

THE CASE OF INCA'S NATIONAL TUMOR BANK MANAGEMENT SYSTEM IN BRAZIL

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ABSTRACT

Information Technologies can provide the basis for new directions in cancer research, supplying tools that identify subtle but important signs from the analysis of clinical, behavioral, environmental and genetic data. The purpose of this paper is to describe and analyze the system developed for managing Banco Nacional de Tumores (SISBNT) – National Tumor Bank System - highlighting its role in the technological innovation of Instituto Nacional do Câncer (INCA) – Brazilian National Cancer Institute. It is a qualitative empirical theoretical paper, descriptive and exploratory in nature, based on the single case study method and on participant observation. The results show the importance of good practices in information management for the full operation of a biobank in a research-oriented pharmaceutical company. There is also evidence that the implementation of SISBNT has contributed to the improvement of cancer treatment quality and to the support of efforts towards the organization of the integration of clinical, translational and basic research. The non-use of data mining techniques for the identification of molecular patterns and structures associated with the different types of cancer undergoing study at INCA seems to occur due to the early stage of Bioinformatics and translational research, as well as the National Tumor Bank, in the institution.

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1. INTRODUCTION

According to the World Health Organization, 2014, one out of eight deaths in the world is caused by cancer. In Brazil, there is a complex scenario in cancer treatment. The occurrences and rates of death have been growing, around 576,000 cases every year: they are particularly high when it comes to prostate cancer in men and breast cancer in women. Research has found that waiting lines for treatment and diagnosis have become commonplace in many regions of the country, resulting in patients being diagnosed at advanced stages of the disease.

According to the Rede Brasileira de Pesquisas sobre o Câncer – Brazilian Cancer Research Network – cancer is a disease caused by the buildup of genetic and epigenetic modifications in the genome of a normal cell. Such modifications result from errors that occur during DNA replication and exposure to mutagenic agents and agents in the cell metabolism. In addition, according to the Brazilian Cancer Research Network, *“the identification of the modified genes in tumor cells which are directly related to tumorigenesis has been the main focus of cancer genetics research over the last 30 years.”*

Promptness in referring patients to proper therapeutic procedures, with a short waiting time, is essential to increase survival rates, improve quality of life and the chance of being cured. Being diagnosed early is one of the most critical success factors: it is, therefore, essential to create organizational mechanisms that simplify the access to pertinent information and to health care services in order to reduce the fragmentation of the services and to speed up diagnosis time and beginning of cancer treatment.

In the Brazilian context, Instituto Nacional do Câncer (INCA) – Brazilian National Cancer Institute – is the federal agency in charge of setting and implementing assistance, education and cancer prevention policies, with a specific coordination team based in the city of Rio de Janeiro. Ever since 1997, INCA has made huge changes in its organization, with the aim of transforming its Research Center (RC) into a Technological Development Center (TDC) that is capable of leading Brazilian efforts towards the development of drugs in the oncology therapeutic class. From this background of change, Information and Communication Technologies (ICTs) have played a relevant role in supporting R&D activities.

The Rede de Atenção Oncológica (RAO) - Oncologic Attention Network - is the main vehicle through which the Brazilian National Cancer Institute (INCA) bases its national integration plan on. Its purpose is to establish a partnership between organizations responsible for research and services in the cancer area. This network translates into a cooperation environment with the aim of joining doctors, administrators and society segments that represent patients. Its goals are the following: i) to make the access to information and knowledge easy on all spheres – doctors, hospital administrators and patients; ii) to create a community for the practice of research and treatment; iii) to develop a friendly environment and easy access to relevant information to support clinical and administrative decision-making processes.

Cancer-related research is a long, complex and high-risk process and involves a myriad of organizations (Goldblatt & Lee, 2010). Brazil still does not have a suitable public structure for the storage of tumor samples used in different cancer research lines. Hence, the creation of a biobank and of an IT architecture that provides easy information access is critical in order to speed up research projects and reduce the fragmentation of the databases used. According to the World Health Organization (2009), the biobank represents an organized collection of human biological material and associated information, collected prospectively and specifically stored for research purposes, in accordance with recommendations and technical, ethical and pre-defined operational standards.

This reality highlighted the need to establish policies that aim to create a national bank of tumor samples (National Tumor Bank). The first step towards it was the investment in the development of technological infrastructure. One important decision was the implementation of a system that could support the network of organizations involved in the collection and processing of normal and tumor tissue samples, blood and clinical data of the most relevant tumors in Brazil, becoming a necessary tool for the advancement of research at INCA.

Studies show that there is a big potential for theoretical and empirical research on the use of Information Science and IS Management to support cancer treatment and prevention (Clauser, Wagner, Aiello Bowles, Tuzzio, & Greene, 2011; Krysiak-Baltyn et al., 2014; O'Brien M., Kaluzny D., & Sheps G., 2014; Peterson, Bensadoun, Lalla, & McGuire, 2011; Pitassi, Gonçalves & Moreno, 2013).

This study broadens scientific knowledge in these areas, in an attempt to answer the following research question: how can modern information and communication technologies contribute to the management of technological innovation in health care, in particular in a biopharmaceutical company, which operates in an oncology therapeutic class? In this sense, the specific purpose of this paper is to describe and analyze the system developed for the management of Banco Nacional de Tumores (SISBNT) – National Tumor Bank System - highlighting its role in basic, translational and clinical research at INCA (Brazilian National Cancer Institute) in Brazil.

2. THEORETICAL FRAMEWORK

As shown by Pronovost and Goeschel (2010), most countries have been facing serious problems in healthcare, arising from: i) the increase in the demand for healthcare due to the growth in the number of elderly citizens with chronic diseases; ii) higher demand for accessibility to extra hospital care which ensures efficiency, equality and individualization of healthcare; iii) limitation of financial resources; iv) difficulty recruiting and retaining personnel. Medical resources, such as specialized personnel, hospital beds and state-of-the-art equipment, are usually costly, which results in a huge budgetary pressure. These challenges help to transform highly complex services, such as cancer treatment, into high relevance areas for the organizations that operate therein (Goldblat & Lee, 2010).

Healthcare organizations have generated massive amounts of data distributed on hospital information systems, patient electronic records, administrative systems, etc (Côrtes & Côrtes, 2011). However, most of this effort has proven unfruitful, as this

information is hardly ever effectively used in decision-making processes (Abidi, 1999). According to this reality, there is a need to create an environment in healthcare organizations that makes it easy to transform all this raw information into knowledge (Barbosa et al., 2009). Therefore, as determined by Wickramasinghe (2000), researchers, doctors, nurses and other professionals in healthcare can be referred to as sophisticated knowledge workers.

They have the means of production, specialists' skills and training obtained throughout the years of formal learning and education, using this experience in clinical decision-making processes and treatment of diseases. Knowledge management in healthcare organizations can be defined as a combination of concepts and techniques to make it easy to create, identify, acquire, develop, disseminate and use intellectual capital (O'Leary, 1998), whose creation and dissemination take place by means of multidisciplinary teams (Fried et al, 1998).

It is important to highlight that cancer patient services are inherently multidisciplinary, involving the primary care doctor, the pathologist, the oncologist and the surgeon (O'Brien M. et al., 2014; Peterson et al., 2011). The quality of these services has been affected by the limited number of qualified oncology professionals and by the reduced number of research professional networks specialized in complex scientific disciplines that involve cancer treatment (Rastogi, Hildesheim & Sinha, 2004; Lenoir, 1998). The use of information technology can contribute significantly to the improvement of healthcare (Abraham, Nishihara, & Akiyama, 2011; Bardhan & Thouin, 2013; Côrtes & Côrtes, 2011). For instance, Galligioni, Berloffia and Caffo (2009) describe their experiences in the development and use of electronic records of medical oncology patients to support research in this area. These records have been designed carefully in order to integrate the spectrum of cancer information and to allow it to be shared between researchers, stressing the importance of the use of Information and Communication Technologies (ICTs).

Despite such reports as the one by Galligioni et al. (2009), the implementation of Information Systems (IS) has basically scratched the surface of possibilities and the potential of applying Information Science to healthcare (Wallace, 2007), especially in the context of developing countries (Turan & Palvia, 2014). Such authors as Catanho, Miranda and Degrave (2007) and Wallace (2007) suggest that basic research using information and communication technologies can provide resources for new directions in clinical sciences. In the context of cancer treatment, Bash et al. (2004) present three fundamental lines of work. The first line has its focus on state-of-the-art clinical medicine, which can include therapies based on evidence and sophisticated and personalized studies on the nature of the patients' tumor and its biological characteristics. The second line regards the systemic approach of the patients' care and needs (physical, psychosocial, functional and spiritual). The third line regards the use of Information and Communication Technologies that support clinical medicine geared towards patients and their care.

As far as the first line is concerned, cell and molecular-related studies generated a large number of data related to genetic mapping and protein structures, turning Biology into a "mathematical" science and, increasingly, based on information (Lenoir, 1998). Researchers in Pharmacogenomics and Pharmacoepidemiology need this and other types of information in order to understand why patients respond differently to the treatment with certain drugs, both regarding adverse effects and efficiency in the treatment (Kim & Gilbertson, 2007). It is noticed, however, the importance of modern information technologies to provide the collection, management

and processing of such data in an efficient and efficacious fashion. In general, their introduction in cancer research and treatment institutions means opportunities for the development and adoption of organizational innovations.

According to the Oslo Manual - The Organization for Economic Co-operation and Development (1997), technological innovations comprehend the implementation of technologically new products and processes, and meaningful technological improvements in products and processes. At the organizational level, innovation “[...] implies combining different types and parts of knowledge and transforming them into useful products and services” (Figueiredo, 2009, p.31). In the biopharmaceutical industry, technological innovation, characterized by the systematic discovery of new drugs or of new uses for the drugs already on the market, depends on the mastering and integration of various scientific disciplines, such as Molecular Biology, Fine Chemicals, Computer Science, Information Science, Physics, Optics, and Mechanical Engineering, among others (Pitassi, Moreno & Gonçalves, 2014). Therefore, the discovery of new drugs depends on the technological capability built by the organization in a variety of areas (Moreira & Pitassi, 2013). Given these characteristics, the pharmaceutical industry was one of the trailblazers in adopting open innovation models (Hughes & Wareham, 2010). Traditional linear and vertical models of innovation, such as the Innovation Funnel (Cooper, 1993), reflect a concern on the part of the companies regarding the “false positive”, in view of the magnitude of the investments usually made in the development of new products (Chesbrough, 2006). In the current technical productive paradigm, due to the risks and costs involved, innovation is established as an interdepartmental and inter-organizational process (Bell & Figueiredo, 2012). Therefore, open innovation models are currently predominant in organizations, including Brazilian organizations, which seek to dynamize in-flows and outflows of knowledge and technology (Pitassi, 2014).

Biopharmaceutical organizations, which focus their research on the oncology therapeutic class, have resorted to (with the purpose of creating more new drug production opportunities) translational research, which guides research from “the bench to the bedside”, as a mechanism to promote the integration between advancements resulting from basic research and clinical trials (Goldblat & Lee, 2010). According to Chiaroni, Chiesa and Frattini (2008), basic research in biopharmaceuticals is done at three essential stages: i) identification of the disease genetic base; ii) identification of the compound for the treatment of the disease; iii) pre-clinical tests. As for cancer, basic research is necessary for the advancement of knowledge on genetic mutation causes that lead to the different stages of the disease (Goldblat & Lee, 2010).

Studies on the possible causes of the poor performance of the information sent out by DNA then gave rise to the research in: Genomics, which analyzes genetic sequencing, aiming to quantify the gene expression in cells; **Proteomics**, which carries out experiments to identify the structure of proteins and their functions in living organisms; **molecular dynamics**, which simulates the physical movement of atoms and molecules (Lenoir 1998).

In general, a clinical trial or clinical study is defined by Good Clinical Practice (GCP) as “any investigation in human subjects intended to discover or verify the clinical, pharmacological, and/or other pharmacodynamic effects of an investigational product(s), and/or to identify any adverse reactions to an investigational product(s), and/or to study absorption, distribution, metabolism, and excretion of an investigational product(s) with the object of ascertaining its safety and/or efficacy. In

the cancer studies, basic research in Molecular Biology is essential for the identification of new drugs and the *a priori* assessment of their positive and negative effects on the treatment of the disease. The development of this type of research is considerably driven forward by the availability of biological samples (Goebell & Morente, 2010). In this sense, biobanks have been developed in many countries with tumor samples (Specimen Central, 2014).

According to the World Health Organization (2009), a biobank is an organized collection of human biological material and associated information, collected prospectively and stored for research-related purposes in accordance with recommendations or pre-defined operational, ethical and technical standards. The challenges to establish, develop and sustain biobanks with the required size and scope for clinical studies are highlighted in the literature (McQueen et al., 2014).

The contribution of comprehensive and structured biobanks, as determined by good information management practices, is seen as a condition for the advancement of translational research on cancer, owing to the difficulty perceiving standards from the variety of causes and manifestations of the disease (Goebell & Morente, 2010). Thus, it is necessary to stress the importance of the standardization of processes for the integrity of the stored samples (Malm et al., 2013), as well as the potential for the use of data-mining techniques in translational research (Krysiak-Baltyn et al., 2014).

3. METHODOLOGY

The empirical theoretical study described in this paper is a field research, with a qualitative approach, descriptive and exploratory in nature (Vergara, 2005). It is descriptive as it shows the motivations for the implementation and main functionalities of Banco Nacional de Tumores (SISBNT) – National Tumor Bank System. It is exploratory as it seeks to analyze the contribution that SISBNT makes towards the integration between clinical, translational and basic research, a process that is still at an early stage in Brazilian pharmaceutical companies.

The study adopts the single case study method (Yin, 1994), having semi-structured interviews and participant observation as the main ways of data collection (Checkland, 1991). The case study, to the extent it takes dimensions of time and space into account (Yin, 1994), has proven to be a suitable methodological tool for the analysis of a phenomenon whose development occurred concomitantly to the huge structural changes that had taken place at INCA as of the second half of the 1990s.

The choice of emblematic cases is a suitable scientific procedure due to the opportunity to understand specific dynamics; therefore, they can teach important lessons to organizations with the same mission statement or organizational objectives (Yin, 1994). Choosing INCA as a single case owes to the fact that the organization is the most qualified in Brazil to perform all the translational research stages in the oncology therapeutic class and to the efforts of incorporating ICTs made by the institute over the last years.

The research analysis unit consisted of organizational units involved in the development and use of the National Tumor Bank (NTB), herein seen as components of a broad information system, supported by equipment and computer technologies. The focus of data collection and analysis was on the role of SISBNT in the

management of the information generated at the biobank and applied to basic, translational and clinical research activities.

Field data collection took place by two different methods. One of the authors of this paper was a member of INCA's Information Technology Division when this research was being done, working on the development and implementation of the organization's IT strategy. As such, he could closely monitor the development and implementation of SISBNT, interacting with the various actors and technological artifacts involved. In addition to the data obtained from the documents related to this process, the researcher's own perceptions were used as an input for the analysis of the investigated phenomena herein.

Consequently, the first method of data collection - participant observation, - performed by him was selected (Argyris, Putnam & Smith, 1985): this method is justified because it was intrinsically associated to the implementation of the Banco Nacional de Tumores (SISBNT) – National Tumor Bank System.

In the second data collection method, the researchers conducted five semi-structured interviews with the persons in charge of the implementation of SISBNT in the area of Information and Communication Technologies and with five representatives of the areas of the Research Center (users of the system) including the manager of the SISBNT. The interviews had been conducted over the first six months of 2011, based on a script with open questions, and structured from the literature review used in the research. Its main purpose was the collection of evidence regarding the role that SISBNT had been developing in basic, translational and clinical research in oncology.

The choice of the interviewed subjects was intentional, made from the identification of the key actors in the process of the implementation of the National Tumor Bank. The fact that one of the researchers was in charge of INCA's ICT contributed not only to the identification of these subjects, but also to the scheduling and quality of the interviews. All the interviews were conducted on the premises of INCA and recorded with the consent of the interviewees. All the answers were transcribed for later analysis.

The data collected was treated by the thematic or categorical content analysis method, triangulating the frequency in which terms and ideas present in the recorded answers occurred, with the observations and data obtained by the aforementioned researcher, in light of the concepts and constructs selected in the literature (Bardin, 1998). This researcher's experience in the implementation of SISBNT was also important to the interpretation of the interviewees' cognitive activity.

It is important to highlight the limitations of this method, given the subjectivity inherent to the interpretation of the researchers' accounts during data analysis. In order to reduce this problem, the researchers' interpretations, emerging at the data analysis stage, were sent to the interviewees for later corrections. However, no correction requests were received by the team.

4. THE CASE OF INCA'S NATIONAL TUMOR BANK

INCA is an organization from the Health Ministry, responsible for the development of activities and their coordination for the prevention and control of

cancer in Brazil. INCA's hospital units are located in the City of Rio de Janeiro, integrating the Sistema Único de Saúde (SUS) – Unified Health System – and offer a full treatment to people with cancer. Patients with mobility issues, or without clinical conditions to attend outpatient appointments, are visited regularly at their homes by interdisciplinary teams. Today, INCA is a landmark institution in Latin America when it comes to clinical trials for oncology therapeutic class. INCA is an active member of the Rede Brasileira de Pesquisas sobre o Câncer – Brazilian Cancer Research Network – whose strategy is the unification of basic, translational and clinical research on the disease. INCA is also a member of the Rede Nacional de Pesquisa Clínica em Hospitais de Ensino - National Clinical Research Network in School Hospitals – whose purpose is to be an institutional model in clinical studies, based on the best research practices, aimed at the Sistema Único de Saúde (SUS) – Unified Health System. Currently, the network is composed of 20 units associated with university institutions, serving all Brazilian regions, with the purpose of incorporating regional research vocations into development practices, in a decentralized management perspective.

4.1 The Banco Nacional de Tumores (SISBNT) – National Tumor Bank System

Over the last few years, INCA has been investing significantly in the implementation of an IT architecture that integrates the organization's main processes and departments and that provides the exchange of information and cooperation between the institute, clinics and laboratories, distributed in its hospital units.

Over the last ten years, the focus of the IT corporate unit has been on the management systems and medical assistance systems, seeking to standardize equipment and software and to unify access codes (single registration). In 2005, INCA developed a project with the purpose of establishing a network for collection and processing of normal and tumor tissue samples, blood and clinical data of the most relevant tumors in Brazil (in relation to their frequency and morbidity). This network is composed of cancer university medical centers and hospitals, including INCA's hospitals, totaling 20 centers in the five geographic regions of the country.

The centers were chosen based on their potential to recruit patients and on the availability of trained personnel for diagnosis, sample collection and data processing. It is important to highlight the fact that such activities are performed in accordance with protocols defined by INCA for collection, identification, storage and transference of samples obtained by the members of the network to the institute's Research Center.

The National Tumor and DNA Bank lies central in the aforementioned project, created with the purpose of supporting studies in the area of markers in diagnosis and therapy, in significant samples of the Brazilian population. INCA's National Tumor Bank consists of a biobank, with the clinical history data of patients who donated their samples to the institute, and of a physical repository for the cells obtained from such samples, in order to carry out clinical trials, and for use in basic research projects. Its development allows the standardization and computerization of the sample collection procedures, clinical data records and monitoring of patients for prospective studies, which may be used as a model for routine hospital conduct.

The Banco Nacional de Tumores (SISBNT) – National Tumor Bank System – is an information system developed by INCA's corporate IT department, in order to support the National Tumor Bank, depending on the demand of the institution's

Research Centre. As it can be seen in Figure 1, the process that SISBNT supports consists of six stages and involves professionals from such areas as Pathology, Surgery and Laboratory.

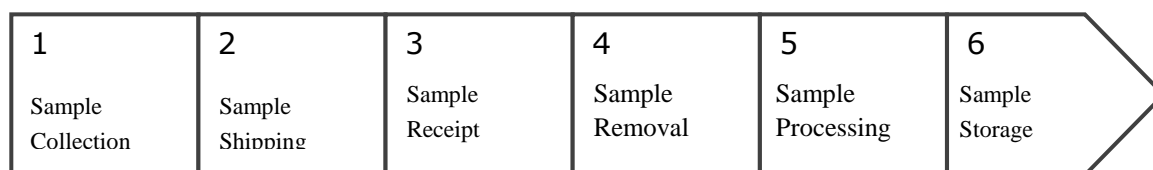


Figure 1 – National Tumor Bank's Workflow Process

Source: by the authors

The National Tumor Bank team's internal workflow process is initiated with the signature of the informed consent document, in which the patient authorizes the collection of their tissue and blood samples during the surgical procedure they are undergoing. Collection procedure is performed directly in the operating theater of the National Tumor Bank's associated hospitals. In the hospitals, there is a computer where the technician in charge of registering samples can perform a patient search by means of three different options: patients' registration, number of the informed consent document, or number of the examination done on the pathological anatomy system, which is integrated to the Banco Nacional de Tumores (SISBNT) – National Tumor Bank System.

The technician in charge inputs the date and time of the collection (automatically entered with current date and time, but with the possibility of changing them in cases of previous date and time entry on the system). The system enables the sample-adding function where the user can add tissue samples and/or fluids to the same collection. For every new sample, the technician in charge inputs the class type (tissue or fluid) and fills out the fields with the characteristics of the sample, listed in Chart 1. Figure 2 shows the screen of the Banco Nacional de Tumores (SISBNT) – National Tumor Bank System - with which the technician interacts at this stage of the process.

Tissue Class Type Characteristic	Fluid Class Type Characteristics
Type of receiver (tube or microscope slide)	Type of receiver (tube or microscope slide)
Part region (A, B, C...)	Subclass
Subclass	Topography
Pathological state	Type of procedure
Type of procedure	Information on blood transfusion

Tissue Class Type Characteristic	Fluid Class Type Characteristics
Topography	Information on chemotherapy
Side	Information on anticoagulant
Type of preservation	Time of the collection
Observation	Type of preservation
	Volume

Chart 1: Characteristics of the Sample Type per Class

Source: by the authors

The screenshot shows the 'Registro de Amostras' (Sample Registration) software interface. It includes a toolbar with icons for 'Iniciar', 'Editar', 'Expurgar', 'Finalizar', 'Cancelar', 'Mudar Hospital', 'Pesquisar', 'Etiquetas', and 'Fechar'. The main form contains the following sections:

- Dados da Coleta:** Hospital: HOSPITAL DO CÂNCER-I; Local da Coleta: CENTRO CIRÚRGICO.
- Opções de procurar por:** Matricula (selected), Nº Termo, Nº Exame.
- Paciente:** Fields for patient name and clinical information.
- Registros de datas:** Data da Coleta: 21/01/2009; Hora da Coleta: 15:56:57.
- Material será coletado?:** Sim (selected), Não.
- Ações da Amostra:** Adicionar, Expurgar.
- Tempo de Coleta:** Alterar? 00:01:11.

Below these sections are two tables:

AMOSTRA DE TECIDO JÁ INCLUIDAS					
Nº Amostra	Recipiente	Classe	Status Patológico	Região	Seq.
09004432	TUBO	TECIDO	TUMORAL MALIGNO A	A	1
09004433	TUBO	TECIDO	TUMORAL MALIGNO A	A	2
09004434	LÂMINA	TECIDO	TUMORAL MALIGNO A	A	

AMOSTRA DE FLUIDO JÁ INCLUIDAS			
Nº Amostra	Recipiente	Sus-Classe	Conservação
09004435	TUBO	SANGUE	EDTA
09004436	TUBO	SANGUE	EDTA

The right side of the interface shows 'Características da Amostra Coletada' (Collected Sample Characteristics) for a 'SANGUE' (Blood) sample:

- Tipo de Recipiente:** Tubo (selected), Lâmina.
- Subclasse:** SANGUE.
- Topografia:** ARTÉRIA PERIFÉRICA.
- Tipo de Procedimento:** PUNÇÃO.
- Paciente Transfundido?:** Sim (selected), Não, Não Informado. Última Transusão: MENOS DE 24 HORAS.
- Recebeu Quimioterapia?:** Sim, Não (selected), Não Informado. Última Quimioterapia:
- Recebeu Anticoagulante / Antiagregante?:** Sim, Não (selected), Não Informado. Anticoagulante / Antiagregante:
- Momento da Coleta:** PRÉ-OPERATÓRIO.
- Tipo de Conservação:** EDTA. Volume (ml): 4.
- Observações:** (Empty field)

Buttons at the bottom include 'Confirmar Dados' and 'Cancelar Dados'.

Figure 2 – Sample Collection

At the end of the sample collection, the technician generates a report containing information on the samples they entered on the system. This report is sent to the National Tumor Bank, together with the receiver of the collected samples. After receipt, the condition of the sample is defined; it can be *removed* (the sample is removed from the bank due to quality issues) or *processed*, which develops one of the following conditions: *restrict use* (sample restricted for the National Tumor Bank’s use only), *available* (sample available for research), *unavailable* (sample unavailable for research), *depleted* (sample that originated secondary components), and *reserved* (reserved for some research).

The National Tumor Bank's storage process is initiated by the barcode reading of the primary sample, from which their secondary components are extracted. According to the class and type of preservation of the primary sample, other types of secondary components are obtained, such as: serum, DNA, RNA, proteins, plasma, total leukocytes, mononuclear cells, layers, manipulated tissue and supernatant fluids.

In order to store a sample, the system needs to provide a map with the available positions in the National Tumor Bank's physical storage where they can be stored (Figure 3). The technician in charge informs which batch (it is possible to choose one among all the batches received and not stored, according to the Banco Nacional de Tumores (SISBNT) – National Tumor Bank System), chooses the samples to be positioned and performs their allocation on the system.

The samples are allocated the first free positions in a receiver, complying with the criterion established for the storage conditions (for instance, blood can only be stored in the -80° freezer and marrow bone, in the -40° one). After the end of the allocation entered on SISBNT, a report is automatically generated, informing the technician in charge where each sample is going to be stored physically.

The Banco Nacional de Tumores (SISBNT) – National Tumor Bank System – also has a search tool that finds the receivers on the system, as well as their storage tree, as seen in Figure 3. It is possible to navigate through its boxes and positions and select one of them in order to obtain a summary of the information on the sample therein stored.

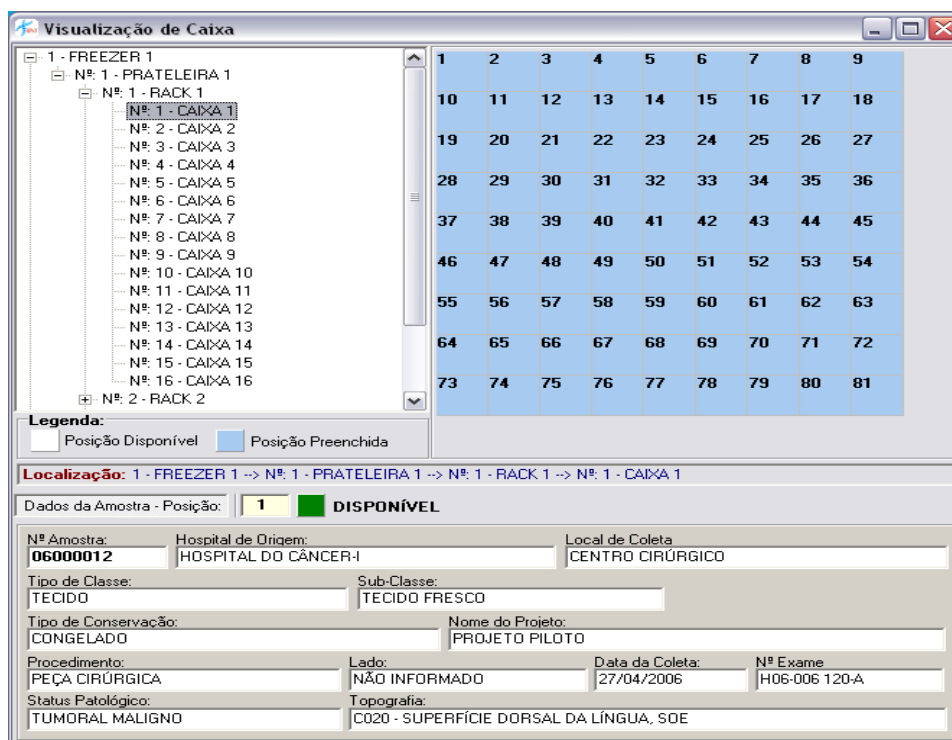


Figure 3 – Storage Map

In addition to the information on the samples, made available by the search in the freezer, the system also provides a sample search by code or donor. By using the sample code or donor's registration, the technician in charge is able to obtain all the information on the sample, as well as the characteristics of their collection, pathological anatomy, clinical laboratory and storage. Figure 4 shows the screen related to this type of search.

Figure 4 – Sample search by code or donor

The Banco Nacional de Tumores (SISBNT) – National Tumor Bank System – has been implemented successfully in four different hospitals in Rio de Janeiro. The system shows an average of 500 searches, made by 237 registered users with management, operational and search profiles. Up until the date of this research, 26.363 samples had been collected and stored at the National Tumor Bank. In addition, 19.721 informed consent documents had been signed and 19.401 clinical questionnaires had been answered.

Due to the nature of storing data and the need to protect the privacy of the patients, the Banco Nacional de Tumores (SISBNT) – National Tumor Bank System cannot be accessed directly by INCA's researchers. It has its own team for the management of the system, which is also responsible for providing the information requested in the experiments. In fact, in order for the researchers to have data available to their project, they first need to sign the terms and conditions at INCA's ethics committee. Therefore, the National Tumor Bank can be regarded as the facility for the institute's basic, translational and clinical research.

4.2 The Banco Nacional de Tumores (SISBNT) – National Tumor Bank System – and INCA's Innovation Management

There was a consensus on INCA's executive board of directors towards the fact that the institute needed to focus its strategic actions on the advancement of cancer knowledge in Brazil. Aligned with this consensus, the role of R&D has taken shape since the middle of the last decade, seeking to transform INCA's Research Center into a Technological Development Center. Among all the initiatives regarded as critical for research to move on to the next level, the National Tumor Bank stands out in the eyes of the interviewees. Figure 5 shows the central role that the National Tumor Bank may play in INCA's scientific research if the efforts towards the development of new compounds continue to advance in the institution.

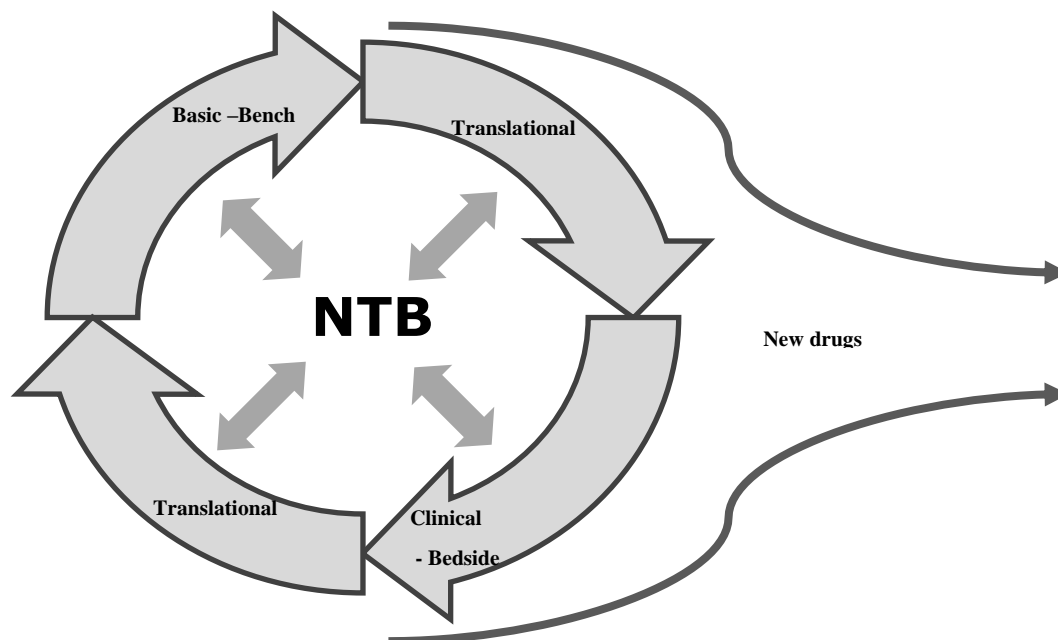


Figure 5 – The role played by the National Tumor Bank in INCA's research

Source: by the authors

The National Tumor Bank was considered by the research coordination team as one of the milestones in the change of direction of the R&D strategies and policies at the institute, which is in line with the importance, highlighted in the literature, of creating and managing biobanks that support research in life sciences (McQueen et al, 2010). It was seen as an innovation, a structuring project for the research field, which initiated its automation process with a biobank that relied on an infrastructure for micro dissection and arrays of tissues and DNA, up to the point of implementing the Banco Nacional de Tumores (SISBNT) – National Tumor Bank System.

Thus, there was a clear strategic purpose behind the development and implementation of the National Tumor Bank system, which was aligned with the view, as far as innovation is concerned, predominant at that time at INCA's executive level. This high level of congruence was a determinant for the project to be supported by the institute's top management, making it a priority at the institution. It is confirmed in this research the idea that the commitment of the main stakeholders of the organization and a strong organizational leadership are highly necessary to the success of the implementation of information systems in healthcare organizations (Cresswell & Sheikh, 2013; Gruber, Cummings, LeBlanc, & Smith, 2009).

Currently, INCA is a landmark institution in Latin America when it comes to clinical trials for stages 1, 2 and 3 of oncology therapeutic class. Around 80% of INCA's clinical studies are sponsored by major global pharmaceutical companies, which use these clinical studies in multicenter tests of new drugs or for new uses for already existing active principles. The remaining 20% of the studies is requested by INCA's own researchers or by the Rede Nacional de Pesquisa Clínica - National Clinical Research Network.

INCA's basic research areas involve experiments focused on the identification of the genetic base of the disease and on the identification of molecules for the treatment of various cancer types. Five years ago, together with the experiments performed in physical laboratories, INCA, reflecting the change in the R&D profile under development, structured its Bioinformatics and Computational Biology, which carry out *in silico* analyses of the data generated in experiments in Genomics, Proteomics, molecular modeling and virtual screening.

The creation of a translational research laboratory was seen by INCA's managers as an essential step towards the effective integration of basic research where Bioinformatics is found - and clinical trials focused on drug projects, contributing to reducing the academic characteristic that INCA's research used to have a short time ago. As a rule, translational research is described in the literature as a link or a linear integration process of basic research into clinical trials (Goldblat & Lee, 2010). At INCA, as seen in Figure 5, the manager of the translational research laboratory manager understands that his projects are going to play an increasingly interactive role.

In line with this perspective, some projects carried out at INCA stemmed from problems observed in clinical practice, giving rise to research questions, whose answers made it necessary to resort to basic research in order to develop the hypothesis, retesting it in the translational or clinical context. The cells stored at the National Tumor Bank lie central in the clinical and retro alignment process, whose moving around is managed by the Banco Nacional de Tumores (SISBNT) – National Tumor Bank System.

The Research Center managers understood that INCA was qualifying itself, based on the new process and systems of Information and Communication Technologies, on the ongoing efforts for the construction of an institutional/legal landmark cancer research in order to support the network of Brazilian researchers (many of them in the academic community who do not have resources to advance their research towards pre-clinical and clinical study stages). Herein, SISBNT plays a critical role by providing objective conditions for this research to advance up to the point it reaches higher complexity stages that involve a higher need for resources, such as stage 1, 2 and 3 pre-clinical and clinical tests.

It is possible to see the important role of leaderships at the institute regarding the integration of the different areas of the organization, with the support of systems that would interconnect, improve and speed up relevant information flows between these areas. As a matter of fact, efforts to integrate and bring together the various sectors within the organization and its ICTs are usually seen as critical for the successful implementation of computational systems in the area of healthcare (Cresswell & Sheikh, 2013; Gagnon et al., 2010). Actually, it seemed that a consensus existed between the various actors involved in the process of adoption of the Banco Nacional de Tumores (SISBNT) – National Tumor Bank System.

This consensus related to the need for development and implementation of a system that properly supported the joint efforts of cancer care providers and researchers. Thus, the investigated case provides additional empirical support to how important it is for users to understand the potential benefits arising from technology and the effective commitment to the project (Yarbrough & Smith, 2007; Yusof, Stergioulas, & Zugic, 2007).

The role played by the Information Technology Division (ITD) in the design and implementation of SISBNT showed evidence that good practices in information management can contribute to the consolidation of the biobank in biopharmaceutical organizations, which adopt translational research in the oncology therapeutic class, as highlighted by Goebell & Morente (2010). The ability of the ITD team, in particular its manager, to discuss with the various stakeholders of the project, to understand their expectations and to define an IT solution that respected autonomy needs of the various areas - and at the same time, that promoted its integration - was essential for the success of the initiative.

As frequently cited in the literature (Cresswell & Sheikh, 2013; Gagnon et al., 2010; Yarbrough & Smith, 2007), the good relationship between the areas involved in the adoption of the new system was critical for the alignment of roles, responsibilities, activities information flows and functionalities inserted into the scope of the Banco Nacional de Tumores (SISBNT) – National Tumor Bank System. As highlighted by Yusof et al. (2007), “technological, human and organizational factors are equally important [to the success of IT adoption in healthcare organizations], as well as the alignment between them”.

At the end of data collection, it was noticed that although the connection between the different research areas of the Research Center was still fragmented, the basic research areas, both in physical laboratories and in Computational Biology, already performed experiments proposed by translational research and they were assessed in clinical trials. Data from SISBNT were already used in basic bench research, in some translational research laboratory projects and in clinical trials.

In part, due to the fact that the *in silico* research still did not focus on the national drug program, the experiments in Bioinformatics had not accessed the data from SISBNT until the end of 2013, although this area had declared its intention to do so shortly. Among the initiatives that contributed for this to happen were the increase in the number of stored samples at SISBNT and the emergence of powerful tools of genetic sequencing and High Performance Computing, acquired in October 2001 and June 2012.

It is worthy of mentioning, however, that as Bioinformatics and translational research, and the National Tumor Bank itself, had been recently created in the institution - the adoption of techniques or data mining tools highlighted in the

literature - with a focus on the recognition of standards, structures and rules (Krysiak-Baltyn et al, 2014), was not evident at INCA by the time this study was conducted.

5. CONCLUSIONS

In response to the previously defined research question, the analysis of INCA's Banco Nacional de Tumores (SISBNT) – National Tumor Bank System illustrates how a biobank with the support of modern information and communication technologies can contribute to the improvement of scientific research in oncology therapeutic class. The benefits of such an innovation are immediately reflected in the improvement of the access to useful knowledge and in the increase of operational efficiency in R&D management. Other benefits are reflected as an increased focus on patients' expectations and their satisfaction, as well as on improvements in transference and dissemination of knowledge.

It is clear in the analysis of the evidence that the implementation of such an initiative demanded, before anything else, that the involved managers clearly understand the process of use of this information and the meaning of the initiative for the repositioning of INCA as an oncology innovation center. It was also confirmed that SISBNT represented an important innovation in the institute's IT area, which meant a paradigm shift at INCA's Research Center. Such an innovation contributed to, according to the interviewees' own answers, positioning INCA as the only Brazilian organization that boasts technical conditions to perform all the stages of research focused on the development of new drugs in oncology therapeutic class. It was also clear that the Banco Nacional de Tumores (SISBNT) – National Tumor Bank System - is regarded by researchers as a critical tool, not only due to the relevance that the data contains, but also due to the fact it was developed in compliance with good practices from Information Science. This fact keeps the organization from resorting to database and technological platforms, which are unsuitable to the objectives of knowledge management, and to the integration of the technological co-development process, as these practices seem to be commonplace in R&D areas, which do not boast a suitable IT support.

The explanatory nature of this research imposes some limitations to the scope of the aforementioned conclusions. First, there is no intention to exhaust the discussion about the contributions to a biobank in cancer technological innovation, in particular regarding the organizational mechanisms and processes, which are necessary to its development and management. In addition, as one of the authors of this research is the person in charge of the implementation of SISBNT, the subjectivity in the treatment of the answers given cannot be ruled out. At last, the context of this research, INCA, a public organization associated with the Health Ministry of Brazil, imposes restrictions on the generalization of results for other private companies and for other countries.

Despite the aforementioned limitations, this research contributed to theory and practice as it highlights the importance of bringing together of IT and R&D in cancer research, as seen in the case of INCA's Banco Nacional de Tumores (SISBNT) – National Tumor Bank System. From this finding, a question for further research is raised: what organizational mechanisms and processes can contribute to a better integration of IT into basic, translational and clinical research? Lastly, it is understood that R&D and IT managers of Brazilian biopharmaceutical companies can use the case

herein described in order to learn important lessons that aim to improve their innovation efforts.

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