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Human Bio Banking as a Team and a Networking Project

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Background

In medical research, human bio banking is directed to investigate the genetic, molecular and environmental factors underlying diseases. Population-based bio banking of blood from healthy individuals in large epidemiological cohorts and of biological fluids and tissue specimens both in healthy as well as in diseased subjects constitutes the "core" of biobanks. Population-based biobanks usually explore germline biological traits, whereas biobanks of specimens from diseased subjects aimed to investigate somatic alterations associated to different types of diseases. More in detail, several types of Bio banks exist: 1) Population bio banks, aimed to obtain biomarkers of identity and susceptibility, usually based on the DNA of a large cohort of healthy donor subjects, representative of an ethnic cohort; 2) Disease-oriented bio banks for epidemiology, based on a large sample number, aimed to identify biomarker exposure, usually following a healthy exposed cohort/case-control design. These biobanks study germline DNA or serum markers on the basis of large amounts of specifically designed and collected data; 3) Disease-oriented biobanks (usually tumor banks) aimed to identify disease biomarkers in a collections of samples and their derivates (DNA/RNA/proteins), usually associated to clinical data and / or clinical trials. The amount of clinical data linked to the sample determinates the availability and biological value of the sample. Biobank organization is a complex tool involving logistic infrastructures as well as specifically developed informatics tools and ethical issues.

Bio Banking in Oncology

Cancer research rely on banked bio-specimens for a wide variety of purposes, including epidemiologic analyses, prevention research, target discovery and validation, research on early carcinogenesis and genetic studies. Associated, well-annotated clinical information are essential to tumour bio bank organization [1]. The Bio banks constitute the infrastructure allowing medical research and biotechnology progresses in human oncology targeted therapy. Novel tumour biomarkers are expected to be discovered and validated through bio banking, allowing clinical trials to be designed [2,3]. In biomarker discover, size of the tissue sample collection and quality of the material requires an advanced organization [4,5]. All over the world, several countries are involved in biobank implementation applying International standards and improving access policies. In Europe, the Consortium BBMRI-ERIC (Bio banking and Bio Molecular Resources Research Infrastructure – European Research Infrastructure Consortium) has been developed, sustained by a forum of EU member states and approved by the European Commission (http://bbmri.eu/). BBMRI-ERIC is one of the leading initiatives aimed to the collaboration of European biobanks and to the creation of a world leading infrastructure for biomedical oncological research in Europe. The availability of quality controlled human samples, such as blood, tissues, cells or DNA, and associated clinical and research data is a major interest of BBMRI-ERIC and of their national Hubs. Improving reproducibility and comparability of molecular data as well as designing multicenter studies / trials involving specimen exchanges among different centers is a further major advance in tumour bio banking. Networking among cancer research centers appears to be also fundamental [6]. Furthermore, the Pathology Department is responsible of the Tumour Registry and plays a central role in providing most of the data to be included in the Institutional Tumor Registry. To establish and to implement a Pathology tumour registry allows also to render an archival (paraffin-embedded) tissue biobank available for retrospective biomarker studies and validation, both in house or for multicenter national and/or international biomarker discovery/validation studies. The IMPACTS group, together with the European Society of Pathology (ESP) and BBMRI is presently developing a pan-European network of archive tissue biobanks (www.impactsnetwork.eu). Bio banking is also a major task that the Clinical Pathology carries out for matched blood, serum, plasma, buffy coat, saliva, urine, requiring a complex storage and advanced technical organization [7]. In a clinical context tissue bio banking is essential to obtain high quality samples for translational research aimed to identify new targets for anti-neoplastic therapy. Moreover, imaging features, either descriptive or metabolic, contribute to the huge amount of data provided from the tissue affected by the neoplasia at the diagnosis and during disease treatment.

Bio Bank Organization

Personnel involved in bio repository establishment and maintenance should share the overall objectives and principles of bio banking, be well-qualified and trained to apply standard operating procedures (SOPs) [8,9]. Biorepositories, as custodians of human specimens, serve as critical resources to the research community in the performance of post-genomics studies. Morphological, biomolecular, clinical and imaging diagnostics require a high integration level among different specialties and clinical Databases (DBs). In fact, the search for new biomarkers brings to collect and to store every relevant element in the patient's personal and medical history. Data include the demographical ones, the lifestyles, the environmental influences, the medical history, the relevant imaging features. In oncological Institutes, huge amount of data are provided from the tissue affected by the neoplasia and from the normal counterpart tissue or from patient's blood. Therefore, the Pathology Department has to preserve and to organize the solid tissue-

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based data collection, so that they can be available for research purposes aimed to discover novel prognostic/predictive biomarkers to be applied in personalized medicine.

Ethical Issues in Bio Banking

It should be acknowledged that relevant ethic issues, medico-legal problems, and also ownership uncertainty issues are associated to biorepository establishment and maintenance. All the health stakeholders should be therefore aware of the bio bank relevance. As an example, the application of broad consent and of study specific consent (both opt-in methods) is very complex and debated [10]. A major challenge is represented by proposing an appropriate informed consent for the collection and storage of biological specimens and by obtaining adequate clinical data for future use, when there is no specific aim at time of collection. It is difficult to completely inform potential donors about anticipated risks and benefits. The informed consent should contain explicit information regarding the level of anonymity of samples and personal data; moreover it should ensure compliance with adequate procedures to allow the identifiability of the donor exclusively during sample collection time; in addition it should be stated that consent is given freely and is revocable at any time [11].

Conclusions

In our Oncological Institute, a multidisciplinary Team is now engaged in implementing our Tissue and Biological fluids based- biobank, both in the Pathology Department and in the Clinical pathology Laboratory. Moreover, the clinical relevant notes are subjected to workup in order to be available with the biological resources. The actually shared IT Biobank Database (DB) is provided with a "common dataset" and its interconnection with existing administrative and clinical DBs is being implemented. In recent years, relevant tumor-specific types including the Lung, Colon, Breast, Prostate, Pancreatic cancers and other relevant killer cancer types such as Sarcomas/Bone tumors as well as Ovarian, Bladder and Brain tumors have addressed the bio banking activity in our Institute. At the same time, some rare cancers traditionally deserving a specific focus of interest such as HPV-associated Head & Neck cancer, Mesothelioma, Thymic Epithelial Tumours, and Lymphomas - which are for their heterogeneity rare tumours as well- have been stored. Now we aim to collect a large amount of patient samples with well annotated demographical, pathologic and molecular data for every cancer type diagnosed. Our efforts are devoted to integrate the "core" biobank elements with clinical DBs by respecting ethical principles and patient informed consent. In Europe Oncological Institutes are requested to participate to the improvement program and quality criteria adopted by the Organization of European Cancer Institutes (OECI) (www.oeci.eu) and to adopt the technical, infrastructural and ethical issues at the basis of modern Biobanks, promoted by BBMRI. In our Institute, we share the common interest and willingness of a significant biobank implementation by promoting recently a global bio banking project integrated among diagnostic disciplines, aimed to improve Quality and Quantity of data available for translational research. Implementation in our Bio banking activity will also promote furtherly the participation to national and international Bio bank network studies.

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