I FAIR

the Sardinian way to support and fund Independent clinical studies that want to be Findable, Accessible, Interoperable, and Reusable

to Zag

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EBHC, Ecosystem of evidence, global challenges for the future, Taormina, 6-9 November 2019
Background:

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

Mark D. Wilkinson et al.

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:
Background: THE AGE OF SURVEILLANCE CAPITALISM
THE FIGHT FOR A HUMAN FUTURE AT THE NEW FRONTIER OF POWER
SHOSHANA ZUBOFF

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.

Benefit and side effect

THE LANCET
Digital Health

Is health-care data the new blood?
Eric Perakis & Andrea Coravos
Open Access Published: May, 2019 DOI: https://doi.org/10.1016/S2589-7500(19)30001-9

Journal of Community Genetics
September 2, 2019
Michael Gill: Patient data for sale

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
Cinzia Pirolo et al., Rossana Ducato, Lucia Martinelli, Silvia Perri, Marta Tomasi, Carla Zuddas, Deborah Mascalini
Open Access Original Article First Online: 18 September 2017 2 Shares 1.5k Downloads
Background:

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”.

Opportunities

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.
Methods:

- Univ. Cagliari, Dept. Medical Sciences and Public Health, Bioethics Unit
- Univ. Sassari, Dept. Medical, Surgical and Experimental Sciences, Clinical Epidemiology and Medical Statistics Unit
- CRS4, Digital Health
- Sardegna Ricerche, Biomedical Research Support Unit
Methods:

The I FAIR Program in 3 stages

1st
Regional Biomedical Research Registry: metadata repository of data and sample collected in Independent and FAIR clinical studies

1st “I FAIR” Call for Independent and FAIR clinical studies

2nd
Regional Biomedical Research Registry: metadata and data repository

2nd and 3rd “I FAIR” Call for Independent and FAIR clinical studies

Introduction of Dynamic Informed Consent

3rd
FAIR data principles mandatory for every independent clinical study funded with Regional resources
Methods:

The I FAIR data flow diagram

The I FAIR Call for independent clinical studies

Clinical Research Question

Data Management

Statistics

Bioethics

Data Steward

Independent and FAIR Clinical Study

Institutional Independent Review Board

Data and Sample Collection

The Regional Biomedical Research Registry

Secondary results

Secondary Users

Metadata Registry

I FAIR Independent Review Board

Secondary Analysis
Results:

The I FAIR Program preliminary results

• 26 Independent clinical studies applied to the 1\textsuperscript{th} 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;
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
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