, Italy;
- 2. Sardegna Ricerche, Biomedical Research Support Unit, Cagliari, Italy;**
3. CRS4, Center for Advanced Studies, Research and Development in Sardinia, Pula (CA), Italy;
4. University of Sassari, Department of Medical, Surgical and Experimental Sciences, Clinical Epidemiology and Medical Statistics Unit, Sassari, Italy.

# SCIENTIFIC DATA

Amended: Addendum

OPEN

SUBJECT CATEGORIES

- » Research data
- » Publication characteristics

## Comment: The FAIR Guiding Principles for scientific data management and stewardship

Mark D. Wilkinson *et al.*<sup>#</sup>

### Box 2 | The FAIR Guiding Principles

#### To be Findable:

- F1. (meta)data are assigned a globally unique and persistent identifier
- F2. data are described with rich metadata (defined by R1 below)
- F3. metadata clearly and explicitly include the identifier of the data it describes
- F4. (meta)data are registered or indexed in a searchable resource

#### To be Accessible:

- A1. (meta)data are retrievable by their identifier using a standardized communications protocol
  - A1.1 the protocol is open, free, and universally implementable
  - A1.2 the protocol allows for an authentication and authorization procedure, where necessary
- A2. metadata are accessible, even when the data are no longer available

#### To be Interoperable:

- I1. (meta)data use a formal, accessible, shared, and broadly applicable language for knowledge representation.
- I2. (meta)data use vocabularies that follow FAIR principles
- I3. (meta)data include qualified references to other (meta)data

#### To be Reusable:

- R1. meta(data) are richly described with a plurality of accurate and relevant attributes
  - R1.1. (meta)data are released with a clear and accessible data usage license
  - R1.2. (meta)data are associated with detailed provenance
  - R1.3. (meta)data meet domain-relevant community standards

# Background:

Journals, Founders and Patients are mandating practice for data sharing as a condition for:



ICMJE INTERNATIONAL COMMITTEE of MEDICAL JOURNAL EDITORS

The NEW ENGLAND JOURNAL of MEDICINE

BMJ

PLOS MEDICINE

**PUBLICATION**



wellcome

BILL & MELINDA GATES foundation

RESEARCH COUNCILS UK

NIH National Institutes of Health  
Turning Discovery Into Health

**FUND RISING**



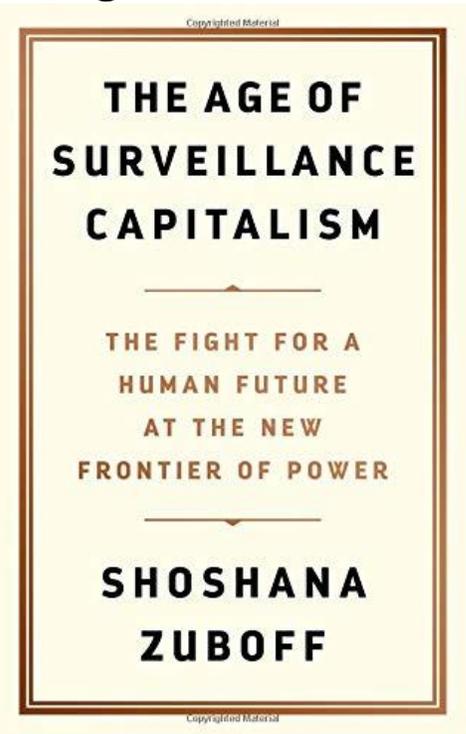
Understanding Patient Data

\* use MY data

**PATIENTS' PARTICIPATION**

# Background:

# Benefit and side effect



Regulating the internet giants  
 The world's most valuable resource is no longer oil, but data

The data economy demands a new approach to antitrust rules



## THE LANCET Digital Health

COMMENT | VOLUME 1, ISSUE 1, PE8-E9, MAY 01, 2019

### Is health-care data the new blood?

Eric Perakslis • Andrea Coravos

Open Access • Published: May, 2019 • DOI: [https://doi.org/10.1016/S2589-7500\(19\)30001-9](https://doi.org/10.1016/S2589-7500(19)30001-9)



[Journal of Community Genetics](#)

April 2018, Volume 9, Issue 2, pp 177-190 | [Cite as](#)

### Legal issues in governing genetic biobanks: the Italian framework as a case study for the implications for citizen's health through public-private initiatives

Authors Authors and affiliations

Cinzia Picicocchi, Rossana Ducato, Lucia Martinelli, Silvia Perra, Marta Tomasi, Carla Zuddas, Deborah Mascalconi

Open Access | Original Article  
 First Online: 18 September 2017

2 Shares  
 1.5k Downloads

nature  
 biotechnology

Analysis | Published: 24 April 2011

### Accelerated clinical discovery using self-reported patient data collected online and a patient-matching algorithm

Paul Wicks, Timothy E Vaughan, Michael P Massagli & James Heywood

Nature Biotechnology 29, 411-414 (2011) | [Download Citation](#)



thebmjopinion Late

### Michael Gill: Patient data for sale

September 2, 2019



## Background:

## Opportunities

Sardinia has been designated a “Blue Zone”, i.e. a location with the highest numbers of centenarians in the world. For this reason it is very attractive for **data** and sample “**exploration**” and “**mining**”.



Studies’ **participants** usually **agree** with the use of their **data** and sample **for other research purposes**, but these often remain **confined inside the originator** research group and its strict collaborators.

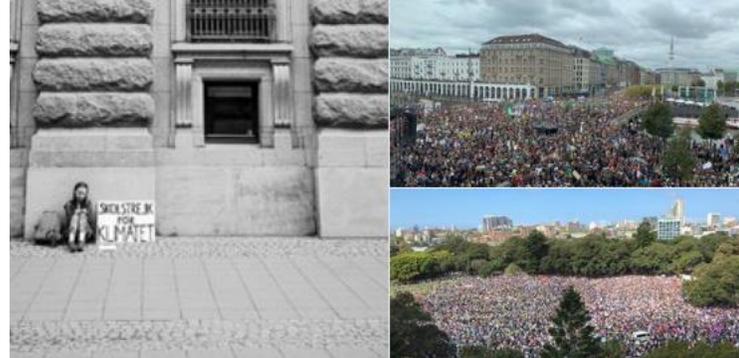


Sardinia is an active partner in initiatives like **BBMRI-ERIC** and **ELIXIR**, but a common practice of sharing data has never been implemented nor supported in the clinical research domain.

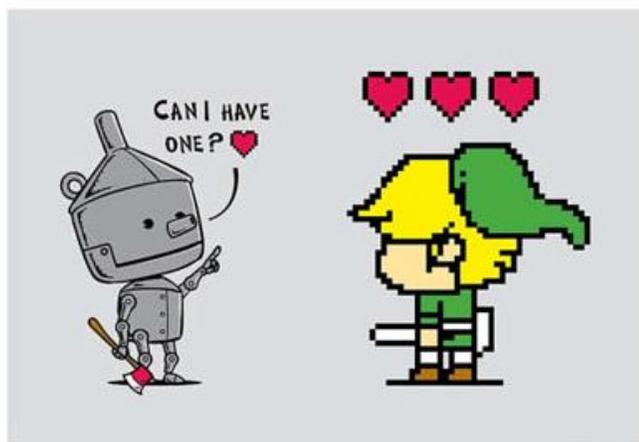


# Aims:

1. Create a **common awareness** of the importance of data quality and sharing **for the many not the few.**



2. Provide the clinical researchers with the **basic tools for the FAIRification** of their dataset.



3. Facilitate the **access to ethically-sourced and consented patient data** and samples.



4. **Involve patients** and their organization in the data sharing process.

**IF YOU WANT TO WIN,  
YOU MUST NOT LOSE!**

# Methods:

## The I FAIR working group

• Univ. Cagliari,  
Dept. Medical Sciences and  
Public Health, Bioethics Unit

**Bioethics**

• Univ. Sassari,  
Dept. Medical, Surgical and  
Experimental Sciences,  
Clinical Epidemiology and  
Medical Statistics Unit

**Statistics**

**Health data  
management**

**Research fund  
management**

• CRS4,  
Digital Health

• Sardegna Ricerche,  
Biomedical Research Support Unit



**1<sup>th</sup>**

**Regional Biomedical Research Registry:**  
metadata repository of data and sample collected in Independent and FAIR clinical studies

**1<sup>th</sup> "I FAIR" Call**  
for Independent and FAIR clinical studies

**2<sup>nd</sup>**

**Regional Biomedical Research Registry:**  
metadata and data repository

**2<sup>nd</sup> and 3<sup>rd</sup> "I FAIR" Call**  
for Independent and FAIR clinical studies

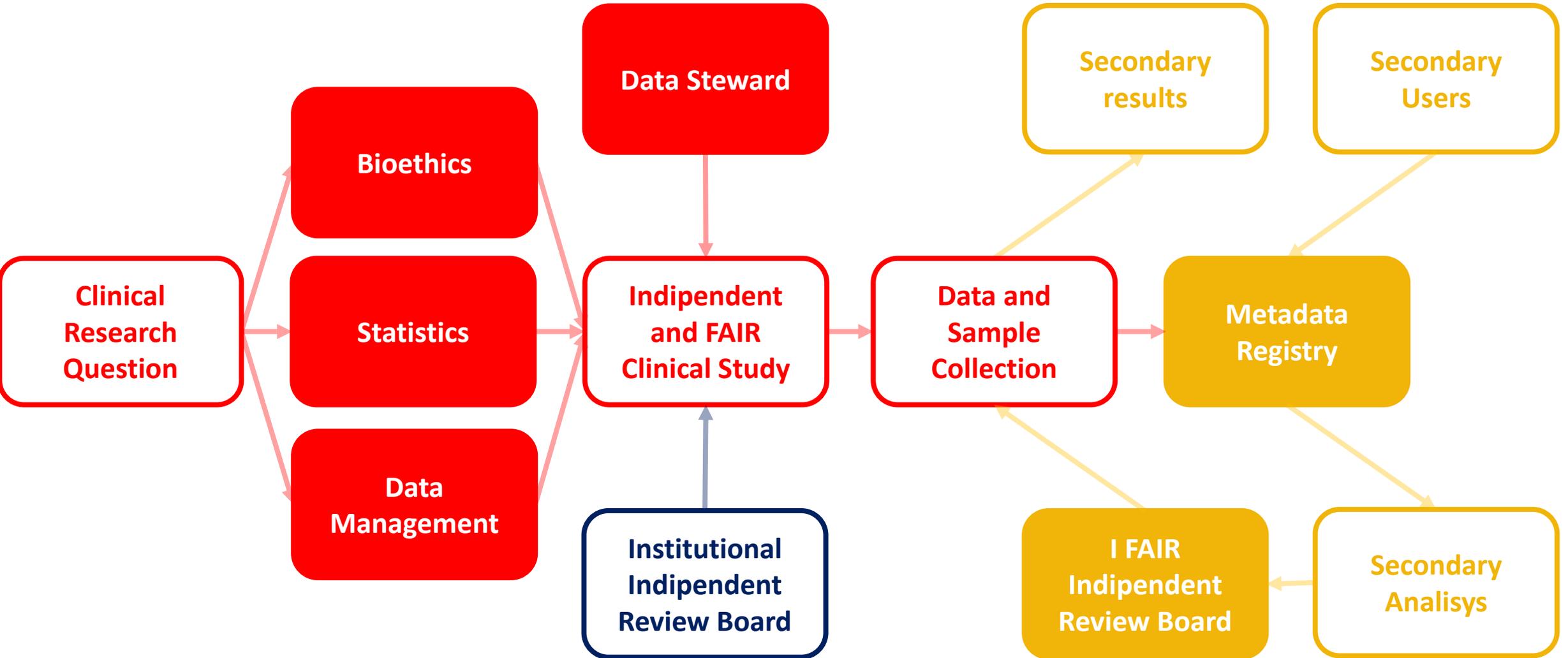
**Introduction of Dynamic Informed Consent**

**3<sup>rd</sup>**

**FAIR data principles mandatory** for every independent clinical study funded with Regional resources

The I FAIR Call for independent clinical studies

The Regional Biomedical Research Registry



- 26 Independent clinical studies applied to the 1<sup>th</sup> I FAIR Call;
- All the 26 studies are receiving support in bioethics, statistics and health data management from the working group;
- 20 studies will receive fund for data stewardship;
- Thousands of participants from 13 different therapeutic area will be informed on the FAIR data principles;

## Bottom line:

The I FAIR Program will:

1. promote **data sharing, reuse and repurposing** among researchers;
2. **inform and protect participants** in clinical studies;
3. provide a **common system for** storing and accessing **metadata** and **data FAIRly collected** in clinical studies in Sardinia.

The I FAIR Program needs to be **tested in practice**.



Thanks

[cappai@sardegna.ricerche.it](mailto:cappai@sardegna.ricerche.it)



UNIONE EUROPEA  
Fondo europeo di sviluppo regionale



REPUBBLICA ITALIANA



REGIONE AUTONOMA DE SARDIGNA  
REGIONE AUTONOMA DELLA SARDEGNA

