

Biobanco-IMM, Lisbon Academic Medical Centre: A Case Study

Biobanco-IMM, Centro Académico de Medicina de Lisboa: Um Caso de Estudo



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INTRODUCTION

For the clinicians who have been involved in clinical and translational research the management of patient's information, together with sample collection, sample processing and storage has been frequently a nightmare. Lack of time for adequately observing patients, combined with shortage of logistic support for research associated activities during the medical appointment, were clearly a stressful combination. On top of that, the absence of trained laboratorial staff to manage samples, the lack of appropriate and safe softwares for keeping the clinical information and the use of laboratorial freezers shared by heterogenous users created the adequate conditions for tragical loss of information or of biological material. Finally, the traditional organization of a research project, including the classic ethical approval just for a predefined research question, without previweing its use for future additional investigations, leads usually to a single use of the clinical and biological information in one or two papers and then all the logistic investment fades away and samples and clinical information are left underused.

On the other hand, many clinical and translational researchers have faced the problem of struggling to organize and implement a research project and when finally everything was ready to start writing the paper, 'magically' other research groups in other parts of the world published more or less the results that had just been locally obtained. Are they individually better researchers? Probably not. They had the logistic support of biobanks and could apply the idea immediately, using samples and clinical information already available, saving time and money.

Biobanks were developed exactly to facilitate reasearch, to improve the adequate and ethical use of human biological and clinical information and to save time and money in research activities. Biobanks are complex structures that receive, store and manage the utilization of a wide range of biological samples donated voluntarily and its correspondent clinical information in order to foster biomedical research.

A case study: Biobanco-IMM, Lisbon Academic Medical Centre

In order to better understand what a biobank is, how

can it be created and how can it be useful for a clinician, the Biobanco-IMM, Lisbon Academic Medical Centre will be used as a case study. This biobank is a component of the Lisbon Academic Medical Centre, and is located at the Egas Moniz building, on the campus that hosts the Faculty of Medicine of the University of Lisbon, as well as the Santa Maria University Hospital and the Instituto de Medicina Molecular (IMM). The vision of the Biobanco-IMM, Lisbon Academic Medical Centre, is to position itself as a major member of the European Network of Biobanks within the next 5 years, offering excellent opportunities for translational and clinical research. Its mission is to promote and facilitate biomedical research that will lead to the identification of new diagnostic and prognostic tests and new therapeutic targets. This biobank has set as its goals to collect a wide variety of high quality human biological samples associated with detailed relevant clinical information and to promote its use for research purposes based on scientific and ethical criteria.

The project of building a biobank at the Lisbon Academic Medical Centre started in 2008. During the first two years, three goals were achieved: attraction of funding (Alto Comissariado Para a Saúde), approval from Santa Maria University Hospital Ethics Committee and reception of the first samples on an experimental basis. After that, a 2 years executive phase started, with a strategic plan that previewed the end of all the preparatory activities (including physical space, equipment, information system, training and legal / ethical authorizations, experimental phase of the operational procedures, standard operating procedures (SOP) and certification) in one year, leaving the second year for testing the model in real life conditions. In fact, by January 2012 Biobanco-IMM, Lisbon Academic Medical Centre officially entered in its full operational capacity and started to receive samples in a complete open way. A dissemination plan involved a formal opening event, interaction with media, informative sessions in all medical departments of the Lisbon Academic Medical Centre and in all Lisbon Hospitals that have shown interest on receiving information, collaboration with patient's associations and medical scientific societies

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and presence in public events (such as Meia Maratona de Lisboa). The interest raised allowed reaching more than 5000 donors and 40000 samples up to now. The biobank is now participating in several international networks and samples from the Biobanco-IMM, Lisbon Academic Medical Centre are started to be requested for research projects all over the world. For the success of this strategy the funding partners (including biotech, pharmaceutical companies, private foundations and medical scientific societies) had a crucial role by supporting key investments in the launching phase of the project, when the visible outcomes were still scarce. This was done with a generous attitude and with the strong belief that the creation of Biobanco-IMM, Lisbon Academic Medical Centre would lead to a global gain to the stakeholders of biomedical research.

Organization of the Biobanco-IMM, Lisbon Academic Medical Centre

The Biobanco-IMM, Lisbon Academic Medical Centre has an office space, a room for sample collection, a laboratory for sample processing, a sample storing cold room and a culture room. The biological samples are stored in a cold room which contains -80°C ultrafreezers and -196°C liquid nitrogen containers. This room is thermally controlled and the freezing equipment has a temperature control system to ensure optimal conditions and rapid detection when a fault occurs. The cold room and the laboratory have restricted access and are exclusively dedicated to biobank samples. In addition to sample storage, this biobank provides other services, such as cell culture and automatic DNA and RNA extraction. The Biobanco-IMM, Lisbon Academic Medical Centre is organized in collections (samples and respective clinical information that share a certain characteristic, for instance, individuals who have the diagnosis of Parkinson)

and a clinical researcher expert in the field acts as the Principal Investigator of each collection, being responsible for the planning of the clinical variables that are collected and the type of biological samples that are stored. He is also in charge of dealing with sample requests to that collection and detains the priority of the use of the collection. A dedicated software for sample and clinical information management can be customized according to the specific needs of each collection and this can be done by the biobank staff members and only exceptionally an informatic expert is needed to help on this.

The Biobanco-IMM, Lisbon Academic Medical Centre is authorized by the Portuguese National Commission for Data Protection and the Ethics Committee of Santa Maria University Hospital. This biobank ensures quality analysis of the stored material and manages the request of samples, all in accordance to approved SOPs. It also guaranties that projects submitted to use samples comply with scientific and ethical requirements, after previous external approval by the Ethics Committee of Santa Maria University Hospital. A team of nine staff members, with laboratorial and medical backgrounds, take care of all the operational activities and is supported by a Scientific Commission (composed by basic scientists and clinical researchers) and a Technical Commission (encompassing a more eclectic knowledge, such as law and ethics, management, engineering and informatics). These commissions meet every 3 months with the staff members or whenever necessary. The Biobanco-IMM, Lisbon Academic Medical Centre is managed by its Director, who reports directly to the IMM Direction and ultimately to the direction of the Lisbon Academic Medical Centre (composed by the clinical director of Santa Maria University Hospital, the director of the medical school and IMM's president).

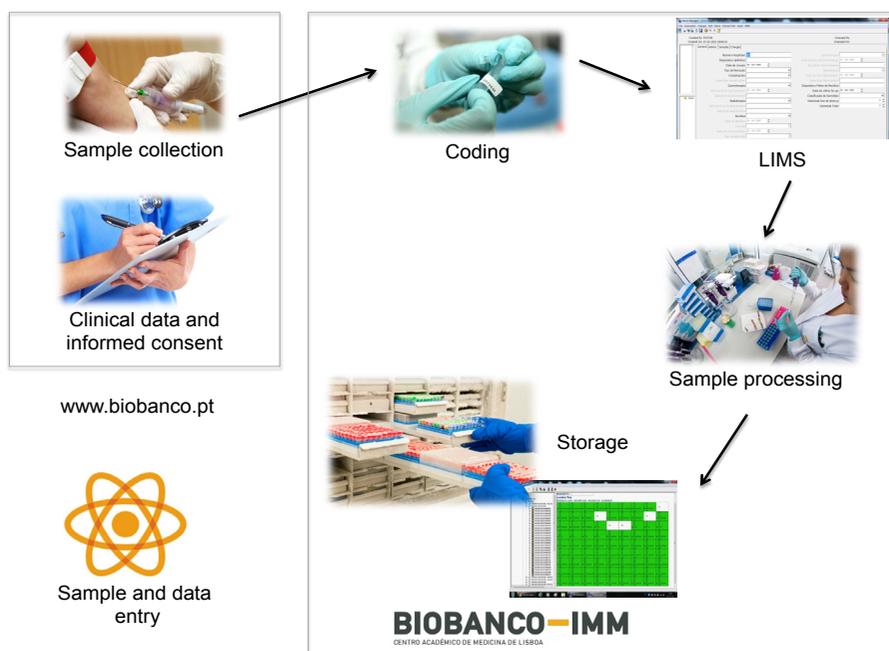


Figure 1 - Workflow for sample and data entry.

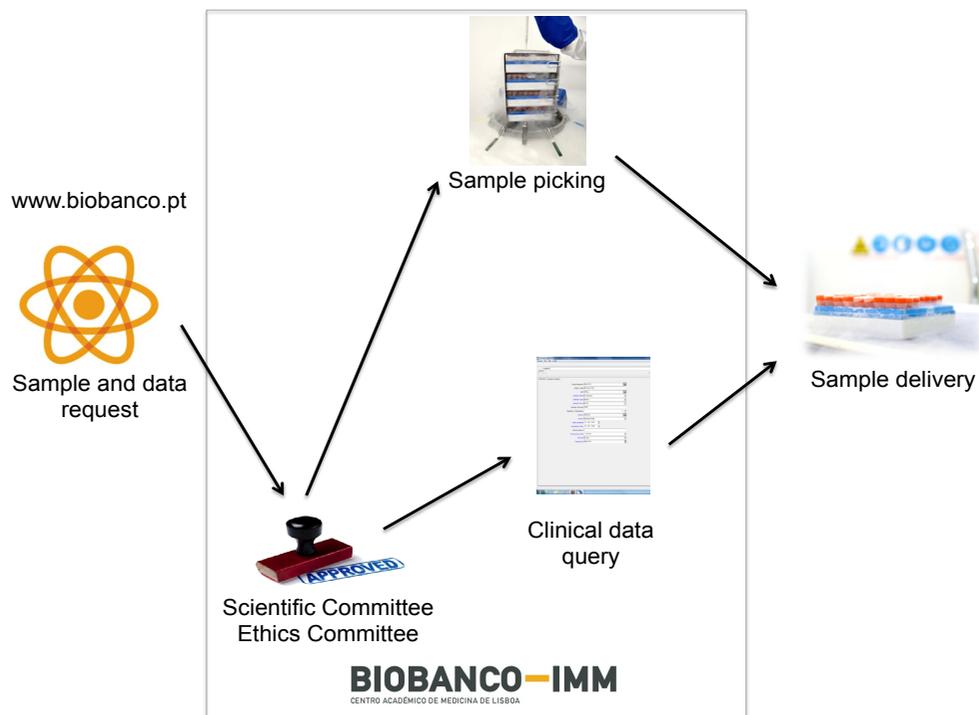


Figure 2 - Workflow for sample and data request.

When a sample and correspondent clinical information is collected, a written informed consent specifically approved by the Ethics Committee of Santa Maria University Hospital and by the Portuguese National Commission for Data Protection is signed by the donor. This document informs the donor about the future use of the sample and of clinical data for medical research, where it will be maintained, how will it be protected and who can use it. The Biobanco-IMM, Lisbon Academic Medical Centre ensures anonymity and confidentiality of data and samples during all operations.

This biobank is affiliated to an European Network of Biobanks (Biobanking and Biomolecular Resources Research Infrastructure, BBMRI) and any researcher can request a sample from Biobanco-IMM, Lisbon Academic Medical Centre. When the request is performed by a researcher external to the principal investigator responsible for the collection of interest the contact is redirected to the principal investigator in order to discuss a possible scientific collaboration. All applications must be approved by the Ethics Committee of Santa Maria University Hospital and by the Scientific Committee. Access to rare and potentially limited samples is carefully coordinated and controlled. All publications based on samples provided by the Biobanco-IMM, Lisbon Academic Medical Centre are required to make explicit reference to that fact.

Conclusion

In our view effective cooperation between academia and pharmaceutical industry, using the Biobanco-IMM, Lisbon Academic Medical Centre as a facilitating platform, will lead to significant scientific achievements with potential

economical impact. This biobank is now heading to a second phase of its development plan, aiming at a sustainable growing process. It will expand the scientific areas of action (for example, by implementing induced pluripotent stem cells, in collaboration with a Spin-Off), expand collections (aiming at 6000 donors by the end of 2013), improve infrastructures (dedicated cell culture room), optimize operational procedures (mainly by increasing the medical team), consolidate visibility (by promoting presentations of the Biobanco-IMM outside our academic centre) and enlarge partnerships (particularly with medical scientific societies).

The strategy here described can be either expanded into a National Biobank or replicated in a network of local biobanks, which should be carefully licensed in accordance to minimum quality criteria, regulated by national science and health authorities and integrated by a common online information system. It is highly recommended that all synergistic efforts should be implemented in order to avoid unnecessary competition for limited resources.

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CONFLICTS OF INTEREST

None stated

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