A pilot study, including biobanks and Patient Organizations, for the implementation and testing of the BBMRI.it national informed consent matrix in TNGB

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Abstract

The European Regulations changed our ELS horizon. In 2017-2018, the BBMRI.it Common Service (CS) ELSI facilitated 2 working groups (WG) on informed consent (IC) involving all the players contributing to the biobanking process (i.e. patient representatives, biobankers, research institutions, Ethics Committees, ELSI experts). Both the WGs aimed at drafting through a participatory approach a matrix of IC for biobanking research, as an ELS co-produced framework for a dynamic informative process.

The Telethon Network of Genetic Biobanks (TNGB) composed of 11 RD-biobanks, to be GDPR compliant, needed to remodel its IC model. Thus, BBMRI.it CS ELSI and TNGB, activated in 2018 a laboratory composed by biobankers and patient representatives, including UNIAMO-RD Italian Federation- where the TNGB IC model became a training ground to implement and validated the BBMRI.it matrix. The matrix was the laboratory concrete framework, a participatory approach - based on dialogue, multidisciplinary, pluralism and progressive co-production - the methodological horizon was applied through several teleconferences and a joint work on a collaborative platform. Turning-points were the achievement of common language, content articulation and link between information and governance. It was critical to discuss the sample preservation time, depletion of the last aliquot and minor re-consent.

The next steps: sharing the outcome with BBMRI community, digitalizing the BBMRI.it/TNGB model and revising from a legal expert.

In conclusion, the new TNGB IC model confirms how joint, equal and participative method involving all RD-biobanking players and infrastructures is a successful approach for co-producing documents and good practices not only legally but also ELSI compliant as well as patient-tailored.

Background

The **BBMRI.it Common Service ELSI (CS ELSI)** [1], established in 2014, is a resource offered by BBMRI.it (BBMRI-ERIC Italian Node) which, in close liaison with the BBMRI-ERIC CS ELSI, provides the national biobanking community with services and tools in order to facilitate compliance with regulatory requirements and best practice standards in their biobanking activities.

The **Telethon Network of Genetic Biobanks (TNGB)** [2] was established in 2007 within the framework of a research project financially supported by Fondazione Telethon. TNGB has always coped with ELSI topics in order to protect the confidentiality of participants. Indeed, it has been promoting the biobanking within Patient Organisations to foster their active participation - a patient representative is in its Advisory Board- and engage them in developing procedures and policies related to ELSI topics (e.g., privacy and informed consent, sample and data ownership and access, return of results, etc.) [3].

BBMRI.it CS ELSI and TNGB have been **collaborating together** since the beginning of their activities by developing joint projects and activities aimed at eventually building a comprehensive IC form **balancing compliance with laws/regulations in force and effective patients' needs, within a participatory biobanking horizon**.

After a public call, BBMRI.it CS ELSI facilitated the participative discussions and interactions among invited stakeholders and TNGB contributed in giving both the RD-biobankers' perspective in the development of a co-produced scheme ("**IC matrix**") for the drafting of a complete and law compliant IC form, taking also into account of the patients' needs and perspectives.

Methods & Results

The laboratory started in December 2018 and participants met almost bimonthly by teleconference taking advantage of open-source platform for collaborative writing.

Main participants were TNGB members and RD-Patients organisations. In other to have a more comprehensive perspective and complete document also other Biobanks, not specifically focusing on RDs were invited. Also UNIAMO, the Federation of Italian RD-patient organisations, took actively part into the discussions. (Figure 1). Discussions were facilitated by BBMRI.it CS ELSI.

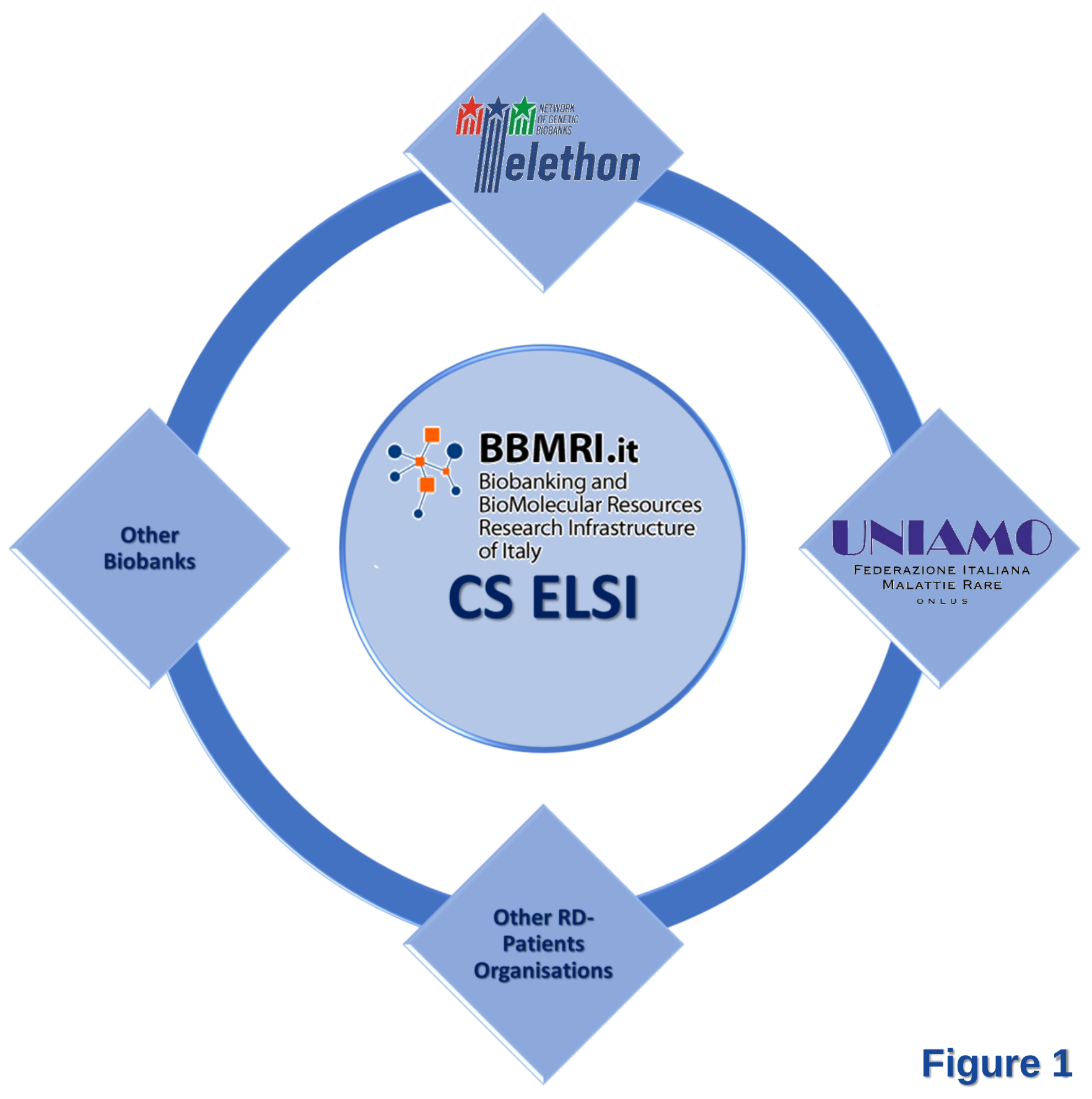

Figure 1

How we worked

Thanks to the participatory and engagement CS ELSI consolidated approach, we used a deliberative method based on experience, built on multidisciplinary settings involving all parties, and on collaborative tools. Our pillars were:

inclusion, transparency, reciprocity and mutual understanding

Key steps were validation of the BBMRI.it IC matrix as a flexible and tailoring tool and rethinking the TNGB IC model as an expression of an informative process taking into consideration the potential biobanking participant's information needs. The laboratory thus has been conducted considering the following topics:

- ❑ Reviewing and regenerating the logic articulation;
- ❑ Co-producing a common biobanking language;
- ❑ Defining and sharing good practice requirements both to make the biobank sustainable and guarantee the biobanking participant the key ELSI turning points, such as **transfer and commercial use of samples, return of results and re-contact.**

Conclusions

The BBMRI.it IC matrix effectively establishes the practical and fair framework to design and work out tailored informed consent tools.

Moreover, the new TNGB IC template proves how joint, equal and participative method involving all RD-biobanking stakeholders and infrastructures is a successful approach for producing documents and good practices not only legally but also ELSI compliant as well as patient-tailored.

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