

Access and sharing.

For a good practice of sharing (from data to results) in biobank-based research

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INTRODUCTION

The sharing process is the driving force and purpose of biobanking itself, as well as of research infrastructures.

It is possible within a shared ELSI & FAIR horizon in which everyone has a decisive role, from the institutions, biobanks and ethical committees that guarantee, to the researchers who develop and return results, to the patients, citizens and their representatives, who through the provision of data/samples are partners throughout the process, within a co-responsibility horizon in sharing, based on

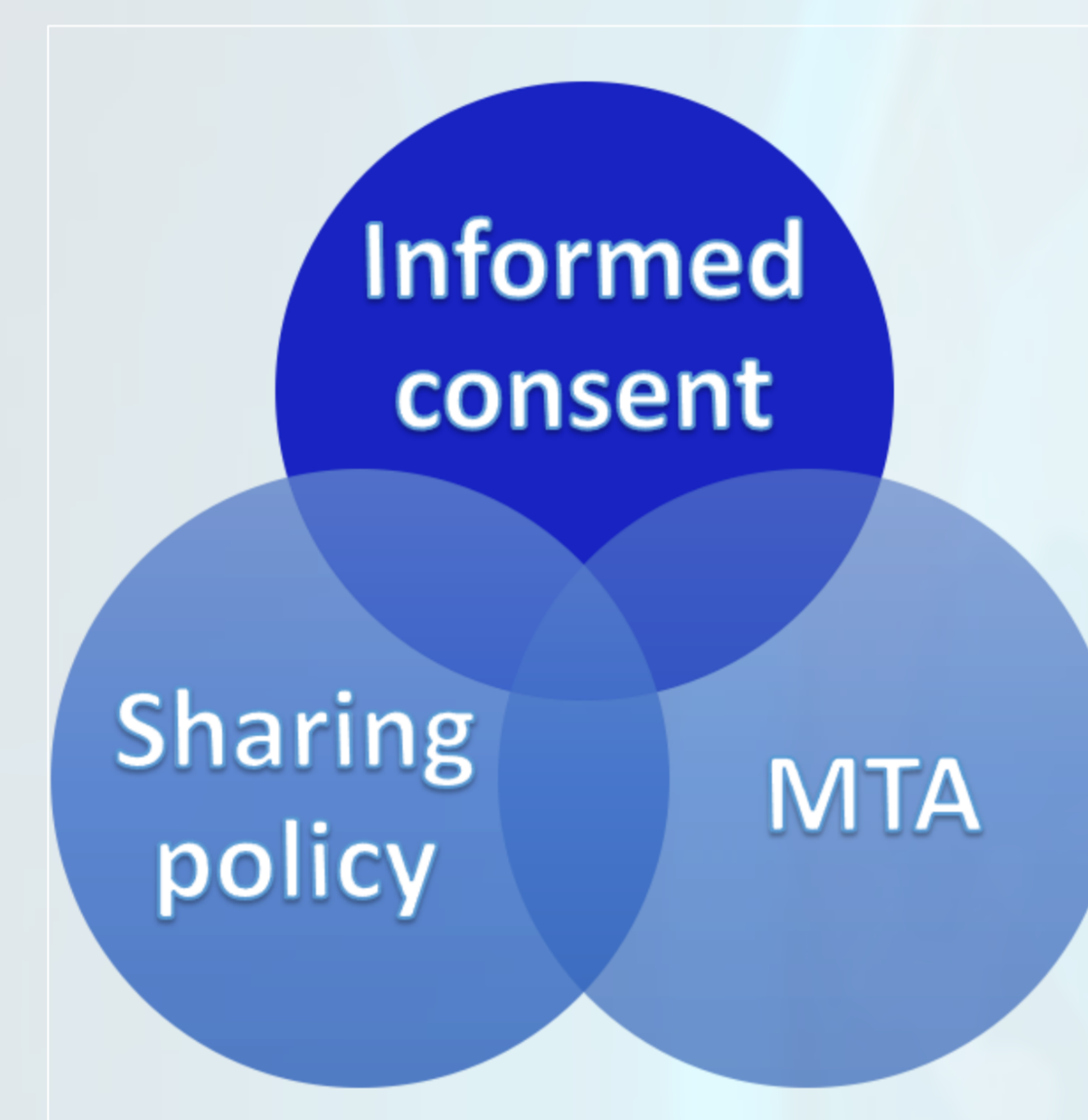
participation, reciprocity, transparency, traceability, third parties.

AIM

to FAIRly harmonize the access process,

- pooling together governance best practices
- co-producing common access and transfer tools
- providing clear, transparent access policies defining access requirements, expected submitting path and highlighting the third-party critical role of the biobank

RESULTS



Our Outcomes

A co-produced guideline for a good practice of sharing and access, with particular attention to

- processes of co-authorship
- sharing benefit/community benefit
- Evaluation criteria & requirements

A Matrix for Material Transfer Agreement with particular attention to recognition

- role of the biobank
- (where present) role Patients' Association



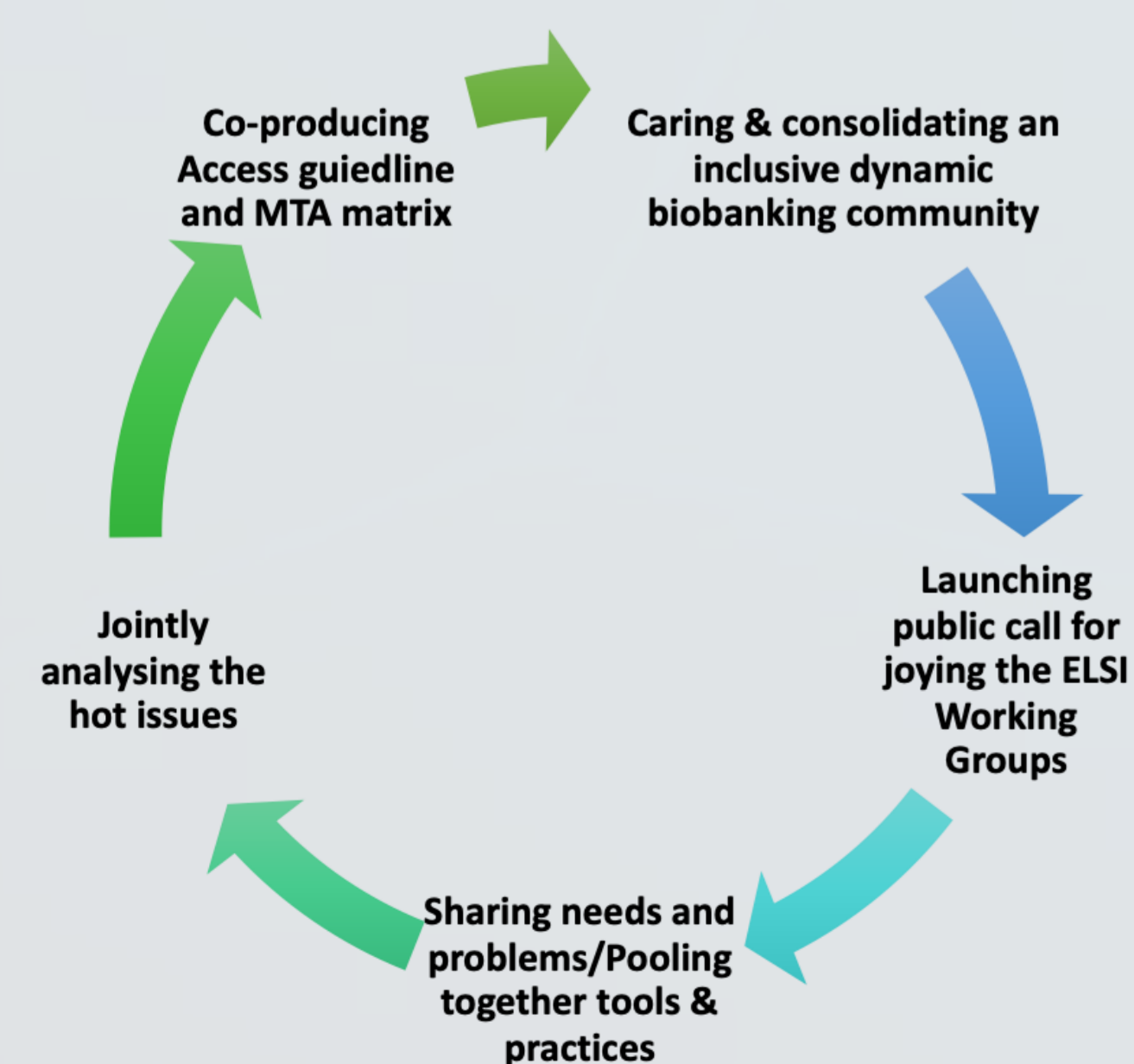
A continuous and active process of information, with the biobank in the front line

- ❑ 1st requirement for a good sharing practice
Declare at the consensus stage that samples could be exchanged with third parties and in countries not necessarily European countries
Guarantee of exercising the right of access, the right of portability
- ❑ 2nd requirement for a good sharing practice
Circumscribe what third parties can or cannot do with this sample.
The biobank must give an internal regulation, which establishes the parameters of the exchange, limits, standards. All this must be shared in advance and in transparency with the patient/participant:
 - code of ethics,
 - code of conduct
 - sharing policy
- ❑ 3rd requirement for a good sharing practice
In the DTA - MTA as a contract, regulate the ownership aspect in a manner consistent with both informed consent and sharing policy

MTA MATRIX ITEMS

- ❑ PREAMBLE
The preparatory statement
- ❑ DEFINITIONS
The importance of a common language and of unequivocal definitions
- ❑ PURPOSE
The agreed reason of the transfer that delimits and determines both the only possible use of the transferred material and the conditions of use.
- ❑ COMPLIANCE WITH LAW, RULES AND REGULATIONS
A key passage to guarantee a GDPR compliance by the adequacy judge as well as by specific warranty clauses
- ❑ RIGHTS & GUARANTEES
A critical turning point for a concrete exercise of the rights of the person who conferred the materials
- ❑ FEES AND SHIPPING COSTS
Recognition due to the costs of a bio-banking in quality
- ❑ INTELLECTUAL PROPERTY RIGHTS
Turning point to negotiate also an economic benefit for the biobank or a sharing benefit for the Patient community
- ❑ PUBLICATIONS
Highlighting the key role of biobanking, biobank and PO, where proactively involved
- ❑ RESEARCH RESULTS
Turning point for returning results both as a pillar of the same transfer and as a patient-participant's right
- ❑ APPLICABLE COURT AND COMPETENT FORUM
- ❑ LIABILITY
- ❑ CONFIDENTIALITY
- ❑ DURATION, WITHDRAWAL AND TERMINATION
- ❑ MODIFICATIONS AND AMENDMENTS
- ❑ ANNEXES

METHOD



In 2018, the common service ELSI highlighted as a priority the need for:

- ❑ a shared matrix for material/data transfer
- ❑ a common horizon for sharing.

Thus, it launched the national ELSI National Working Group “Access and sharing”, 74 representatives of the biobanking community, including Patient Organization and Ethics Committees joined it.

During all the 2019, we worked with a multidisciplinary and participatory approach tackling the close relationship between biobanking governance and data and results sharing and highlighting the ELSI requirements of the sharing process (from biosamples/data to results).

All the working session were on-line and pooling based on a collaborative institutional platform

CONCLUSIONS

Setting up together the MTA matrix increases in every participant the awareness of MTA as an instrument of law, to act one's rights, highlighting the key role of a biobank to guarantee both a FAIR access and participant's rights.

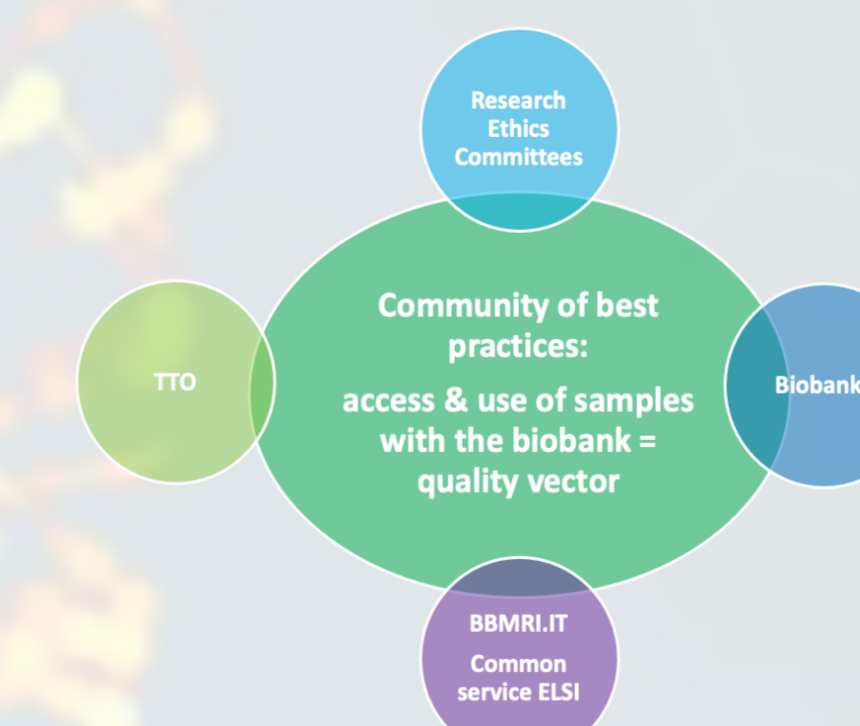
The biobank is the real responsible for the circulation of the sample, it must be able to answer for its use:

- the biobank should always remain the controller of the processing to fully fulfill the function of guarantor of the effectiveness of participant's rights
- a recovery cost should be required. The sample as a common good to answer for
- there should be a contractual possibility to allocate a part of the proceeds to the biobank that represents the community of participants; through the expected fee, cost recovery, etc. the biobank can improve, increase the quality of its activities.

Sharing benefit - community benefit, negotiable with and in the MTA

Transparency by making public the criteria for access, composition of the body responsible for assessing access requests

2020: from the results of the WG ELSI "Access and sharing" to the Joint community with IRCCS* Technical Tables



A common guideline to harmonize the Transfer across all the 52 IRCCSs. The key items:
Beyond the collections, for an institutional biobanking

- ❑ Access procedures
- ❑ Core requirements for the transfer
- ❑ Technology transfer clauses (to be negotiated) in the MTA
- ❑ Prototype of Material Transfer Agreement - MTA

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