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Development of a performance measurement system in the Research Office of the IRCCS Carlo Besta

Autor: Ana González Mateos, 915733

Supervisor: Cristina Masella

Co-supervisor: Flaminia Reale

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Abstract (English version):

Performance measurement systems, such as the Balanced Scorecard (BSC), have proven to be effective tools for measuring the performance of an organization and linking the goals with the strategy, while involving the corresponding personnel.

The aim of this project is to give answer to a necessity that was born in the Research Office of the Neurological Institute IRCCS Carlo Besta (Italy), through the design of a BSC for the management of research projects.

The methodology followed has been that of working together with a team in charge of the development of a software for the management of the research projects and the active participation to different meetings with the personnel involved. This has allowed to extract the necessary information and the understanding of the objectives and necessities of the Research Office that have to be matched.

Since an effective adoption of the BSC requires the adaptation of the generic instrument to the specific realities of organizations, in this project it has been developed a completely customize tool. At the end what has been obtained is a scorecard composed by five different perspectives (i.e. scientific knowledge growth, research process, financial, internal business processes and innovation, learning and growth) and thirteen key performance indicators (KPI).

The BSC, which is thought to be used together with the software for the management of the research projects, can help the Research Office to keep the performance updated along time, being useful for monitoring important internal processes and adaptable to changes during its life.

Keywords: University hospitals, Research Office, Balanced Scorecard, Key Performance Indicators.

Abstract (Italian version):

I sistemi di misurazione delle performance, come la Balanced Scorecard (BSC), sono strumenti efficaci per misurare le prestazioni di un'organizzazione e collegare i suoi obiettivi alla strategia attraverso il coinvolgimento di tutto il personale.

L'obiettivo di questo progetto è quello di dare risposta a una necessità dell'Ufficio Ricerca dell'Istituto Neurologico IRCCS Carlo Besta (Italia) attraverso la progettazione di una BSC per la gestione dei progetti di ricerca.

La metodologia adottata ha previsto la collaborazione con un team incaricato dello sviluppo di un software per la gestione dei progetti e la partecipazione attiva a diversi incontri con gli attori coinvolti. Ciò ha permesso la raccolta delle informazioni necessarie e la comprensione dei bisogni dell'Ufficio Ricerca.

Il progetto ha previsto la realizzazione di uno strumento adattato alla realtà del Besta. Il risultato del lavoro è un cruscotto composto da cinque prospettive (i.e. scientific knowledge growth, research process, financial, internal business processes and innovation, learning and growth) e tredici indicatori chiave di performance.

La BSC finale, progettata per essere utilizzata insieme al software per la gestione dei progetti di ricerca, è un sistema dinamico che aiuterà l'Ufficio Ricerca a monitorare nel tempo le prestazioni e i principali processi interni.

Parole chiave: University hospital, Research Office, Balanced Scorecard, Key Performance Indicators.

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Executive summary:

This project consists in the development of a performance measurement system, a Balanced Scorecard (BSC), for the Research Office of the IRCCS Carlo Besta, working in parallel with a team in charge of the development of an IT system for the management of the research projects.

The project has been developed in the context of the Italian National Health System (NHS), which was created in 1978 and provides healthcare to all citizens by a mixed public-private system. Under the Italian Constitution the responsibility for health care is shared by the state and the 20 regions, by which the country is composed. The State has the exclusive power to set the “Essential Levels of Care”, while the Regions have the responsibility for the organization and administration of publicly financed health care. The Local Health Agency company must protect the health of the population in its territory.

It has been developed inside an IRCCS (*Istituti di Ricovero e Cura a carattere Scientifico*), which are hospitals of excellence that pursue research purposes, mainly clinical and translational, in the biomedical field and in the organization and management of health services. They also implement admission and treatment of high specialty or other activities, having the characteristics of excellence. The recognition of scientific character is the procedure through which these emerging realities, which treat particular national diseases, are qualified as IRCCS. This character confers the right to use of a state financing, added to the regional one, aimed at accomplishing the research activity related to the recognized subjects.

Medical research is a structured investigation into a field of reference. Clinical research purpose is to develop new knowledge of a condition or disease in order to add them to the already existing knowledge. Translational research is the process of applying knowledge from basic biology and clinical trials to techniques and tools that address critical medical needs. It is specifically designed to improve health outcomes.

The IRCCS are of a different legal nature, public or private. The public IRCCS are public institutions of national importance subject to regional control and supervision by the Ministry of Health. The main organs conforming the general

institutes are the Board of Directors, the President of the Foundation, the General Director and the Scientific Director.

The activity of research that is developed by this type of centre, must necessarily find an outlet in therapeutic applications in hospitals. Their activity is focused in the well-defined research areas whether they have received recognition for a single subject or for multiple integrated biomedical areas.

The **IRCCS Carlo Besta Neurological Institute Foundation**, of national importance and founded in Milan in 1918, is statutory as a participation Foundation, in which the subjects represented on the Board of Directors take on particular importance. The Besta Foundation is a recognized centre of excellence for neurological research and the treatment of the major neurological diseases.

The IRCCS Carlo Besta pursues the following fundamental goals: health care and biomedical and health research, clinical and care-oriented (translational research); development and implementation of vocational training and health education programs; support to universities (pre and post graduate education and training); testing of innovative forms of management and organization in the health and biomedical research fields.

The research activity is driven by the **Scientific Direction**. The Scientific Direction, in the person of its Scientific Director (Tagliavini Fabrizio), programs, directs and coordinates the scientific research activity in the biomedical translational and public health field. The Scientific Office is composed by different offices, in particular it is interesting for the development of this project, the role of the department of the **Research Office**. It deals with management and monitoring of research activities and relations with the Ministry. Normally manages the projects of research financed by national and international public and private bodies and won by the Foundation a follow-up of participation in specific calls; when funding involves a clinical trial interacts with the Department of Clinical Research and Development.

As set before, the **objective** of this project is the development of a performance measurement system, in particular a Balanced Scorecard (BSC), for the Research Office.

Performance measurement is the process of collecting, analysing and reporting information about the performance of an individual, group, organization, system or component. A performance measurement system can be defined as the set of metrics used to quantify both the efficiency and effectiveness of actions. There are a lot of different performance measurement system models, that are established in the business world. They use very different tools and techniques, among which one of the most successful one is the Balanced Scorecard. It was developed by Robert Kaplan and David Norton in 1992, to provide a better measurement of the organization.

The **Balanced Scorecard** is a strategic planning, management and performance metric, which is used to improve the internal business functions and their outcomes. The balanced scorecard provides a framework for managing the implementation of strategy while at the same time allows the strategy itself to grow in response to evolutions in the company's competitive market and the technological environment. The Balanced Scorecard supplemented the financial measures that are traditionally used in companies, summing the other three perspectives which are customers, internal business processes and learning and growth.

But what has been learned from studying different literature, is that these traditional four perspectives, do not fit with the particular situation of a research and teaching hospital. The Balanced Scorecard was firstly designed for companies belonging to the industrial sector, the reason why a deeper research on the application of the BSC to these institutions has been done.

Despite being able to find different applications of the BSC to similar institutions to the IRCCS Carlo Besta, any of them talked about the particular situation of a Research Office. For this reason, in order to design the Balanced Scorecard for the Research Office of the IRCCS Carlo Besta, a transformation of the traditional one has been done. The conclusion has been that the BSC had to be customized to fit into the mission and objectives of the Research Office of the IRCCS Carlo Besta.

For the development of this project and before the design of the performance measurement system, a particular **methodology** of work has been followed.

The project has been preceded by a phase in which different information has been collected, thanks to the development of external interviews to clinicians and other personnel involved, done by other team members. Also, the active participation to different meetings with different departments and the company in charge of the development of the IT system, has helped to have a deep knowledge of the opportunities, necessities and structure of the Research Office.

Everything has been important in order to develop the performance measurement system. A full understanding of the solution proposed by the company in charge of the development of the software for the management of the research projects, is essential. It is because for the construction of the BSC, different reported information and measures from the software will be used.

Based on the state of the art literature and the information from the meetings, the different perspectives and indicators have been chosen, following the main mission of carrying out a translational research, promoting the professional development of researchers and contributing to the innovation and knowledge, everything while pursuing the scientific excellence. Here, not only the chosen perspectives are important, but also their position from top to down.

Having this in mind, the proposed solution of perspectives and indicators is the one showed in the next Table 1.

Perspective	Indicators
Scientific growth	Normalized Impact Factor – IF _n
	Transferability – T
Research processes	Number of success research projects – NRP
	Number of excellent scientific publications – NSP
	Number of active researchers – NAR
Financial	Project costs per point of IF – PC
	Fund raising – FR
	Research investment – RI
Internal business processes	Deviation of the budget – DB
	Number of deadlines budget met – NBM

	Number of deadlines steps met – NSM
Innovation, learning and growth	Number of clinical researchers – NC
	Degree of software implementation – DSI

Table 1: Different perspectives and indicators of the BSC.

For a full description of the indicators, perspectives, formula and its relationships go to [\(Chapter 7\)](#).

The BSC has been designed to be used together with the software that is being developed. The importance of its implementation can be seen in the high impact that has the indicator Degree of software implementation, that measures the use of the software, in many other indicators.

As explained before, the traditional BSC has been transformed, the perspectives and its order, to fit into the necessities of this particular institution. At the end, it is composed by five perspectives and thirteen indicators. The indicators are composed by financial and non-financial measures, which in this case are even more important and they are completely customized to fit with the mission and the objectives of the Research Office. In particular, it is:

- A system that has been designed to match the necessities and objectives of the Research Office.
- A system that will help the Research Office to have the performance updated along time.
- A system that will help to monitor important internal processes.
- A system that is built in parallel with a software from which most of the indicators take their value from it for its calculations, making easier its management.
- A system that is adaptable to changes during its life (new indicators or relationships can be added, or old ones can be dropped).

At the end, it has been designed a tool that will help the Research Office with the management of the performance and will give to them the necessary information and measures, for internal and external monitoring. It can be said that the objectives of this project have been met.

Finally, regarding the limitations of this project, due to time constraints, the BSC has not been tested with data. The future development would be, once the software has been installed and started up, to test the BSC with the data and its integration.

Reviewing the structure of this project, for its development a first literature research has been done. [Chapter 1](#) gives a description about the Italian health system, reviewing its main characteristics and organization. [Chapter 2](#) describes the research and teaching hospitals, emphasising the role of the University health care in Italy and the integration of the triple mission of university hospitals. [Chapter 3](#) is dedicated to the description of the IRCCS and in particular the IRCCS Carlo Besta. It details its main characteristics, the organization and the assistance, research and teaching activities. [Chapter 4](#) gives a description about the Performance Measurement Systems, focusing in the Balanced Scorecard and its application in research and teaching hospital.

Thus, [Chapter 5](#) summarizes the different Research Questions done in order to develop the previous literature research.

[Chapter 6](#) contains the information regarding the development of the work, as the followed methodology, the different information obtained from interviews and meetings and its analysis, and the description of the functional requirements of the software solution proposed by the company WEBRATIO [\[16\]](#).

[Chapter 7](#) describes the development of the Balanced Scorecard. It examines the vision and mission of the IRCCS Carlo Besta, the different perspectives, objectives and indicators chosen and its relationship.

Finally, [Chapter 8](#) exposes the outstanding conclusions of this project

1. Italian health system review:

1.1. Country Profile:

Italy is a country located in the southern Europe which has a population around 60 million (2020). The 1948 Constitution established the current parliamentary republic, which has a bicameral parliament – the Chamber of Deputies and the Senate. The head of state is the President, who is elected for seven years by a joint session of the Chamber and Senate, while the government is headed by the Prime Minister, who is usually the leader of the party that has the largest representation in the Chamber of Deputies.

The country is divided into 20 regions (Figure 1), which are extremely varied, differing in size, population and levels of economic development. Since the early 1990s, considerable powers, particularly in health care finance and delivery, have been devolved to this level of government. [\[1\]](#)

The health systems in transition profiles are country-based reports that provide a detailed description of a health system and of the reform and policy initiatives in progress or under development in a specific country.

Some indicators show that the Italian population health has improved in the last decades. Average life expectancy has reach 82.7 years (2019) and the mortality rate for adults an infant has fallen significantly. However, in almost all demographic and health indicators, there are marked regional differences for both men and women, reflecting the economic imbalance between the north and south of the country. Italy's indicators of health system outcomes, quality and efficiency are over the average of the OECD (Organisation for Economic Co-operation and Development). The life expectancy is one of the highest of the OECD and the healthcare in Italy is accomplished at low-cost (3027 \$ per capita), as it spends less than the adjoining countries such as Germany (4652 \$ per capita), Austria (4593 \$ per capita) or France (4121 \$ per capita) [\[4\]](#).



Figure 1: Physical and political map of Italy. Source: Mapamundi.online

1.2. History of the Italian National Health System:

The **National Health Service** was created in 1978. It provides healthcare to all citizens by a mixed public-private system. The public part is the “National Health Service” - NHS (*Servizio Sanitario Nazionale - SSN*), that is organized under the Ministry of Health and it is administered on regional basis. The National Health Service, in the Italian legal system, identifies the complex of functions, activities and assistance services managed and provided by the Italian State.

Before its establishment, the health-care system was based on numerous "mutual agencies" or "mutual funds". The most important of these was the National Institute

for Health Insurance. Each institution was competent for a specific category of workers.

Finally, the law of 23 December 1978, n. 833 suppressed the mutual system and established the National Health Service, with effect from 1 July 1980. The new health system, based on the fundamental role of the Regions, was implemented on the initiative of the Minister of Health in the Cossiga II governments and Forlani. Since the eighties, the concept of health as a universal good and free (and therefore right for autonomy) has gradually changed into that of a good necessary for equity, as a matter of equity towards the poor, rather than a good for all those present in society.

With the 1990s and the reforms that took place on the basis of the delegation law of 23 October 1992, n. 421, with the transformation of public structures from Local Health Units (LHU) into Local Health Agencies (LHA), in competition with each other, they enter the health sector as in other areas of public administration, logic born of private companies, such as attention to the cost and the result and to the quality of the service provided. The legislative decree 19 June 1999, n. 229 introduced a discipline, motivated by the potential conflict of interest, for the employed doctors working at the LHA with the prohibition to carry out private activity inside the public structures and externally, and the obligation to choose between one of two types of activity. Subsequently, the possibility of carrying out public and private activities was reintroduced. In 2012, the Balduzzi decree then concerned the reorganization of the healthcare system in Italy and the regulation of medical and scientific activity. [\[6\]](#)

1.3. The organization of the Italian National Health System:

The Italian health care system is a regionally based national health service that provides universal coverage free of charge at the point of service. The national level ensures the general and fundamental objectives and principles of the national health care, while the regional governments, through the regional health departments, are responsible for ensuring the delivery of a benefits package through a network of population-based health management organizations, Local Health Agencies, and public and private accredited hospitals.

Under the Italian constitution, the central **government** controls the distribution of tax revenue for publicly financed health care and defines a national statutory benefits package to be offered to all residents in every region – the “Essential Levels of Care” - ELC (*Livelli Essenziali di Assistenza - LEAs*). The list of the essential levels of care is defined in terms of a positive and negative list. The positive list contains the services that the National Health System is required to provide uniformly in all regions. The negatives exclude categories of defined services based on criteria, including proven clinical ineffectiveness. Regions can offer services not included at the essential levels of care but must finance themselves.

The different levels of competence of how the Italian National Health System is structured, are shown in Table 2.

The National Health System	Protects the Health
The Regions	Ensure Essential Level of Care
The Companies	Provides the Services

Table 2: Levels of competence of the Italian NHS.

Regions enjoy significant autonomy in determining the macro structure of their health systems. Local Health Agencies are managed by a general manager appointed by the governor of the region, and deliver primary care, hospital care, outpatient specialist care, public health care and health care related to social care. [\[3\]](#)

The Figure 2 summarizes the main organizational actors and the relationship between them.

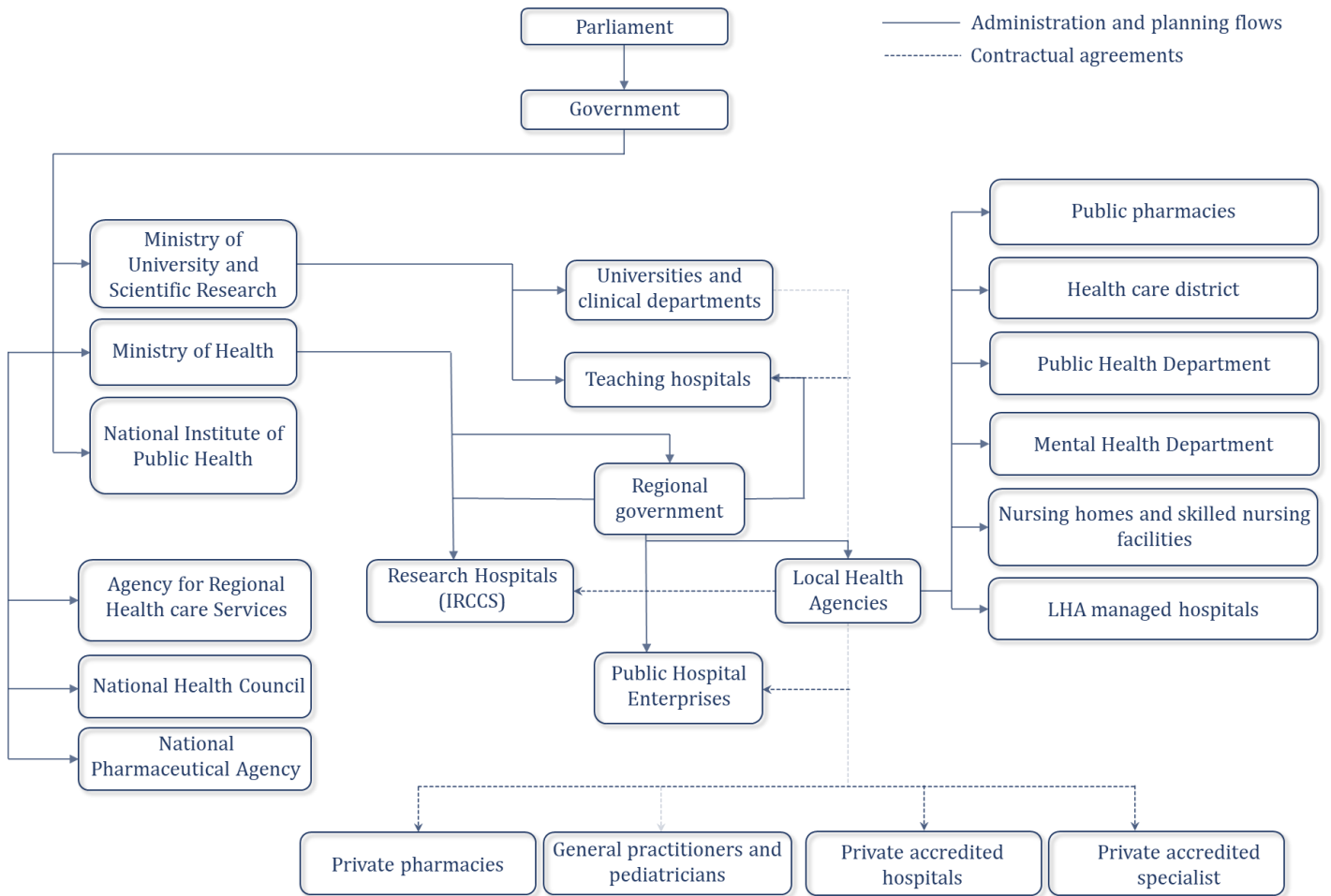


Figure 2: Overview of the Italian Healthcare system. Source: Commonwealth fund.

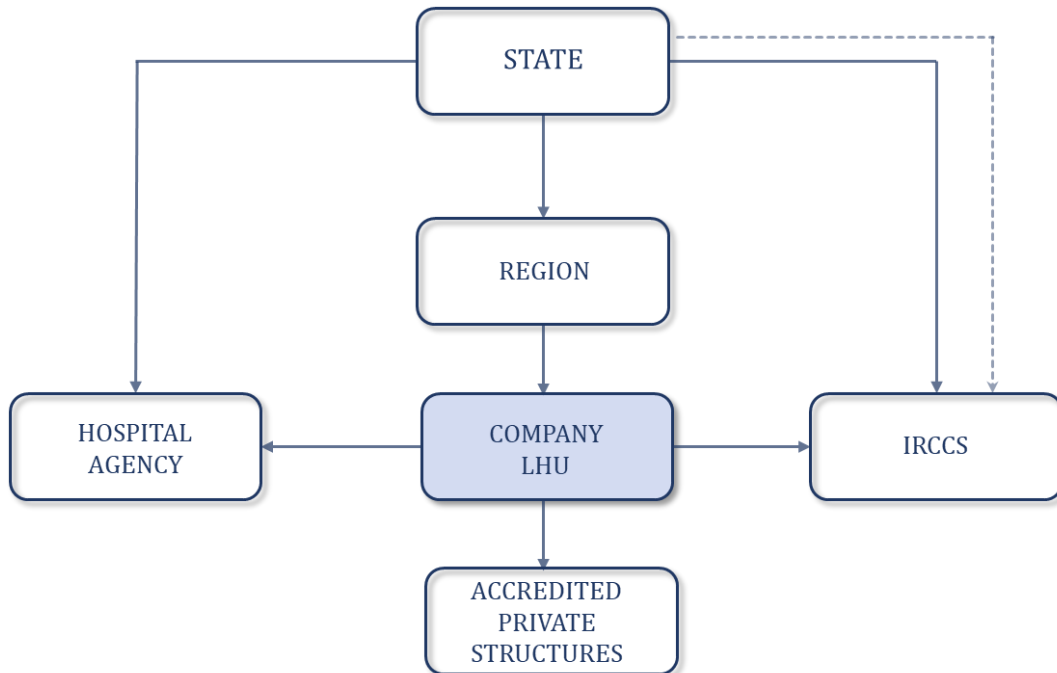


Figure 3: Simplification of the organization of the Italian National Health System.

Under the Italian Constitution, responsibility for health care is shared by the state and the 20 regions.

Figure 3 shows a simplification of the organization of the Italian national health system in which the following main actors are involved.

The **state** has exclusive power to set the 'Essential Levels of Care', or basic package, which must be available to all residents throughout the country and is responsible for ensuring the general objectives and fundamental principles of the national health care system.

Regions have virtually exclusive responsibility for the organization and administration of publicly financed health care. They have the "competing power" with the state in health matters.

- It is considered the "holding" of the Health Service, because it exercises the role of owner of public health agencies in its territory. It finances, coordinates and controls them.
- These functions are carried out through their institutional bodies (Regional Council, Council), by their own Health Councillor and by the Social Agency and Regional Healthcare.
- It defines the Regional Health Plan and annually resolves the program and the objectives to be assign to the Health Authorities.

The **Local Health Agency (LHA) Company** must protect the health of the population residing in its territory. It is responsible for giving assistance.

- It is the pivot on which the health system of its geographical area (one or more provinces) rotates.
- It can produce, but also buy services: for this reason, it established supply agreements with Hospitals, IRCCS and Private Accredited Structures.
- It has been established as a Company since 1992 with Legislative Decree 502/92. Healthcare companies have public legal personality and entrepreneurial autonomy like a private company.
- It is financed with per capita budget (calculation based on age, gender, mortality or population density).

The hospital assistance can be provided both by LHA companies and by **hospital agencies**.

- Hospital unit of the LHA company: it is the hospital managed by the Local Health Agency.
- Hospital agency: it is a hospital unit transformed into a company, with independent and autonomous management.
- University hospital: it is a general hospital with the Faculty of Medicine inside.

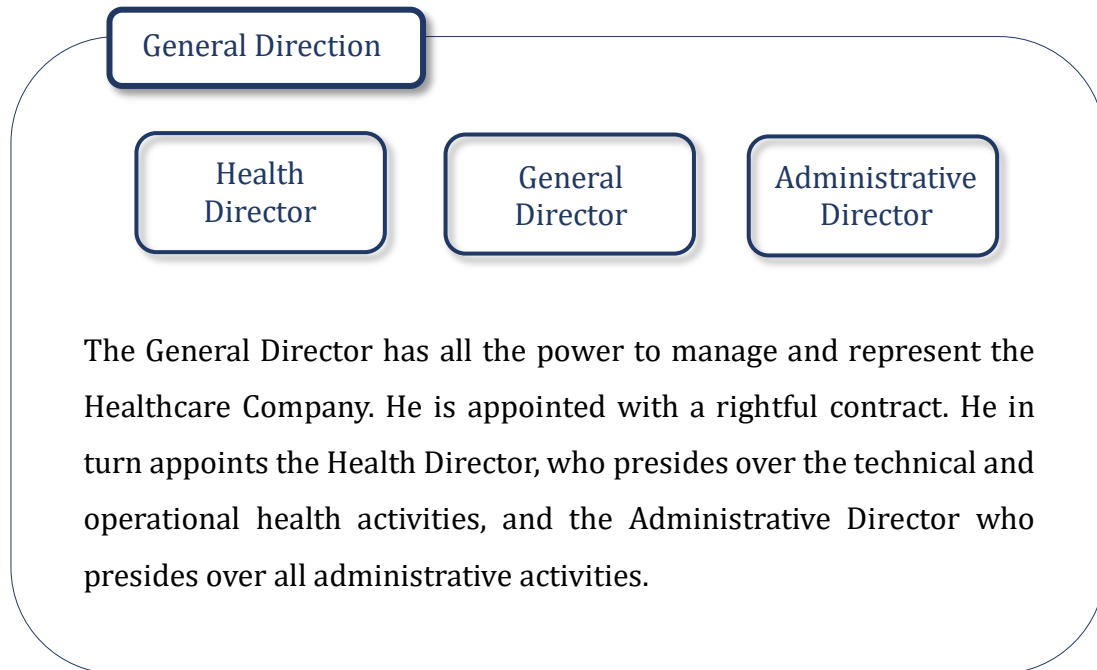
The **accredited private structures** are private structures that have all the requirements to work in the health system.

- Health accreditation: all providers must possess a set of minimum technical requirements for the opening of health facilities and for exercising health activities.
- Institutional accreditation: more stringent and essential technical and organizational requirements to carry out activities on behalf of the Regional health system.
- Agreement: indispensable requirement to carry out activities charged to the Regional health Service. The agreement takes place directly between LHA Company and service providers.

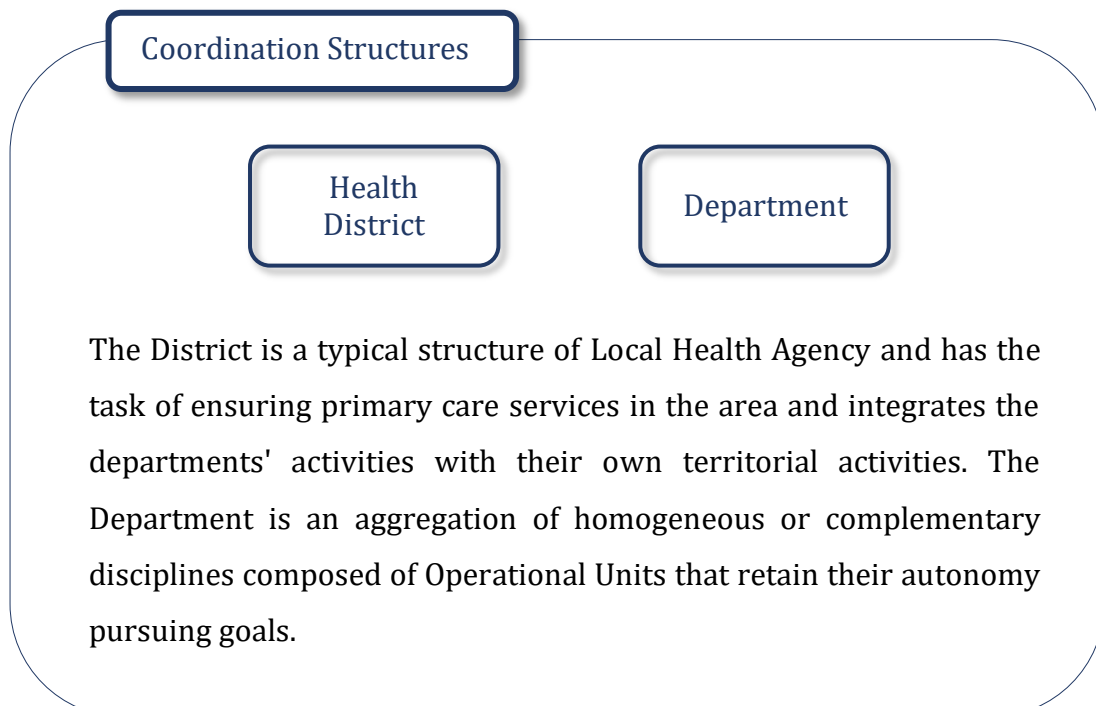
The Scientific Institutes of Hospitalization and Health Care (**IRCCS** - Istituti di Ricovero e Cura a carattere Scientifico) are hospitals of excellence that pursue research purposes, mainly clinical and translational, in the biomedical field and in the organization and management of health services. They also implement admission and treatment of high specialty or other activities, having the characteristics of excellence. They can also be private or public [\[3\]](#). Unlike the traditional hospital structure, the IRCCS are regulated by a national reference standard (legislative decree), which defines these bodies as entities of national importance, autonomous and highly specialized.

1.4. The public health Italian Company:

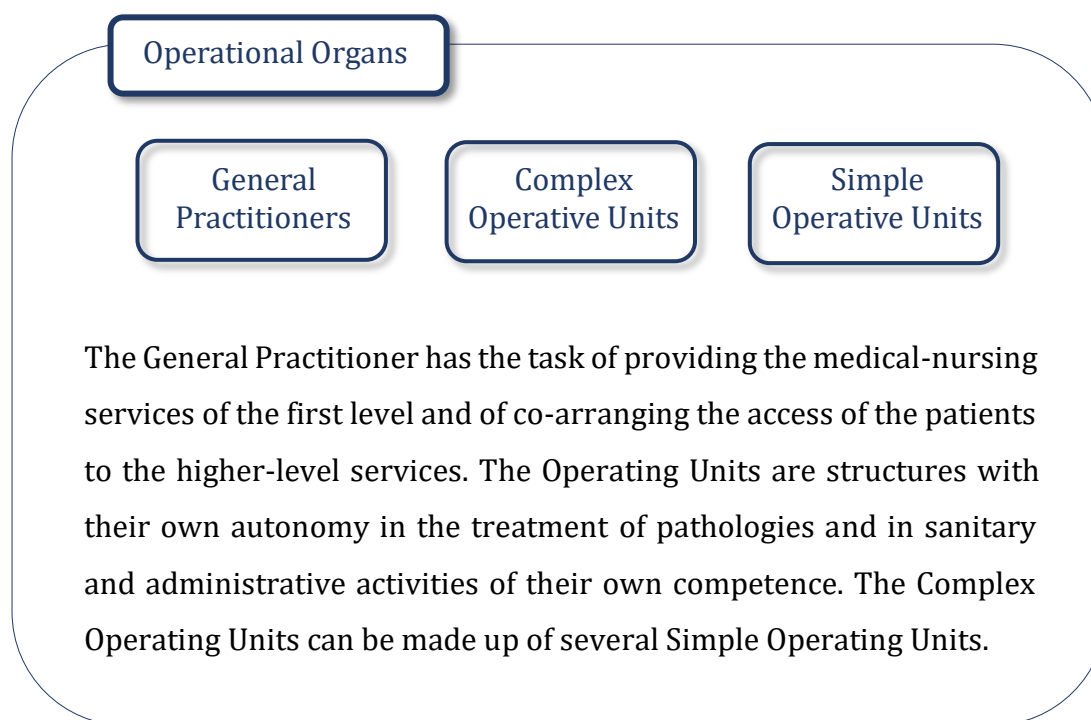
The public health Italian Company is a gear that links financing from the Region, the investment to buy productive factors and the production of health benefits. It is formed by the next different organs [\[3\]](#):



The General Director has all the power to manage and represent the Healthcare Company. He is appointed with a rightful contract. He in turn appoints the Health Director, who presides over the technical and operational health activities, and the Administrative Director who presides over all administrative activities.



The District is a typical structure of Local Health Agency and has the task of ensuring primary care services in the area and integrates the departments' activities with their own territorial activities. The Department is an aggregation of homogeneous or complementary disciplines composed of Operational Units that retain their autonomy pursuing goals.



Regarding the board of statutory auditors, it checks the administration of the company from an economic point of view, monitors compliance with the law, verifies the regular keeping of accounts and the compliance of the financial statements with the results of the books and accounting records.

1.5. Covering of the Italian health care:

Two main types of covering can be found depending on who is covered ^[51]:

Publicly financed health care: The National Health Service covers all citizens and legal foreign residents. Coverage is automatic and universal. Since 1998, undocumented immigrants have access to urgent and essential services. Temporary visitors receive health services by paying for the costs of treatment.

Since the National Health Service does not allow people to opt out of the system and seek only private care, substitutive insurance does not exist, but complementary and supplementary private health insurance are available.

Privately financed health care: Private health insurance plays a limited role in the health system, accounting for roughly 1 percent of total spending in 2014. Around 6 million people are covered by some form of Voluntary Health Insurance (VHI),

which generally covers services excluded under the essential levels of care, offering a higher standard of comfort and privacy in hospital facilities and wider choice among public and private providers. Some private health insurance policies also cover co-payments for privately provided services or a daily rate of compensation during hospitalization. Tax benefits favour complementary over supplementary voluntary insurance.

There are two types of private health insurance: corporate, for which companies cover employees and sometimes their families, and noncorporate, with individuals buying insurance for themselves or their families. Policies, either collective or individual, are supplied by for-profit and non-profit organizations. The market is characterized by three types of non-profit organizations: voluntary mutual insurance organizations and corporate and collective funds organized by employers or professional associations for their employees or members. There is no information on the number of policies sold by each type of VHI provider, but non-profit insurers cover the majority of the insured.

In 2010, around 5.5 percent of the population had individual VHI coverage (1.33 million families), while around 2.5 million people had group coverage. [\[5\]](#)

Regarding what is covered the next list of services can be found [\[5\]](#):

Services: Primary and inpatient care are free at the point of use. Positive and negative lists are defined using criteria related to medical necessity, effectiveness, human dignity, appropriateness, and efficiency in delivery. Positive lists identify services offered to all residents; examples include pharmaceuticals, inpatient care, preventive medicine, outpatient specialist care, home care, primary care, and hospice care. Negative lists identify services not offered to patients, such as cosmetic surgery; services covered only on a case-by-case basis, such as orthodontics and laser eye surgery; and services for which hospital admissions are likely to be inappropriate, such as cataract surgery.

Prescription drugs are divided into three tiers according to clinical effectiveness and, in part, cost-effectiveness. The first tier (*class A*) includes lifesaving drugs and treatments for chronic conditions and is covered in all cases; the second (*class C*) contains all other drugs and is not covered by the NHS. There is an additional tier

(*class H*) comprising drugs that can be delivered only in a hospital setting. The three tiers are updated regularly by the National Pharmaceutical Agency based on new clinical evidence. For some categories of drugs, therapeutic plans are mandated, and prescriptions must follow clinical guidelines.

Dental care is generally not covered, except for children up to 16 years old, vulnerable populations, and people in economic and emergency need.

Cost-sharing and out-of-pocket spending: Procedures and specialist visits can be prescribed either by a general practitioner or by a specialist. While there are no user charges for general practitioner consultations and hospital admission stays, patients pay a co-payment for each prescribed procedure or specialist visit up to a ceiling determined by law.

To address rising public debt, in July 2011 the government introduced, along with other economic initiatives, an additional 10 euros co-payment for each prescription. Co-payments have also been applied to outpatient drugs at the regional level, and a 25 euros co-payment has been introduced for “unnecessary” use of emergency services. No other forms of deductibles exist. Public and private providers under a contractual agreement with the National Health Service are not allowed to charge above the scheduled fees.

All individuals with out-of-pocket payments over 129 euros in a given year are eligible for a tax credit equal to roughly one-fifth of their spending, but there are no caps.

In 2015, 22 percent of total health spending was paid out-of-pocket, mainly for drugs not covered by the public system and for dental care. Out-of-pocket payments can be used to access specialist care, and to a lesser extent, inpatient care delivered in private and public facilities to paying patients.

Safety net: Exemptions from cost-sharing are applied to people under age 6 and over age 65 who live in households with a gross income below a nationally defined threshold; people with severe disabilities, as well as prisoners, are exempt from any cost-sharing. People with chronic or rare diseases, people who are HIV-positive, and

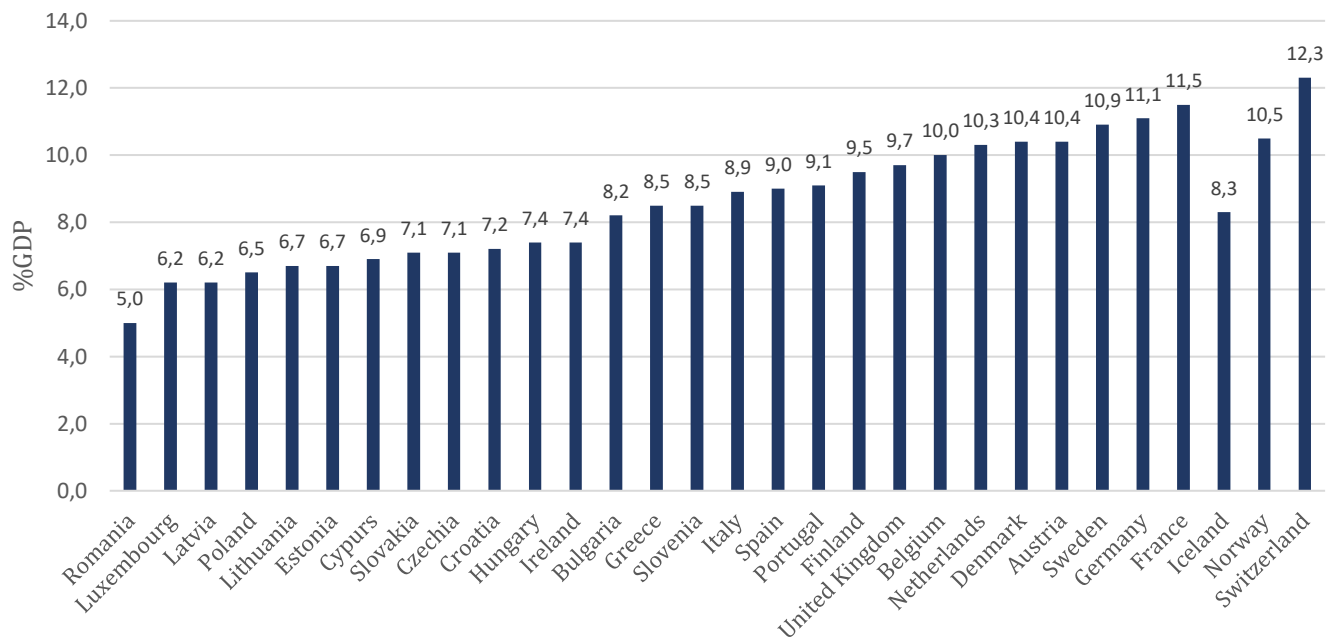
pregnant women are exempt from cost-sharing for treatment related to their condition. Most screening services are provided free of charge. [\[5\]](#)

1.6. Financing of the health system:

The 1978 health reform build the Italian National Health System according to the principles of universal coverage and a fully tax-based public health care system. During the late 1990s, Italy's administrative and institutional setting started to become those of a federal state. The reforms that contributed to this transition included several packages that modified the architecture of health care financing. The progressive move towards fiscal federalism started in 1997 with the abolition of social insurance contributions and the introduction of a regionally collected system of tax financing. General taxation was left to play a complementary role; its main role was now to redistribute resources to regions with a narrower tax base in order to ensure that all residents receive adequate levels of care.

The total amount expended on health based as a percentage of the gross domestic product (GDP) of the county has grown from 7.9% in 1992 to around 8.9% on 2016, below the EU average equal to 9.9% [\[28\]](#) (Graph 1). Following the economic crisis of 2008, total health spending per capita in real terms remained flat or decreased, but it has started to increase again since 2014. Public sources account for 76% of total health spending, while private sources make up the remaining 24%, most directly out-of-pocket payments, as voluntary private health insurance plays only a marginal value.

Healthcare expenditure 2016 (percentage of GDP)



Graph 1: Spends in world countries on health care. Source: Eurostat.

Although Italy has a low public share compared to total health care expenditure among European Union (EU) countries, the volume of public health care expenditure remains an important issue for the Government, both at the national and the regional levels, mainly because of the existence of a large public deficit. Some differences in regional expenditure are mainly explained by socioeconomic factors, such as differences in GDP and in supply of health care.

Italian central government influences core funding and service guidelines, while Italian Regions have responsibility for the allocation of funds and the organization and administration of services locally.

Healthcare is financed principally by the central and regional taxes. The taxes are collected nationally but 90% of its revenues is allocated back to the region in which are collected, this way favouring those regions with a stronger industrial base. The regions are allowed to generate their own additional revenue, leading to further interregional financing differences. Every year, the Standing Conference on Relations between the State, Regions, and Autonomous Provinces (with the

presidents of the regions and representatives from central government as its members) sets the criteria (usually population size and age demographics) to allocate funding to regions. Local health units are funded mainly through capitated budgets. [\[6\]](#)

1.7. Performance of the health system:

Low amenable mortality rates suggest that the Italian health care system is generally **effective**. It is effective in dealing with life-threatening conditions. Indicators of quality of care suggest a generally good performance of hospitals in saving the lives of people, although variations arise across regions and hospitals.

Despite full coverage for basic medical services, 2.6% [\[28\]](#) of Italians over 16 reported some unmet needs for medical care in 2018 either for financial reasons, geographic reasons (having to travel too far) or waiting times. The proportion of people in the lowest income group reporting some unmet needs for medical care is higher than among people in the highest income group. Most of them are due to care being too expensive, with waiting lists and geographic barriers accounting for a relatively small share. [\[4\]](#)

2. Research and teaching hospitals:

2.1. Why medical research is important:

Medical research is a structured investigation into a field of reference. Clinical research purpose is to develop new knowledge of a condition or disease in order to add them to the already existing knowledge. The output of this medical research is usually the new or improved medical treatments.

The high level of health care that can be experienced today, is the result of years of effort by the different medical experts. They have investigated for years what could cause a disease and its potential treatments.

Clinical research, defined as research that involves living humans as subjects, is composed of a wide spectrum of research types such as clinical trials, translational research, epidemiological research, health services research, and outcomes research. It is critical for translating the results of basic science into useable health care products and services.

Translational research is the process of applying knowledge from basic biology and clinical trials to techniques and tools that address critical medical needs. Unlike applied sciences, translational research is specifically designed to improve health outcomes. Translational medical research pursues to carry out the discovery that have been made in laboratories, to medical practices that can be implemented by the expert required, in order to impact the lives of patients. Supporting medical research means to improve the future of medicine.

Clinical trials are clinical research studies which seek to answer to the specific health questions. It is not known if a new treatment could offer a real benefit to the patient until the clinical research is finished. The difference with the standard medical care is that these are the traditional approaches that are used in the present when caring for the health of patients. The clinical trials are research studies that pursue a new or improved treatment or intervention before they are commercialized. [\[7\]](#)

2.2. University hospitals:

The concept of university hospital must be used for defining a tertiary hospital in which the assistance of excellence goes hand in hand with the exercise of pre and postdoctoral teaching (resident doctors, undergraduate students, postgraduate students) of quality and clinical and experimental research.

The hospital is committed to incorporate professionals at different levels, all integrated in the hospital structure, in order to generate critical research mass within the discussion of the patient's pathology. [\[10\]](#)

Thus, lines of work already started are consolidated and new ones are generated to develop a translational medicine, in its preventive and diagnostic-therapeutic aspect. In return, the hospitals co-finance or finance the salary of researchers, in various amounts depending on the type of contract and the year of the same, and these are integrated into the health system.

The medical student is integrated into the hospital by performing clinical rotations in different services, where numerary professors, associate professors, clinical teaching and medical collaborators will ensure their practical training.

From the practical point of view, the reality of many countries shows that a university hospital is understood, first and foremost, as a highly complex medical care centre that has several characteristics [\[8\]](#), such as:

- Important role in tertiary level medical care.
- Strong commitment to teaching and research activities related to the type of medical care provided.
- High concentration of physical, human and financial resources in health.
- Important political role in which it is inserted, due to the high level of resources consumed.

2.2.1. Triple mission of university hospitals:

Nowadays, it is recognized that a public university hospital must implement the triple function: assistance, teaching and research.

Although all these functions are inherent to an hospital that educate human resources, research and education are strategic activities for its development. This

is the reason why planning them is very important, in terms of infrastructure and structure, thus investment in training and research development should be considered.

Education and research are both related to each other and to the quality of patient care. They are tools of a strategic organization and have academic responsibilities. Research, on the other hand, not only has the potential to generate knowledge that contributes to the solution of problems, but also promotes an environment in which established knowledge is questioned, advances are discussed and decisions are based, which is beneficial for the achievement of growth and institutional excellence. The function of scientific research is not only to create scientific knowledge but to apply them for the benefit of the entire community. [\[8\]](#)

Research works should be formally programmed based on the circumstances of each institution and of the priorities resting on objective criteria. The health services research assures making a valuable contribution to the global health.

The role of Higher Education is essential to create the intellectual capacity to produce and use knowledge for lifelong learning, to update knowledge and skills; issues of importance in a society in which knowledge is the main engine of development and economic growth.

However, for having the ability to produce knowledge and lifelong learning, the persons need to have research capabilities. In medical training in particular, both research training and formative research are essential. The advancement of medicine is undoubtedly due in large part to research.

Training research aims to disseminate existing knowledge and develop the necessary skills for lifelong learning necessary to update the knowledge and skills of professionals.

The integration of research with clinical practice guarantees a better quality of health services and a better implementation of medical advances in the prevention and treatment of diseases, and a more ethical and efficient patient care.

The university hospital gathers the characteristics for nuclear translational research and allows the approach between assistance and research. The hospital organization must be deeply transformed to meet the challenge of translational research. Hospital managers must be aware that biomedical research is also a hospital product. The training and research trajectory of hospital professionals is essential. [\[9\]](#)

2.2.2. Opportunities to improve university hospitals:

Some reflections must be done in order to discover opportunities for improvement.

Professionals, students, doctors in training, hospital and academic authorities and, ultimately also society, must understand that the tertiary level of health care constitutes the highest level of assistance to complex pathology.

Being a university hospital must entail the performance of excellence assistance, teaching and research. This implies expenses that have to be assumed, health professionals that must be integrated into their lines of work and researchers that must be coupled with the development of quality translational research.

Rules for access to the university hospital must be delivered. Not every doctor or researcher is or have to be predisposed to this type of work, but neither can be called a hospital “university” where their professionals decide not to integrate into their functions. [\[10\]](#)

The increase in research activity in university hospitals must go hand in hand with the increased fundraising by researchers, both national and international, as it generates wealth and acquisition of quality inventory material to improve our infrastructure. This is the best example of the professional assuming responsibilities in the improvement of devices, without permanently demanding from the institutions.

2.2.3. Governance and funding models of university hospitals in the principal occidental sanitary systems:

The objective is to understand the main mechanism of governance and funding models of the teaching hospitals, in some of the biggest industrialized countries. [2]

The results show that for these main health systems there are two models regarding the teaching hospitals (Figure 4):

- **Cooperation model:** in which the hospital and the medicine faculty are independently structured, and they regulate the activities based on agreements.
- **Integration model:** in which the medicine faculty is fully integrated in the teaching hospital influencing the decisional processes and foreseeing the presence of its members in the intuitional organism.

From a juridical point of view, the teaching hospitals are mostly public, with a private presence in the USA and in a limit way in Italy and Spain. In Holland, the teaching hospitals are of the non-profit organisations.

Model of University Report (Faculty of Medicine and Surgery) and Teaching Hospital

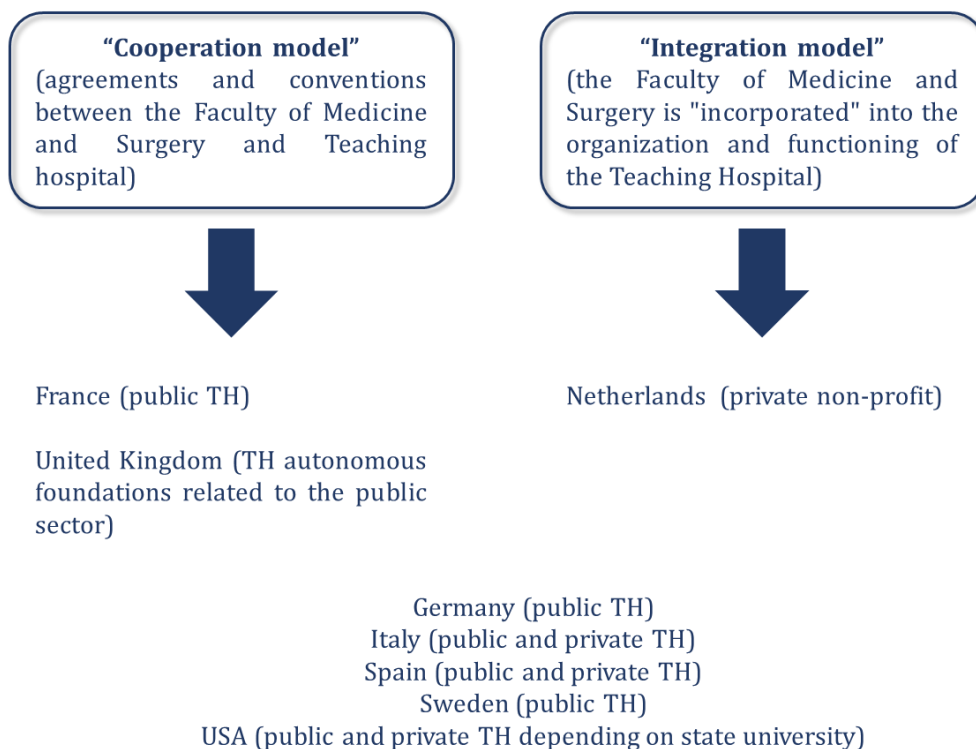


Figure 4: Organizational models of teaching hospitals. Source: Ministero Salute CERGAS 2011.

2.3. Teaching management in university hospitals:

The hospitals are not usually prepared to address the management of training and teaching in a unitary way.

The scenario in which training and teaching is usually carried out is that of different concerts or agreements with educational centres (under the protection of which teaching collaboration is done), with activities that are poorly related and sensitively dispersed by the hospital, using educational resources of diverse origin, and with very different educational techniques. The lack of coordination can reach studies or programs within the same level, and those teachers of the different programs hardly find a forum for the study and analysis of such programs, the achievement of educational objectives and the evaluation of their results.

The centre should accommodate or develop certain structures that will facilitate the training of its professionals, or that are configured as support structures for teaching at all levels.

In those institutions where they have been configured for these purposes, they have contributed an additional value that is not always taken into consideration: it is the research in educational techniques and resources, in addition to research in training results. Without doubt, they constitute a powerful tool to facilitate teaching and training in large hospitals, in order to correctly use educational resources when such resources are large, the training activity is voluminous, and the demands of professionals in the field of training are growing.

2.4. University health care in Italy:

2.4.1. Connection between universities and hospital assistance:

The connection between the universities and the hospital assistance activities was initially envisaged by law n. 132 of 1968 which introduced the instrument of the convention between universities and hospitals establishing that the internal organization of clinics and university institutions must be adapted to the internal order of hospitals and have an analogous organization.

The following, DPR n. 129/1969, confirms the conventional instrument, and identifies the subjects covered by the relative agreement, referring, for the agreements, to a model scheme issued by Ministerial Decree 24 June 1971. [\[2\]](#)

The ministerial decree of 1971 defines the relations between the two institutions through the creation of university-hospital structures: the hospital body assumes the management of the assistance connected with the institutional purposes of the university and uses the assistance provided by the clinics and institutes university students of hospitalization and care. On the other hand, the Universities use the teaching and research potential of the hospital, always based on specific agreements.

2.4.2. The 1978 health reform:

For the regions and universities to achieve appropriate coordination of their respective institutional functions, Article 39 of Law 833/1978 transiently confirms the instrument of the convention until the reform of the university system and medical faculties. In this sense the conventions are part of the regional health plans as they govern the contribution of the medical faculties to the realization of the goals of the regional health planning. [\[2\]](#)

Law 833/1978 outlines two different organizational models of the university-hospital assistance link:

- the mixed model, managed by the local health units with regard to the use of the NHS care facilities by the faculty of medicine, which provides for the stipulation of specific agreements between universities and the region, and a further conventional agreement for implementation in the local area, of which the model type of agreement carried by the Ministerial Decree 9 November 1982.
- the university-run polyclinic that provides for the uniqueness of the conventional regional level, with a planning and operational value, aimed at a real integration of the university structures in the field of the NHS regulated by the DM 12 May 1986.

2.4.3. Integration between the activities of assistance, teaching and research:

Legislative Decree 502/1992, dedicates article 6 to the relations between universities and the NHS, establishing that, to meet the specific needs of the NHS connected to the training of post-graduates and to access to the managerial roles of the NHS, the universities and the regions stipulate specific protocols of understanding to regulate the methods of mutual cooperation.

The relationships in implementation of these agreements are regulated by specific agreements between universities and hospitals, local health units and scientific institutions for hospitalization and care. The ownership of university teaching courses is entrusted to managers of the facilities where it is carried out the training itself, in compliance with the memorandums of understanding that stipulate that the training of personnel takes place in a hospital. [\[2\]](#)

The AOU (Azienda Ospedaliera Universitaria – University Hospital Company) was established with the Legislative Decree 517/1999. In Italy they are characterized by a very quick development. It is seen the necessity of an effective relaunch of the medical faculties and the AOU, for allowing both to be set into the same conditions of developing the own specific mission, that is the integration of the general assistance program with the scientific didactic program of the medicine faculty. [\[2\]](#)

The AOU can and must be the instrument for eliminate malfunctions and to recover the economic and clinic efficiency, integrating the most classical aspect with a new interest in the innovation, the research and the didactic.

Pursuing a research of excellence, at the same time that providing activities of assistance and teaching, the Scientific Institutes of Hospitalization and Health Care (*IRCCS - Istituti di Ricovero e Cura a carattere Scientifico*) are born.

Legislative decree no. 288 defines the IRCCS as "bodies of national importance with autonomy and legal personality which, according to standards of excellence, pursue research purposes, mainly clinical and translational, in the biomedical field and in that of the organization and management of health services, together with hospitalization services and high specialty care". [\[2\]](#)

3. Scientific Institutes of Hospitalization and Health Care (IRCCS).

3.1. IRCCS general characteristics:

The Scientific Institutes of Hospitalization and Health Care (*IRCCS - Istituti di Ricovero e Cura a carattere Scientifico*) are hospitals of excellence that pursue research purposes, mainly clinical and translational, in the biomedical field and in the organization and management of health services. They also implement admission and treatment of high specialty or other activities, having the characteristics of excellence.

The “recognition of scientific character” is the procedure through which these emerging hospital realities, which treat particular national diseases, are qualified as IRCCS. This character confers the right to the use of a state financing, added to the regional one, aimed at exclusively accomplish the research activity related to the recognized subjects. [\[2\]](#)

According to the art. 13 of the legislative decree 16 October 2003, n. 288 and subsequent amendments and additions, the recognition of the scientific nature of public and private structures is subject to the possession on a valid basis, of the following requirements [\[2\]](#):

- Legal personality of public or private law.
- Entitlement to health authorization and accreditation.
- Low cost and efficiency of the organization, quality of the structures and technological level of equipment.
- Characteristics of excellence in the level of performance and health activity carried out in the last three years, or the technical or scientific contribution provided, in the context of biomedical research activity recognized nationally and internationally, in order to ensure higher quality of the care activity, attested by public structures of the National Health System.
- Excellent character of the research activity carried out in the last three years relative to the specific discipline assigned.
- Demonstrated ability to network with research institutes in the same area of reference and collaboration with other public and private bodies.

- Demonstrated ability to attract independent public and private funding.
- Quality certification of services according to internationally recognized procedures.

The scientific confirmation process is regulated pursuant to art. 15, paragraph 1, according to which every two years the IRCCS Foundations, the non-transformed Institutes and the IRCCS under private law, send their updated data to the Ministry of Health confirming the permanence of the legal requirements, in accordance with the provisions of annex B to the Decree ministerial 5 February 2015.

The IRCCS are of a different legal nature, public or private. The public IRCCS are public institutions of national importance subject to regional control and supervision by the Ministry of Health. The IRCCS under the public law, at the request of the region in which the Institute has the main site of clinical and research activities, can be transformed into foundations of national importance, open to the participation of public and private subjects and contingent on the supervision of the Ministry of health and the Ministry of economy and finance. The transformed entities take on the name of IRCCS Foundation.

On the other hand, the private IRCCS have greater freedom of action, and control over them is performed only on the value of the research implemented.

The main organs conforming the general institutes are the Board of Directors, the President of the Foundation, the General Director and the Scientific Director. The **Scientific Director** in the IRCCS is named by the Ministry of Health, in accordance with the President of the Region where the Institute is based.

The nomination of Scientific Directors is regulated by Presidential Decree 42 of 26 February 2007, following the changes introduced by Legislative Decree 288 of 16 October 2003 (although it did not provide for any specific procedure for the nomination of Scientific Directors of the IRCCS).

The regulation provides that the nomination takes place following a public call for tenders with reference to:

- Scientific production activities (impact factor, page rank, citation analysis, continuity of scientific activity, patents, etc.).

- Managerial capacity (management of research institutes, IRCCS, CNR, universities, private institutions, national or international, for a minimum of five years; organization and maintenance of laboratories and/or banks of biological material, etc.).
- Ability to organize research and national and foreign productive groups.
- Specific skills.

At the end of the selection the commission will indicate a list of three candidates, from which the choice will be made motivated by the Ministry of Health.

Annually, the IRCCS communicate the list of scientific publications in the respective recognition areas of the Health Ministry in order to allow the allocation of the annual resources of the current research.

Below there is an example of the evaluation criteria of the current research. The funding is divided according to these criteria [\[2\]](#):

1. Scientific production and relative efficiency and impact of the scientific production (55%).
2. Capacity of resources attraction (10%).
3. Assistance activity (20%).
4. Capacity to operate in network (10%).
5. Technological transfer (5%).

The activity of research that develop this type of centre, must necessarily find an outlet in therapeutic applications in hospitals. Their activity is focused in the well-defined research areas whether they have received recognition for a single subject or for multiple integrated biomedical areas. These are the research **areas**, indicated by the Ministry of Health [\[2\]](#), in which the IRCCS are involve:

- Cardiology
- Dermatology
- Image Diagnostics
- Pharmacology
- Gastroenterology
- Genetics

- Geriatrics
- Infectious diseases
- Complexity medicine
- Neurology
- Neurorehabilitation
- Ophthalmology
- Oncology
- Orthopedics
- Pediatrics
- Psychiatry
- Rehabilitation

In Italy it can be found 51 IRCCS in the national territory, including 21 public and 30 private, referred to different areas. [\[2\]](#)

3.2. IRCCS Carlo Besta institute:

3.2.1. Besta framework and context analysis:

The IRCCS Carlo Besta Neurological Institute Foundation, of national importance and founded in Milan in 1918, is statutory as a participation Foundation, in which the subjects represented on the Board of Directors take on particular importance. The Besta Foundation counts the Lombardy Region, the Ministry of Health and the Municipality of Milan among the Founders which have a specific representation within the Board of Directors. [\[11\]](#)

It became a public body in 1923 and underwent considerable development in the early 1930s. In 1935 the first pediatric neurology clinic in Europe was created within the Institute. The clinic eventually became a Department and was further expanded in 1960. In 1952, the Institute was designed “Specialized Institute for Research and Treatment” of neurological disorders and in 1981 was recognized as I.R.C.C.S. by the Italian Ministry of Health. In 2006, and with the support of the Region of Lombardy, Italian Ministry of Health and Municipality of Milan, the Institute became a Public Foundation. [\[11\]](#)

In June 2009, an agreement was signed stipulating the entry of the 'Mariani' Foundation into the "Carlo Besta" Foundation as the first private participant alongside the public Founders.

The Besta Foundation is a recognized centre of excellence for neurological research and the treatment of the major neurological diseases. The Institute is the national and regional reference point of numerous ultra-specialist centres for the treatment of specific neurological disorders. The fundamental objective of the overall activity of the Foundation is to respond to the need for health according to criteria of quality, ethics, efficiency and scientific innovation, having as value reference the centrality of the person. [\[11\]](#)

In the regional and national health framework, the IRCCS Carlo Besta Foundation stands as a centre of excellence for the research and treatment of the most significant neurological diseases. The Besta combines in a synergistic way the activities of scientific research, diagnosis and treatment - which give rise to a continuous improvement of therapeutic efficacy - in the field of clinical and basic neurology and deals with the neurological disorders of adults and children, of neurosurgical and oncological pathologies, of chronic and rare diseases.

The **clinical area** in which the centre is developed is the neuro-oncology area. It has been growing and nowadays it is organized in a functional department. The department of neuro-oncology includes all the branches of brain tumour's diagnosis and therapy, aiming to the best integration of disciplines to ensure complete care of patient.

The **research area** involves a wide range of projects in clinical and laboratory research. The major focus is on glioblastoma and other malignant gliomas. One area of growing relevance relates to the novel use of ultrasound devices to improve identification of tumour borders.

The IRCCS Carlo Besta pursues the following fundamental goals: health care and biomedical and health research, clinical and care-oriented (translational research); development and implementation of vocational training and health education programs; support to universities (pre and post graduate education and training);

testing of innovative forms of management and organization in the health and biomedical research fields. [\[11\]](#)

3.2.2. Besta general organization:

The structure of the institute includes a President, a Board of Directors, a Board of Statutory Auditors, a General Manager and a Scientific Director. There is also an Administrative Management and Health Department.

The Board of Directors and the Technical Scientific Committee respectively assist in the activity of the General Management and the Scientific Direction.

In Figure 5 is represented a simplified scheme of the general organization, approved by the regional organ with DGR X/6250 of 20 February 2017, currently being implemented. [\[11\]](#)

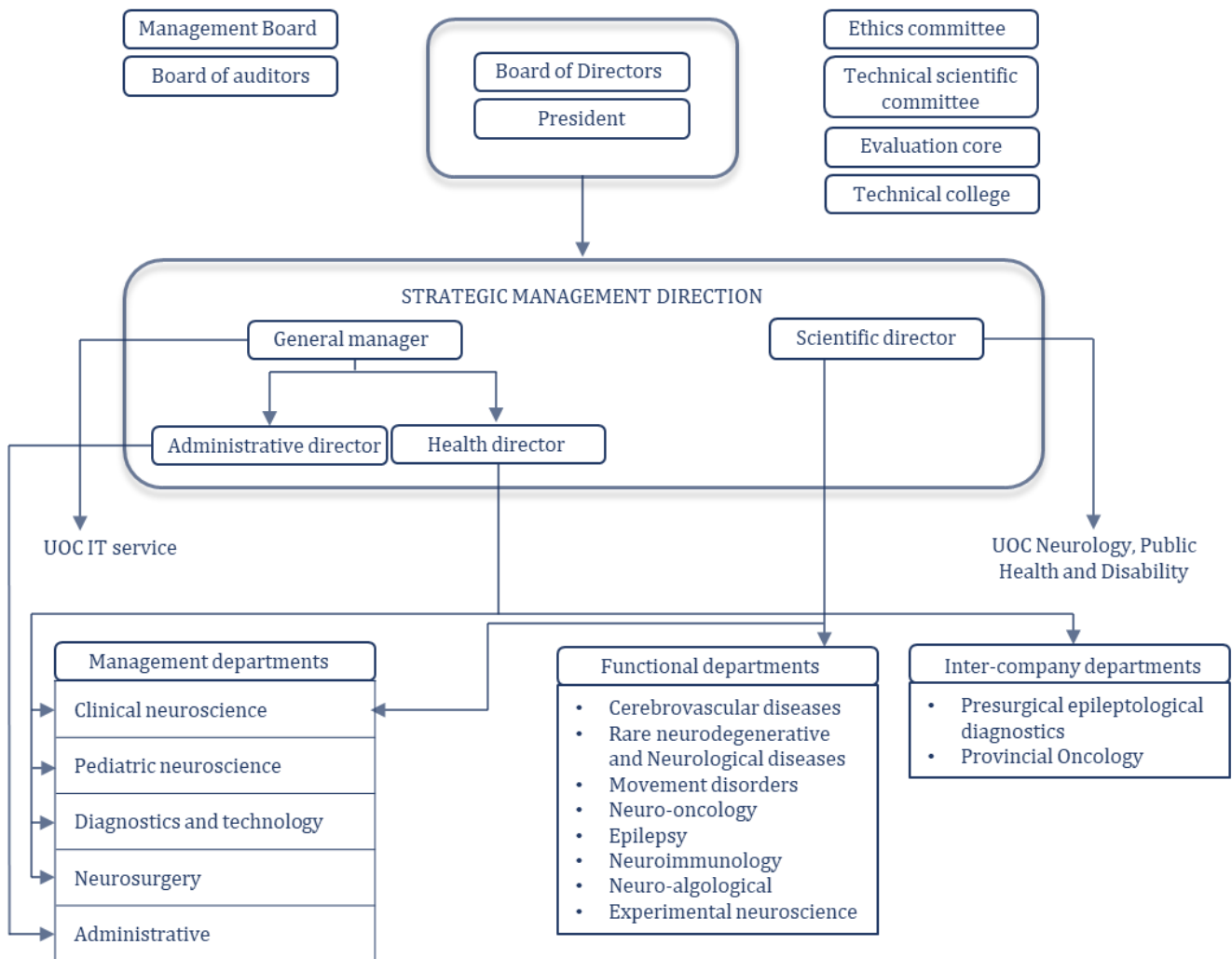


Figure 5: Actual organization structure. Source: Commissione Besta 2018, Ministero della salute.

The research activity is driven by the **Scientific Direction**. The Scientific Direction, in the person of its Scientific Director (Tagliavini Fabrizio), programs, directs and coordinates the scientific research activity in the biomedical translational and public health field according to the indications contained in the Legislative Decree 16 October 2003, n. 288 and in line with the health research program referred to in article 12-bis of Legislative Decree n. 502 of December 30, 1992 and subsequent amendments as well as regional planning on the matter.

Its main function is to promote and coordinate the strategic and programmatic lines of research, organizing its activity with particular attention to the translational aspects and innovation, the network collaboration activity and the pre-clinical research development activity, and of the clinical research of which it is guarantor of the accomplishment and the ethics of execution. It also promotes and coordinates initiatives and research activities in the field of public health and disability and, in conjunction with the Health Department, preventive and rehabilitative medicine. Particular attention is given to teaching and high scientific training. [\[11\]](#)

The IRCCS uses a complex organizational model with departmental organizational character (Table 3), divided into Management, Functional Technical-Scientific and Intercompany Departments.

		Functional Departments		
Management Departments	Administration	Clinic Area	Preclinic Area	Intercompany
	Neurosurgery			
	Clinic Neuroscience			
	Pediatric Neuroscience			
	Diagnostic and Technology			
	Research and Clinic Development			

Table 3: Departmental articulation of the IRCCS Carlo Besta.

The **Departments**, characterized by the assignment of a single budget and the integrated use of resources, including Complex Operating Units (UOC), with the respective Simple Structures (SS) and Simple Departmental Structures (SSD) which have organizational and managerial autonomy of human resources. The

responsibility of the Department is entrusted by the General Manager to a Director of UOC related to the same.

The organs by which the Departments are composed are the department Director, department Committee, department Regulation and the Resources assigned to the operative units. [\[29\]](#)

3.2.3. Besta assistance activity:

Clinical-assistance activity is carried out by the different departments. It is organized in different assistance settings: ordinary and day hospitalization, outpatient services, complex outpatient services and outpatient packages (services provided in one or two days of access to the Institute).

The activity of the department of Clinical Neuroscience is strongly integrated with the diagnostic and research structures; an important sector of the Institute's activity concerns the diagnosis, therapy and research in the field of Rare Diseases.

National and international collaborations have allowed the drafting of guidelines, including those for the treatment of epilepsies in children and those for clinical management of the most frequent form of Neurodegeneration with Brain Iron Accumulation.

The pathologies for which there are hospitalizations at the Institute appear perfectly in agreement with the thematic area of accreditation of the IRCCS. Welfare excellence is also demonstrated by the high proportion of hospitalizations coming from outside the region, which for some DRGs reaches 50%. Giving some numbers, in 2017 the number of ordinary recoveries were 5682 while the index of bed occupancy was 68.86%. [\[11\]](#)

3.2.4. Besta research activity:

The Institute is recognized as a centre of national and international excellence in the field of neuroscience - neurology, child neuropsychiatry, neurosurgery and rare diseases, for adults and children - both in terms of assistance and field of clinical and preclinical research.

The integration of these two sectors, assistance and research, offers people with neurological diseases the best treatment and health possibilities and has been a special feature of the Institute since its foundation in 1918.

As the Besta is a national and regional reference centre for numerous pathologies of choice, for which it is able to offer pathways of diagnosis, treatment and taking charge of excellence, especially for those rare or particularly complex pathologies that require diagnostic skills through advanced approaches to technology and highly qualified personnel involved in continuous specialist training processes.

Regarding the research activity, it is developed in the field of neurological sciences of adults and children, of neurosurgery and advanced technologies, as thematic area of recognition [\[11\]](#). There are four main **research lines** as follow:

- Preclinical Experimental Neurology. This line of research is devoted to the study of the molecular bases and the pathogenetic mechanisms of neurological diseases, to the identification of biomarkers and new therapeutic targets, and to the development of innovative treatments in cellular, animal, cell-free and in silico experimental models. The diseases of interest include epilepsies, brain tumours, degenerative, immunomodulated, metabolic, cerebrovascular, neuromuscular, neuropathic pain and hereditary rare diseases. These activities are integrated with clinical research within the Functional Departments and go hand in hand with the development of new models and experimental technology platforms.
- Pathogenesis of Neurological Diseases. This line is aimed at the clinical, instrumental and laboratory (biochemical, genetic and morphological) characterization of patients affected by diseases of the central and peripheral nervous system and of the muscle. The pathologies of interest include epilepsies, neurodegenerative diseases, immune-mediated diseases, cerebrovascular diseases, neuromuscular pathology, tumours of the nervous system and diseases of brain development. The aims of this line are the accurate definition of phenotypes and the identification of molecular bases and pathogenetic mechanisms, with the goal of obtaining more timely and accurate diagnoses and more effective therapies.

- Clinical Trial in Neurology and Neurosurgery. This research line is dedicated to the conception, management and implementation of clinical trials in neuroscience. The studies are focused on epilepsies, diseases of brain development, neurodegenerative diseases, movement disorders, neurometabolic, neuroimmunology diseases, neuropathic pain and cranio-facial pain, cerebrovascular diseases, rare diseases and nervous system tumours. Furthermore, experiments are carried out aimed at innovation in the field of bio-imaging, advanced neurophysiology and neurosurgery, and the development of cell therapies and gene therapy.
- Outcome research: from indicators to Clinical Recommendations. The primary objective of this line is the experimental verification and the transfer of research results to clinical practice, orienting the use of interventions, diagnostic-therapeutic and operative procedures, of proven efficacy and safety. It produces high quality results with the aim of ensuring that the decisions of doctors, patients and policy makers are well informed by the best available evidence derived from pre-clinical and clinical research, with particular focus on degenerative, immunomodulated, metabolic diseases, vascular, oncological, pain, epilepsy and rare diseases. It includes collaborative studies with IRCCS, Regions, ATS, Population Registers, international organizations (such as EAN, EuroBioBank, Cochrane, WHO) and national and international patient associations. The goal is to ensure that the resolutions of healthcare professionals, users and policy makers are based on the best available evidence and that the diagnostic, therapeutic and care interventions implemented are proven to be effective and safe.

The following **departments** are responsible for the Scientific Direction [\[11\]](#):

- Scientific Library: The Scientific Library, with a considerable book heritage, is specialized in the field of neuroscience and works in support of clinical-assistance and research activities, facilitating access to biomedical information to Foundation personnel and all health professionals.
- Neuroepidemiology service: The Neuroepidemiology Service has been dealing for years with clinical neurological research promoting

epidemiological investigations of an evaluative nature - clinical trials, accuracy of diagnostic tests, validation of outcome measures - and descriptive, such as case-control and cohort studies. Research activities are carried out nationally and internationally and in cooperation with the Foundation's researchers and clinicians. The main areas of activity are the Nervous System Tumour Registry, Outcome Research, Clinical Trials on Complex Healthcare Interventions. The Neuroepidemiology Service also houses the editorial base of the Cochrane Multiple Sclerosis Group and rare diseases of the central nervous system.

- UOC Neurology, Public Health and Disability: The UOC Neurology, Public Health and Disability deals with research, scientific consultancy and training in the context of the definition of policies, socio-health pathways, validation and identification of classification tools, assessment and measurement, health research and impacts social diagnosis and treatment of neurological diseases. The research area is that of disability, social health and public health policies. In particular, the UOC deals with disability in neurological diseases of adults and children, can provide scientific advice for the development of research in multiple sectors and therefore collaborates with: Research centres for specific projects, Scientific societies, Associations and patient organizations, Universities, ASLs and Hospitals. In the area of disability, the UOC is also a consultant to government agencies, WHO (World Health Organization), the European Commission, the Ministry of Labour and Social Policies and the Ministry of Health.
- Department of Clinical Research and Development: The Clinical Research and Development Management Department was created to optimize the management of Clinical Trials and disseminate the culture of clinical research conducted according to Good Clinical Practice (GCP). The Clinical Research and Development Management Department supports the Foundation's researchers in their research and laboratory activities, offering the possibility of a comparison with personnel with experience in both administrative and scientific fields. By constantly interfacing with the Secretariat of the Ethics Committee, it facilitates communication between the

latter and researchers who intend to start a trial and therefore require their approval.

The department is related to the Scientific Direction, with the aim of optimizing the management of Clinical Trials, which constitute a significant activity, the reorganization and rationalization of laboratory medicine activities in four Technological Platforms and the realization of a Biomedical Engineering Platform to coordinate engineering, physical and bio-computer activities. [\[11\]](#)

- The Technical Scientific Committee (CTS): The Technical Scientific Committee is appointed by the Board of Directors upon proposal of the Scientific Director who chairs it. The CTS meets at least once a year upon call by the Scientific Director, or at the request of a third of its members or of the Chairman of the Board of Directors. The CTS is informed by the Scientific Director about the activities of the Foundation and formulates advisory opinions and proposals to the Board of Directors on the programs and objectives of the Foundation, with regard to those of a scientific and technological development nature.
- The Technical Scientific Secretariat of the Ethics Committee: The Ethics Committee is an independent body, made up of internal and external members whose job is to protect the safety, integrity, rights and well-being of all the subjects participating in clinical trials by expressing an ethical and scientific opinion before of the start of any clinical trial.

The Scientific office is composed by the offices showed in Figure 6. In particular it is interesting for the development of this project, the role of the department of the **Research Office**. It deals with management and monitoring of research activities and relations with the Ministry. Normally manages the projects of research financed by national and international public and private bodies and won by the Foundation a follow-up of participation in specific calls; when funding involves a clinical trial interacts with the Department of Clinical Research and Development.

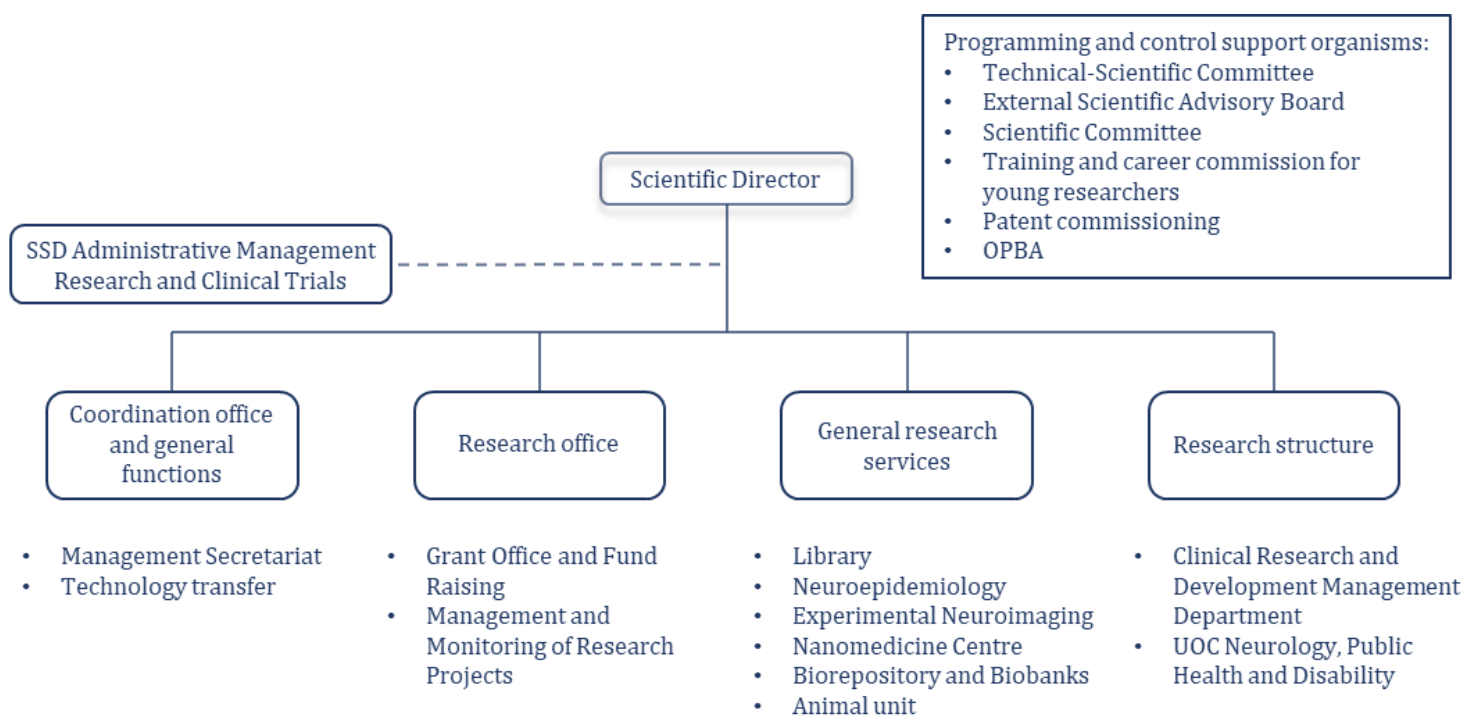


Figure 6: Organization of the Scientific Direction.

3.2.4.1. Besta activity and the university:

The IRCCS Neurological Institute "Carlo Besta" Foundation has always carried out an important and intense training activity in the specific field of neuroscience promoting the cultural, professional and human growth of the researcher at various levels.

From this point of view, the Foundation has developed and consolidated collaboration agreements with some of the most important national universities and research and care centres. It is involved in the elaboration and implementation of advanced training programs in neurology, neurosurgery and neuroscience and has been active for years with numerous universities, specialization schools, research doctorates and second level university masters. At European and international level, it participates in exchange programs (ERASMUS, Marie Curie Action) aimed at training young doctors, biologists, etc. The Besta NeuroSim Centre deserves special mention in this regard, the first training and neurosurgical simulation centre in Europe.

The activation of the agreement with the University of Milan represents an aspect of primary importance in the medium and long-term programmatic vision, as it offers the possibility of selecting future doctors, biologists and researchers able to continue the path of excellence that has placed the Besta Foundation at national tops. Through the agreement signed in July 2017, the Besta makes a decisive contribution to the training of doctors and researchers in the area of neuroscience, providing the clinical and experience heritage to students, post-graduates and graduate students in Neurology, Neurosurgery and Child Neuropsychiatry scientific. The agreement concerns the single cycle master's degree course in Medicine and Surgery, for the educational activities that qualify the neurological and neurosurgical curriculum and for the specialization courses in Neurology, Neurosurgery and Child Neuropsychiatry.

Training courses have also been active for some years with High Schools of Secondary Education as part of the activities planned for the School-Work Alternation. [\[11\]](#)

3.2.4.2. International relationships and participation in organism and institutions:

The progressive internationalization of socio-economic systems is increasingly concerned with the health sector.

The indications contained in the strategic lines and programming of the Lombardy Region (D.G.R. of 26 November 2008, n. 8501) underline the need to develop the so-called "Health alliances" for a positive internationalization of the health system, as well as governance models of Research and Technological Development set according to the logic of subsidiarity and, therefore, with the role of first actors of all the subjects that constitute the regional health system.

The IRCCS Foundation Neurological Institute Carlo Besta as a leading centre in neuroscience, contributes to these strategies with innumerable initiatives of international level and is part, among other things, of the H.P.H. (Health Promoting Hospital), a project of the World Health Organization aimed at promoting health.

In the context of international twinning experiences, the Besta Institute has ongoing and studying health cooperation projects in depressed areas, underdeveloped or characterized by particular pathologies or health emergencies.

These multiple relationships have also guided the organizational choices.

The Business Organization Plan for the years 2008 - 2010 (*POA – Piano di Organizzazione Aziendale*), among the organizational functions of the Foundation's staff, has identified a specific function of coordination of international relations.

The activity is carried out in a function of supervision and coordination of the various initiatives of international level both in the clinical field, and in the scientific research to be carried out directly under the Presidency and in close collaboration with the General Management and the Scientific Direction.^[11]

The Foundation, in accordance with its mission, has established and participates, with other public and private structures, in various consortia/associations/companies, such as 'Ce.rt.S.Ma.S', 'Association for Clinical and Rehabilitative Neuroscience', 'CNAO Foundation' or 'Terranuova Bracciolini S.p.A. Rehabilitation Centre'.

The Foundation also participates, as a member, in various associations including 'Italian Federation of Healthcare and Hospitals', 'Alliance Against Cancer Association', 'Disability Italian Network', 'Italian Diagnostic Centre S.p.A.' and 'A.O. San Carlo of Milan'.

These relationships with organisms, both national and international, contributes to the development and expansion of the research activity that undertakes the foundation.^[11]

4. Performance Measurement System (PMS):

4.1. Introduction about the Performance Measurement Systems:

Performance measurement is the process of collecting, analyzing and reporting information about the performance of an individual, group, organization, system or component [\[17\]](#). A performance measurement system can be defined as the set of metrics used to quantify both the efficiency and effectiveness of actions.

Over the past years, the global business environment which is becoming more and more complex and the increasing business competitiveness, have revealed the importance of performance measurement. Performance measurement methods have been extensively adopted and had received more and more attention. [\[18\]](#)

A performance measurement system (PMS) is a system in the purpose of improving the organization performance. It creates a very important connection between organizations due to the measurement in the organizations system which is straightly related with the organization strategy [\[19\]](#). A well design and developed PMS helps the organization to improve the decision-making process in the business environment. They are characterized as strategic expert systems by which organizations can observe and measure their tangible performance elements in the form of quantitative assessment. In particular, it is a brief and precise set of measures that can be financial or non-financial and that supports the decision-making process of an organization by collecting, processing and analyzing quantified data of performance information. [\[20\]](#)

There are lot of different performance measurement system models, that are established in the business world. They use very different tools and techniques, among which one of the most successful one is the Balanced Scorecard (BSC). It was developed by Robert Kaplan and David Norton in 1992 [\[21\]](#), to provide a better measurement of the organization. It produces a measurement model in the performance management that overcomes the weakness of traditional financial measurement systems. The BSC not only helps to review the existing performance, but also to improve the future of the organization.

4.2. The Balanced Scorecard (BSC):

The **balanced scorecard** is a strategic planning, management and performance metric, which is used to improve the internal business functions and their outcomes. Organizations use it to set the company goal while aligning the day-to-day work with the company strategy. It helps in measuring and monitoring the progress towards the strategic goal.

The balanced scorecard provides a framework for managing the implementation of strategy while at the same time allows the strategy itself to grow in response to evolutions in the company's competitive market and the technological environment. The balanced scorecard reaffirms the relation of measurement to strategy and the cause-effect linkages that describe the hypothesis of the strategy.

The balanced scorecard supplemented the financial measures that are traditionally used in companies, summing the other three perspectives which are customers, internal business processes and learning and growth. It supports the tracking of financial results while at the same time monitoring the progress in building the capabilities the company needs for future growth.

The balanced scorecard fills the gap that can be found in traditional management systems, that is the inability to link the company short term activities and actions with the long-term strategy. In order to do it, the balanced scorecard introduces four new management processes. [\[22\]](#)

The first new process 'translating the vision' help managers to build a consensus around the organisation strategy and vision. The second process 'communicating and linking' allows managers to communicate the strategy at all levels of the organization and link the objectives of the individuals and the departments. The third process 'business planning' facilitates companies to integrate their business and financial plans. The fourth process 'feedback and learning' gives companies the capacity for strategic learning.

With the balanced scorecard as the centre of the management system, the companies can monitor short-term results from all the perspectives. It also helps companies to modify the strategies to reflect real-time learning. [\[22\]](#)

The balanced scorecard gives the three elements that are basic for strategic learning. It articulates the company's shared vision, supplies the essential strategic feedback system and facilitates the strategy review that is essential to strategic learning.

Companies are mainly using the balanced scorecard to:

- Keep the strategy updated.
- Communicate the strategy at all levels of the organization.
- Align the individual and the departmental goals of the organization.
- Align strategic objectives with long-term targets and annual budgets.
- Develop performance reviews periodically to improve the strategy.

The balanced scorecard was introduced to provide a framework for describing the value-creating strategies that link intangible and tangible assets. It does not want to value the organization's intangible assets, but to measure them in units other than currency. [\[21\]](#)

4.2.1. The four perspectives in the balanced scorecard.

The balanced scorecard implements a structure for organizing the objectives of a company into the next four different perspectives [\[21\]](#):

1. *Financial*: the whole company strategy regarding the incurred risk, the profitability or the future expected growth, is seen from the shareholder perspective. The objective is usually the increase in the shareholders' value, typically following the approaches of increasing the revenues and productivity.
2. *Customer*: this is the strategy for generating value and differentiation from the customer perspective. The customer value proposition is usually the center of any business strategy. It describes the product, service, price, relationship and image that the company offers to the customer. It also identifies which are the planned outcomes from the offered value proposition.
3. *Internal business processes*: defines the strategic priorities of the business processes that generate value for the customer and the shareholders

satisfaction. It sets the organizational activities that are critical for delivering the value proposition.

4. *Learning and growth*: the importance to create the conditions for supporting the organizational change, innovation and growth, which are defined by the managers. It includes defining the employee's capabilities, the corporate climate or the technology to support the strategy.

Organizations, when moving to a Balanced Scorecard from a traditional Performance Measurement System, built on the basis of classifying the already existing measures into the four mentioned categories.

4.3. From traditional PMS to BSC in healthcare systems.

When firstly implementing the Balanced Scorecard to other than the traditional organizations, it was a challenge to apply the traditional BSC to nonprofits or government organizations. They tried to take the mission of the organization and develop their work in the most efficient way. Taking into account the particular case of the health organizations, the development of a balanced scorecard for this kind of institutions needs to adapt to them, to get a successful use of it.

The healthcare systems are particularly complex due to the heterogeneity of their activities, entities or processes and the involvement of patients, researchers, clinicians, also the government or other professional. [\[23\]](#)

The use of BSC in the health care sector has increased, primarily because it can accommodate the complexity of healthcare organizations, by developing a multidimensional system to measure and manage organisational effectiveness. The BSC has been discussed for years as an appropriate tool for healthcare organizations. Several authors suggested methods for implementing the model, while others noted that the BSC should be modified for reflecting the reality of this organizations [\[25\]](#). In particular, examining the cases in which the BSC has been applied to health care institutions, it can be identified that some cases used the original structure, others used a partial version of the BSC but keeping the

architecture and other cases completely change the original framework, both in number and type of perspectives.

4.3.1. Applying the BSC to research hospitals:

For complex organizations as the research and teaching hospitals which are characterized by management complexity, organisational fragmentation or inefficiency issues, the BSC has proven to be an effective tool for linking the strategic goals with the mission while involving the corresponding personnel.

Public research institutions are particularly characterized by the presence of a high number of stakeholders, each one with particular different need, and the production of research and development activities that requires taking into account multiple goals of multiple stakeholders. [\[24\]](#)

One differentiating thing between the private sector and the public organization is the need to search for research funding. In Government funded research institutions, such as public research institutions, the research activity represents the core mission of the organization and it needs to be financed. This structure implies two main things. On one hand, there is a central role played by the research activity. On the other hand, there is an essential need to look for funding, while at the same time demonstrating the ability to generate research outputs and value for the society.

As presented in the examples in (*Trotta, 2013*) [\[25\]](#) they illustrate how university hospitals have been able to reduce costs and resolve financial crises. In some cases, the adoption of the BSC has increased hospital performance in terms of the satisfaction of the patients and healthcare professionals and in terms of average costs reduction. Here it is exposed that when applying the BSC to teaching and research hospitals, the traditional architecture needs to be modified, adapting the different perspectives to the particular mission that characterizes this type of organizations.

Two of the examples from which results are extracted in the previous mentioned paper, was the application of the BSC to two hospitals: the *European Institute of*

Oncology and the *Ospedale Pediatrico Bambino Gesù*, both organizations known as IRCCS. [\[25\]](#)

Most of the studies include a completely revised framework with additional perspectives, according with the mission proposed for each one. The proposed framework of this study presents five different perspectives including some traditional ones and transforming or adding some others, resulting in a schema composed by: stakeholder, financial and economic, teaching, care, research and innovation and growth perspectives. [\[25\]](#)

These results show that the BSC needs to be modified for being applied in these particular organizations, taking as a reference the particular mission of each one and customizing the different perspectives to address the objectives of these organizations.

Later on, it is important to choose the indicators that represent the objectives and the strategy of the organization, considering the kind of service offered and the personnel involved. The ideal framework should include a balanced number of financial and non-financial indicators of the interrelated dimensions.

Other example appears in the study developed in the haematology department of a research hospital (*Catuogno, 2017*) [\[23\]](#), where they use a participative methodology for developing a BSC. Their mission was to provide the patients with a high-quality care service, so having this in mind they also changed the traditional perspectives into these ones starting from the top: stakeholder satisfaction, care process, research process and financial perspective.

What emerges from the study of these cases, are for example some difficulties, gaps or advantages when applying the BSC to this kind of hospitals. Some general difficulties reported are for example that there is not a unique model that could be used for all the cases, but it needs to be customized for the one under study. Also, that this kind of organization are usually linked to the government and the need to meet some objectives to take into account.

The main gap reported is that usually these organizations do not have a strategic map to clearly communicate the strategy, so they do not have a strategic direction or clear goals to follow.

Finally, they reported different advantages some of them aligned with the general advantages coming from the use of the BSC, as it puts together the financial and the non-financial parts, it can be used to monitor the activity of a department in a dynamic way along a period of time, it can be used to communicate at different levels of the organization and it is also a multidimensional tool.

For this project, it will be developed a BSC for the research office department of the IRCCS Carlo Besta, following the guidelines emerged from the literature and thanks to the future application of an IT system that will help to use existing data more effectively, to assist in establishing new data bases and to collect new data.

5. Research questions:

This work was born to give answer to a necessity proposed by the Scientific Office of the hospital IRCCS Carlo Besta. To be able to answer to this need, first it is important to understand the environment in which this work has been developed, doing a deep research in the literature of the Italian National Health System, the IRCCS Carlo Besta and its structure.

The Italian National Health Service provides healthcare to all citizens by a mixed public-private system. The Scientific Institutes of Hospitalization and Health Care (IRCCS) are public or private hospitals of excellence inside the Italian health system structure. The IRCCS Carlo Besta is a public recognized centre of excellence for neurological research. This project has been developed inside the Scientific Direction, in the department of the Research Office. It deals with the management and monitoring of research activities and relations with the Ministry. Inside the Institute it is developed a training activity, promoting the cultural, professional and human growth of the researcher at various levels, for which the hospital can be said to develop the triple mission: assistance, teaching and research.

The objective of this project is the development of a performance measurement system, inside the Research Office of the IRCCS Carlo Besta. A performance measurement system is a system in the purpose of improving the organization performance. One type is the Balanced Scorecard, which was first developed by Kaplan and Norton and which was composed by four main perspectives (i.e. financial, customer, internal business processes and learning and growth). This one was first developed in traditional industrial organizations, but what can be learnt from studying different literature is that this traditional organization of the Balanced Scorecard does not fit when it is applied to research and teaching hospitals. Literature shows that other perspectives need to be taken into account, depending on the main mission of the hospital. Also, the order of the perspective must change because in an institution like these ones, the financial perspective is not the most important one, or the one that is closer to the mission. For complex organizations as the research and teaching hospitals, the BSC has proven to be an effective tool for linking the strategic goals with the mission while involving the different personnel.

From the analysis of the literature, there is not an answer for the application of the BSC to a Research Office inside an IRCCS, in charge of the management of the research projects.

Moving to the objective of this project and the development of the performance measurement system, some different questions have been presented, for being able to obtain the necessary information to meet the objective. First the general question about *what a performance measurement system is*; then other questions related to the performance measurement system in research hospitals as for example, *how to apply this performance measurement system to this kind of institutions or how they need to be changed in order to fit to the special characteristics of this organizations*.

These questions were easy to answer, but if it is asked a more specific question as *how to transform the performance measurement system for being applied to the Research Office of an IRCCS*, there is no a clear answer in the literature.

This means that this project could help to give answer to this question, developing a completely customized performance measurement system for the specific Research Office, with the help of the related literature that give answer to the other questions.

6. Development of the work:

6.1. Methodology for the development of the project:

The methodology followed for the development of this work, started with and exhaustive analysis of the **literature**, in order to understand the context and gather all the necessary information for answering the questions.

The development of this project consists of a collaboration work with Research Office of the IRCCS Carlo Besta, and together with a team that in parallel is in charge of a project consisting on the development of an IT system for managing the research projects. The system is done in order to answer the needs and the specific requirements collected during the different meetings and interviews.

For understanding the situation of the hospital and the necessities, it was extracted different information from **interviews** previously done by other team members, to clinicians and other personnel involved as for example the Research Office. The different interviews have been considered in order to understand the problems, necessities or other important information useful for the evolution of this work. The interviews to clinicians were developed in the same way, following the lines of intervention previously defined.

The information obtained from the interviews was then decomposed and analysed, to isolate the relevant information and be able to understand the needs and the requirements of the personnel.

Different **meetings** were then developed with the personnel involved in the research, economic and scientific office, and the company who was in charge of the development of the software (WEBRATIO) [\[16\]](#). The participation to these meetings has been important in order to understand the environment, the requirements and the key measurers that are important for the personnel involved, for the future development of the BSC and the correspondent indicators.

All the work was developed in the office of the Scientific Direction and research department. This helped to get a deep knowledge of how they work and of the work they do, facilitating the work developed later.

Finally, a more autonomous work was done for the development of a performance measurement system, but always contrasting the information and ideas with the Research Office.

6.2. Introduction to the interviews and meetings:

A first meeting with the actors involved in the project, identified some general lines of action. Working in parallel with a team in charge of the development of the IT system for the management of the research projects, helped to understand the situation and the important indicators for the Research Office. Also, the understanding of the software and the report of information that it could offer, is useful for the development of the performance measurement system that comes later.

The **Research Office** of the scientific direction is in charge of the management and the monitoring of the research activities and projects. As they have expressed during the different interviews and meetings, it is necessary to structure the management process of the research projects that consider the entire life of the projects, from the presentation, the funding approbation, until the end of the project. The Research Office is the starting point of this process in which different offices and the different structures of the Foundation should be engaged. Each one, inside of the own competence, should be able to use, update and control the projects. This should allow the Research Office to have a panoramic view of the project phases, not only from a scientific point of view, but also from the funding utilizations. Also, the researchers must have access periodically to know the ongoing of the project from an administrative point of view (cost and deadlines). Right now, this is done through a telephone call to the Research Office, which slow down the work. For this reason, it would be useful that the potential system could allow the visualization of the updated funds status, shared with the researcher with customized personal access.

Recently has been defined by the Ministry a new contract type for the research personnel working in the IRCCS. This new contract will expose a critic situation regarding the alignment of the fund management, the contract duration and the division of the workload between the different projects.

Regarding the 'reporting' topic to the Ministry for the accreditation as an IRCCS and for the evaluation of the annual productivity, it is needed a system more structured that allows the management of the different data and the related reports. The Ministry provides a system for the management of bibliometric data (PURE) which is low efficient, and lot of publications must be added by hand in the system.

From an **administrative** point of view, it is not easy to manage. The budget tab contains the clinic indicators (for example the waiting time, the number of recoveries or the production revenues) and the performance indicators of the scientific activity. More than a half of the activities contained in this tab are introduced manually, spending lot of time.

The elaboration of reports is composed by several phases, which results in a complex process. For the cost management part, there is a partial integration with the software OLIAMM, a software used for the management of the economic data. It is needed an analytic accountability that subdivides the assistance activity for the single operative unit, activity of recovery/ambulatory/etc. And the research is divided into 3 sections: staff, current research and finalized research.

The hospital direction is towards the identification of the roadmap for the development in the next years, and a map of applications that have been installed in the last years inside the institute and the definition of the scenarios of integration. The objective of the project is the development of a performance measurement system that helps the research office, and for which the development of the software has been followed in order to use the data that can be obtained from it, to establish the indicators. For this reason, it is important to understand the functions of the software and the reasons why it has been developed.

Summing up, right now there is not a software that could allow for the institute:

- Having a vision or managing the entire project life (from the presentation, approbation of funding and the close and report of the project). An updated reading of the funds in an integrated way and shared with the project manager with personalized access levels.
- The instrument from the Ministry for the bibliometric data is not reliable and there is not an internal system.

- Everything is translated into an overload of the researcher activities and the administrative personnel.

The software will be developed in line of eliminating these criticalities and improving the experience of the tasks to be done in the lifecycle of the projects.

For more information and characteristics of Clinical research IT systems, goes to [Appendix I](#).

6.3. Interviews analysis:

The interviews to clinicians and other personnel, were developed. For the lines of interest, some **critical points** can be extracted:

- It is difficult to know the availability of funds, the control of the budget or the ongoing of the project without direct contact with the offices;
- Bureaucracy is too much detailed and time consuming;
- Request to be excessively punctual in the description of each activity;
- There is not an automated system to directly know the expenditures and the deadlines, for which they need to contact directly the offices;
- Lack of a system that allows a real-time monitoring of progress;
- Difficulty of monitoring the use of funds and understanding what the absorption of resources is, the costs must be associated with planning.

In particular, the actors involved ask for a system that should be:

- Shared system: a web based and multi-department system, that allows the management of research projects from the clinic department and the research laboratory.
- Flexible system: flexible in the management of the budget that is built along the different rules from the funder, through an instrument than could be configured in n different ways. The Research Office is the actor that pre-impost and personalize the mask (economic picture) individualising the parts of interest in the range of values allowed.
- Integrated with other management systems: integration with current systems and elimination of the solutions that can be substituted. In

particular, it is important the integration with the administrative system and the human resources system.

- Accessible with different degrees of activities: different access depending on the role.
- Extraction of reports of interest. This is a very important point, as the information from these reports can be use for the calculation of different indicators in the performance measurement system.

6.3.1. Critical sections of the projects.

During the meeting with the actors involved, some important issues were discussed such as which departments to include, the critical points or how to structure the different important parts of the research projects. It is important in order to structure the IT system according with the development of the projects and to report in each phase the important and useful data.

Three important **phases** can be identified in the projects:

- Planning: during this phase, it is defined the economic framework of the project. The project starts when the researcher “open” the project. Here there is a critical point because right now there is not a connexion with the office staff.

It is needed to include in the master system, not only the financing entity, but also the partners. The solution could be to do a single registry with the whole cast of funders (e.g. Ministry of Health). As each entity is different, it could be done a template which could be then customized.

It is also interesting to include some limits regarding the overhead of the project for the different operative units. The budget should be clearly identified (different levels and family).

Finally, it is also useful to include an alarm to give notice about the times and the possibility to print directly the reports.

- Negotiation: once the budget is approved, there is a period in which they discuss about if the project should or not go ahead.
- Financing: here it is discussed how the project is paid or how the money arrives. Also, the deadlines for the reports and the distribution of partners. It

is necessary to introduce a section in the IT system that allows to describe for example the participants in the projects, how they work in the time, the contracts or the possibility to select a person for more than one project depending on the availability.

It is interesting to introduce a timesheet of the project and a section to manage all the researchers in terms of costs (it is now done by an external software).

6.4. Software general characteristics and requirements:

The IT system proposed by WEBRATIO [\[16\]](#) has the objective of structure the current management of the research projects providing an aggregate view of its lifecycle (from the presentation, the financing approval, to the close and report of the projects).

The application will be accessible from the web browser without installation or license and will manage a profiling based on user roles. It will allow the management of research projects of different departments and their approval workflow, with the possibility of managing the budget, spending plan, personnel cost, funding and scientific and economic reporting. It will allow the users of the scientific Research Office to manage all the information of a project and the researchers to have access only to the projects in which they are involved, with the possibility to monitor the use of funds.

The system could be used as a repository of the attachments and the material of the projects, as well as the publications. Regarding external software, it is expected an integration with the actual system of accountability OLIAMM, in order to acquire directly the data from orders and invoices. A section dedicated to Reports, would allow to extract the information regarding the activity of the institute.

As mentioned before, different profiles could be created depending on the user and his role. Regarding this, Table 4 describes the level of **accessibility** of each user.

User/Role	Description
Research Office	View and manage project data of all departments.
Principal Investigator	For the projects in which he is involved, visualizes the information and the spending plan.

Complex economic and financial operating unit	View and manage the project spending plan and related financial reports.
Read only	Read-only access to information and to the spending plan of the projects of the departments associated to the specific user. This access can be used for other offices (Human Resources, Authority, etc.) that may need to access the system in consultation, without making changes.
Administration	User dedicated to the technical administrator of the system who accesses the management areas of application parameters and dictionaries.

Table 4: Role and access description to the IT system.

6.4.1. Functional requirements:

Furthermore, the functional requirements of the application areas being developed are described.

Users:

The **management of users** is done by the administrator, who could manage the application users indicating the name, surname, email and role. This will allow to create the account for each **user authentication**, so that they would have access to the application using their own credentials.

In the section of **parameters and dictionaries management**, it will be possible to manage the application parameters and the dictionaries (such as the list of departments, funding bodies, etc.).

Research projects:

The **research projects** involve all the users. The main section of the system will be dedicated to these, which will be divided into the following areas:

- Call for proposals: in this section the Research Office will be able to create a new project proposal. It will also be possible to create draft project proposals, visible only to the user who has created them. Once a proposal is ready to be presented to the funding body, the user will change its status and the project will move to the next section.

- Projects submitted to the financing body: this section will list the projects presented to the financing body in pre-proposal and proposal status, the projects being negotiated, and any projects not accepted. When the funding body accepts the project and it becomes active in all respects, the user will change its status and the project will move on the next section.
- My projects: in this section each user, based on their own profiling, will be able to access the projects accepted by the funding body and active in all respects.

Users of the Research Office will be able to access all three sections, edit and modify the projects of all departments of the Institute. Researchers will be able to access "My projects" section, viewing the projects in which they are involved, without the possibility of modification. Users of the Economic Financial Unit can access "My projects" section, viewing the projects of all the departments. Read-only users, on the other hand, can access the "My projects" section, viewing the projects of the departments to which they are enabled.

From the "Participation proposals in the call for tenders" page, it will be possible to create a new project by starting to fill in the data. Not all the fields of the project will be mandatory in this phase, but a subset of them that will be defined. To be able to effectively make a project active, the remaining mandatory data set will be required. It will also be possible to create a project that has already been approved from "My projects" page, in the event that someone wish to insert existing projects into the system bypassing the initial state changes.

From the project lists in the three sections it will be possible to access the detailed page of a project by clicking on the corresponding line. On the same lists, there will be a feature to extract the main data of the projects in Excel format. This is a very important step for later being able to use the information.

A research project consists of a series of fields and objects related to it, which can be compiled and inserted even at different times by users who have the permissions to act on specific objects. Some examples of the master fields of a project are the internal progressive ID, the project code, the project name, the type of research (if it is finalized or current), the responsible, the role in the project, etc.

On a project it will be possible to upload several attachments, specifying a description. The system will register the user and the file upload date. Even the Principal Investigators will be able to upload attachments to the project.

It will be possible to define the different loan instalments for a project by defining dates, amounts and status. It will also be possible to define transfers to the project partners if the Institute is the coordinator. In the event that OLIAMM also supplies the data of the loans and the transfers to the partners, it will be possible to directly acquire the information from this system, without the need to have to re-enter them also on the Intranet.

During the presentation and approval phase of the projects, it will be possible for the Research Office to compile the budget through a specific section within the detail page of the individual project. The budget will be defined by filling in a series of fields that will be dictated by the budget template chosen during the creation of the project.

In a special section of the administration area it will be possible to define the budget templates that can be selected during the creation of the project, based on the different rules of the funding bodies of the tender calls. A budget template will consist of a series of expense items with the relative percentages to be applied to the project amount.

It will be possible to define a single budget for the project but also different budgets for each operating unit and partner involved in the same, with rules that will guide the compilation with respect to the main budget of the project.

Changing a budget that has already been committed, will result in the historicization of the previous version of the budget. For each version the user and the date of compilation will be stored. It will be possible to export an Excel file with the items and amounts defined in the various budgets.

A separate section with respect to the projects, will allow managing the list of people who collaborate with the Institute, the participants, with the possibility of defining the beginning and end of the contract (even for non-consecutive periods), type of

contract or monthly final and forecast costs with and without IRAP (Imposta Regionale sulle Attività Produttive - Regional Tax on Production Activities).

Within the single project it will then be possible to associate the different people involved, dividing them into structured personnel, consultants or scholarships. With regards to the structured personnel, it will be possible to define the number of forecast and final hours dedicated to the project in the different reporting periods, inserting any additional rewards and resources, and calculating INPS (Istituto Nazionale della Previdenza Sociale – National Social Security Institution) and IRAP fees, if applicable. Regarding consultants and VAT (Value Added Tax) number, for each person can be defined the number of accesses to be made and performed in the various periods, with relative cost, with the possibility of inserting VAT, social security fund, etc. As far as scholarships are concerned, a cost can be defined for each period to calculate IRAP and INAIL (Istituto Nazionale Assicurazione contro gli Infortuni sul Lavoro - National Institute for Insurance against Accidents at Work).

Within the single project it will then be possible to define the project's expenditure plan. It will be possible to define an expense plan for each organizational unit involved in the project, which will be based on a calendar of economic reports defined by the appropriate fields inserted during the creation of the project. The expense plan will consist of the same items defined in the budget template, with the possibility of defining forecast and final amounts of each item. The total of all the forecast items will have to respect what is defined in the budget, while its subdivision on the different items may vary over time. For each change, the previous version of the expense plan will be stored, storing user and date of compilation.

For each item of expenditure and for each reporting period, it will be possible to define a forecast amount and, as far as the final balance is concerned, it is envisaged to directly query the OLIAMM database to recover orders and invoices, and associate them (through COGE – General Accounting - information) to the expense item for the year. It will also be possible to add extra expense items and related amounts.

Regarding the expense items related to personnel costs, the personnel costs will be calculated based on the participants, their involvement in the project and their cost

defined in the specific section dedicated to the project participants, declined on the different reporting periods.

Again, it will be possible to export the various expense items and details to Excel.

For a project it will be possible to define two types of reports: economic and scientific, as well as an end-of-project report.

As for the economic reports, the system will create a schedule starting from the project start date, based on the number of months defined on the project itself. Each report will have a submission deadline that will command an email alert to the project manager a certain number of days in advance of the expiration. For each report, the final amounts of the expense items defined in the expenditure plan (including personnel costs) relating to the period of interest will be listed, with the possibility of uploading an attachment and defining whether it was then approved or not. Also, the loan instalments arrived in that reporting period will be included in the single report. In the event that the amount of funding exceeds the amount of the audited certificate, a video alert will be shown.

About scientific reports, the schedule will be created when the user (Research Office) will specify whether to report by period or only at the end of the project. The project manager can then enter the individual reporting and fill in the data. An alert will inform the manager of the need to complete a report before its expiring date. For each scientific report it will be possible for the person responsible to associate files, and for the Research Office to set a flag to indicate whether it is approved or not. The end-of-period scientific reporting will be similar to periodicals, but without the need for a schedule.

Publications:

The users involved with publications will be the Research Office and the Principal Investigator.

A special section of the application will allow the Principal Investigators to insert publications related to research projects. A publication may relate to one or more projects, with the possibility for a project to have multiple publications associated with it. In the research projects the user will be able to choose from those of "current

research" of the operating unit to which the user belongs, and those of "finalized research" for which they are responsible or part of as a participant. It will be possible to enter the DOI (Digital Object Identifier) code to check the uniqueness of a publication, the name of the publication, the date of publication, an attachment and a description field of the publication itself. The inserted publications will then be shown on the detail page of the individual projects.

Quarterly income statement:

The user involved here is the Economic and Financial Unit. A special section of the application will be dedicated to the calculation of the quarterly income statement. The user will be able to select two fields "DAL" and "AL" and the system will calculate the cost schedule of all the projects for the selected period. The extraction will include the calculation of the personnel costs for the chosen period and the final expense items recovered by OLIAMM.

The report will be calculated in the background and an email will notify the user when the report is ready. The report will be in simple Excel format, in which all the projects will be listed with information regarding funding body, expense item, participant or amount in the form of a list.

Reporting:

All the users are involved in this section. The application will include a Reporting section from which to download aggregated reports of the projects managed in the application.

Depending on the type of user, the following will be considered:

- for the Principal Investigators, only the projects for which he is responsible,
- for the Research Office, all projects (with the possibility of filtering only those that involve trials),
- for Economic and financial Unit, only projects subject to second level audits.

The reports initially available will concern the number of projects presented in a given time period grouped by:

- Principal Investigator
- Financing body

- Keyword ERC (European Research Council)
- With the Institute as leader or partner
- With clinical trial
- State
- With partnership agreements to be made
- Subject to second level audits

There will also be a report on the next reporting to be made on all projects with relative status. Any other reports will be evaluated and listed separately at a later stage based on the need to monitor the progress of the research by the Research Office.

At the end there will be a software that:

- Is an instrument that can be used as a unique organization system for all the departments.
- Is an instrument that can be used by the personnel involved in research that can cover its necessities and accelerate some processes.

For the development of this work it has been important the knowledge of this software and understanding the why of each reported value. The next step is done thinking on the Research Office and the possibility to use this software for obtaining the necessary values to be used in the performance measurement system.

7. Development of the performance measurement system:

7.1. Mission and vision of the IRCCS Carlo Besta:

In order to understand the important measures or indicators that can help to explain the performance of the Carlo Besta institute and in particular where this project is focused which is the research office, first it has been analysed the mission and vision of the Foundation, developed in its performance plan (year 2019-2021).^[26]

The fundamental objective of the activity delivered by the Foundation is to respond to the need for health according to criteria of quality, ethics, efficiency and scientific innovation, having as a reference value the centrality of the person.

The Institute pursues the following fundamental purposes:

- carry out health care and biomedical, healthcare and clinical research and the research related activities (translational research),
- develop and implement professional training and health education programs,
- promote the professional growth of researchers by actively collaborating in post-graduate training in close contact with universities,
- testing and monitoring innovative forms of management and organization in the sanitary field and biomedical research,
- contribute to the increase of knowledge in the medical-scientific field,
- contribute to the definition of public health policies.

The objectives of the Research Office are aligned with the objectives of the Besta, in terms of the management of research. The Institute pursues the scientific excellence for care and research in the neurological area for which it develops in a synergic way both activities.

To improve the performance the Institute generates some performance objectives, some of which are also of interest for the area of the Research Office, such as the scientific and clinic excellence or the technological strengthening and digitalization.

Following these lines, it will be described the main perspectives and objectives starting from the top (the one more related to the mission) and then continuing with others that influence each other, with the objective of describing the important measures that are useful to monitor the performance.

7.2. Different perspectives, objectives and indicators of the Balanced Scorecard.

With the different performed meetings, data collected from the performance plans and following some guidelines provided in the BSC literature, it has been defined the set of different KPIs linked to the pursued strategy.

Following the main mission of carrying out a translational research, promoting the professional development of researchers and contributing to the innovation and knowledge, everything while pursuing the scientific excellence, the perspective and objectives described below are defined.

Each objective is born from answering to how the delivered value could increase thank you to the related activity delivered by the Research Office.

The chosen perspectives do not follow the typical approach, as for example placing the financial objectives at the top which is typical of the classic view, appears inconsistent with the aims of the research hospitals. For this reason, at the top are placed the most related with the mission of the hospital and in particular of the Research Office.

Table 5 shows the different perspectives and related objectives of the BSC

Perspectives	Objectives
Scientific knowledge growth	1. Contribution to the knowledge in the field medical-scientific.
Research process	2. To increase scientific and clinic excellence.
Financial	3. To reduce costs. 4. To increase research investments.
Internal processes	5. Compliance with the budget. 6. Compliance with deadlines for projects.

Innovation, learning and growth	7. To contribute to professional training 8. To increase technological empowerment, innovation and digitalization.
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Table 5: Different perspectives and objectives of the BSC.

Based on the strategic objectives, for each perspective it has been developed a set of key performance indicators (KPI). The indicators or KPIs are the values that will give information about the evolution of the performance. Each one is related with a different perspective and objective. Table 6 shows the different objectives for each perspective and the indicators.

Objectives	Indicators
Scientific knowledge growth perspective	
Contribution to the knowledge in the medical-scientific field	- Normalized Impact Factor - Transferability
Research process perspective	
To increase scientific and clinic excellence	- Number of success research projects - Number of excellent scientific publications - Number of active researchers
Financial perspective	
To reduce costs	- Project costs per point of IF
To increase research investments	- Fund raising - Research investment
Internal business processes perspectives	
Compliance with the budget	- Deviation of project budget
Compliance with deadlines for projects	- Number of deadlines budget met - Number of deadlines steps met
Innovation, learning and growth perspective	
To contribute to professional training	- Number of clinical researchers
To increase technological empowerment, innovation and digitalization	- Degree of software implementation

Table 6: Objectives of each perspective and key performance indicators.

7.3. Description of the Key Performance Indicators (KPI):

Table 7 shows the different KPIs with its corresponding formula, description, objective, target value, frequency, and origin of the value and the data.

Scientific knowledge growth perspective

Name	Normalized Impact Factor - IFn
Formula	<p>According to the Ministerial criteria [27] (Current research 2019-2021), each publication presented in the reporting phase of the current research is assigned a calculated IF, starting from the normalized IF value (IFn), applying the criteria relating to the type of publication and to the number / position of the authors.</p> <p>Each paper published in a magazine is given the IF of that magazine. "The raw IF of a magazine, in a given year, is the average value of citations that the magazine articles have obtained in the previous two years".</p> <p>IF is then normalized as described in section A.1 of the plan. [27]</p>
Description	<p>It represents the numerical-statistical indicator best known and used to categorize, evaluate, compare and order scientific publications, by which the scientific community measures the frequency with which an average article of a specific journal is cited by the other journals included in the database in a given year or time frame.</p> <p>The normalization of the raw IF is a criterion developed by the Ministry of Health, in particular in relation to the evaluation of the research of the IRCCS, in an attempt to solve the problem of different weight of an IF within the different disciplines.</p>
Goal	The objective is to increase the IFn with respect to the previous years.
Target value	IFn of current > average IFn of the previous three years
Frequency	This indicator can be revised annually.
Indicator origin	From the objectives defined for the hospital in the performance plan. [26]
Value origin	Calculation with the provided tools by the Ministry of Health. Target value obtained from the Besta performance plan. [26]
Name	Transferability - T
Formula	$T = \% \text{ of research projects that have an effect in the welfare}$
Description	Transferability refers to the degree to which the results of qualitative research can be generalized or transferred to other

	contexts or settings. It is the welfare effects of research products.
Goal	The objective is to increase the transferability and to be higher than a minimum target value.
Target value	$T > \text{target value (85\%)}$
Frequency	This indicator can be revised annually.
Indicator origin	From the objectives defined for the hospital in the performance plan. [26]
Value origin	From the analysis of the publications and the impact of them. Not all the publications can be considered, but those that produce guidelines, new techniques or that improve old ones, or those that increase the knowledge in one field. Target value obtained from the Besta performance plan. [26]

Research processes perspective

Name	Number of success research projects - NRP
Formula	$\text{NRP}_i (\%) = (\text{sum of projects passed during year } i / \text{sum of all presented projects during year } i) * 100$
Description	This indicator refers to the total number of research projects that have been developed with success during a year of reference. This indicator is aligned with the mission of the hospital of developing an activity of biomedical research, aimed at the cure of patients and the increment of the scientific and clinical excellence.
Goal	This indicator gives a percentage which is representing a success capacity. The objective in this case is to increase it with respect to the previous year, which would mean that the research success capacity is increasing.
Target value	$\text{NRP}_i > \text{NRP}_{i-1}$, where $i = \text{year}$
Frequency	This indicator can be revised annually.
Indicator origin	From the mission of the hospital defined in the performance plan. [26]
Value origin	This value can be obtained from the software and the timely calculations.
Name	Number of excellent scientific publications - NSP
Formula	$\text{NSP}_i = \text{sum of the number of scientific publications in journals with an IF in the upper quartiles during year } i$
Description	This indicator refers to the total number of scientific publications that have been published during a year of reference but takes only into account those that have been published in journals with an IF in the upper quartiles (Q1,

	Q2). This is a measure that for example also considers the Ministry of health. This indicator is aligned not only with the scientific and clinical excellence, but also with the contribution to the knowledge in the field medical-scientific.
Goal	The objective could be to increase this indicator for each current year with respect to the previous one.
Target value	$NSP_i > NSP_{i-1}$, where $i = \text{year}$
Frequency	This indicator can be revised annually.
Indicator origin	From the mission of the hospital defined in the performance plan. [26]
Value origin	This value can directly be obtained from the software.
Name	Number of active researchers - NAR
Formula	$NAR_t = (\text{sum of the number of active researchers during three-year period } t / \text{sum of the total number of researchers during three-year period } t)$
Description	An active researcher is the one that publishes at least 4 publications in the three-year period. This indicator is aligned with the objective of increasing the number of active researchers in the three-year period and the increase of scientific production.
Goal	The goal could be to increase this indicator for the current three-year period with respect to the previous three-year period.
Target value	$NAR_t > NAR_{t-1}$, where $t = \text{three-year period}$
Frequency	This indicator can be revised for the three-year period.
Indicator origin	From the mission of the hospital defined in the performance plan. [26]
Value origin	This value can be obtained from the software, from the analysis of the researchers and the publications of those ones.

Financial perspective

Name	Project costs per point of IF - PC
Formula	$PC_t = (\text{total financing volume for three-year period } t / \text{normalized Impact Factor of the three-year period } t)$
Description	This indicator measures the costs of each point of normalized Impact Factor for the three-year period. The total financing volume measures the total value of the project.
Goal	The objective could be to reduce the costs that are measured for each point of normalized Impact Factor, with respect to the value of the previous three-years period.

Target value	$PC_t < PC_{t-1}$, where t = three-year period
Frequency	This indicator can be revised for the three-year period.
Indicator origin	From the objectives of the research department and the information obtained during the meetings.
Value origin	This value can be obtained from the software and the timely calculations.
Name	Fund raising – FR
Formula	$FR_i = \text{total amount of fund raising during year } i$
Description	This indicator sums all the amount that has been collected through fund raising during the current year. It is aligned with the objective of increasing research investments.
Goal	The objective could be to increase this amount and in particular with respect to the average of the previous three-year period. The higher this amount, the higher the quantity that could be destined to research.
Target value	$FR_i > \text{average FR of the previous three-year period}$, where i = year
Frequency	This indicator can be revised annually.
Indicator origin	From the mission of the hospital and the objectives of the research department, defined in the performance plan. [26]
Value origin	This value can directly be obtained from the software.
Name	Research investment - RI
Formula	$RI_i (\%) = (\text{total annual research budget of year } i / \text{general budget of the institute of year } i) * 100$
Description	The general budget of the institute is composed by the research and assistance activities. At the end this indicator gives the percentage of the amount that is destined to research. It is related to the objective of increasing the investments in research.
Goal	The objective could be to increase this quantity with respect to the previous one or at least to be higher than a target value.
Target value	$RI_i > RI_{i-1}$ or $RI_i > \text{target value}$, where i = year
Frequency	This indicator can be revised annually.
Indicator origin	From the mission of the hospital and the objectives of the research department, defined in the performance plan. [26]
Value origin	This value can be obtained from the software and the timely calculations. The target value can be extracted from the Besta performance plan. [26]

Internal business processes

Name	Deviation of project budget - DB
Formula	$DB_i = \sum_{j=1}^{\text{total n. projects}} (\text{expected budget } j - \text{real budget } j)$
Description	This indicator gives the sum among all the projects of the amount that has been exceeded in the budget. This indicator is placed in this perspective because it is useful as a tool of internal monitoring.
Goal	The objective will be to reduce this value with respect to the previous year or at least to keep it lower than a target value.
Target value	$DB_i < DB_{i-1}$ or $DB_i < \text{target value}$, where $i = \text{year}$
Frequency	This indicator can be revised quarterly and annually.
Indicator origin	From the objectives of the research department and the information obtained during the meetings.
Value origin	This value can be obtained with the software and the timely calculations. The target value must be defined by the personnel involved.
Name	Number of deadlines budget met - NBM
Formula	$NBM (\%) = (\text{number of projects in which the deadline for the budget report has been met}) / (\text{total number of projects}) * 100$
Description	This indicator is linked with the financial reporting. The calculation can be done for the intermediate and final financial reporting (12, 24, 36 ... months).
Goal	The objective will be to keep this indicator as higher as possible and at least higher than a target value.
Target value	$NBM > \text{target value } (\%)$
Frequency	This indicator can be revised for each intermediate and final reporting date.
Indicator origin	From the objectives of the research department and the information obtained during the meetings.
Value origin	The value can be obtained from the software. The target value can be defined by the personnel involved.
Name	Number of deadlines steps met - NSM
Formula	$NSM (\%) = (\text{number of activities in which the deadline of each step activity has been met}) / (\text{total number of steps}) * 100$
Description	This indicator is linked with the capacity of having an internal monitoring of the intermediate activities. Not meeting the deadline of the activities means to stop the predefined ongoing of the project, stopping the following activities.

Goal	The objective will be to keep this indicator as higher as possible and at least higher than a target value.
Target value	NSM > target value (%)
Frequency	This indicator can be revised for each intermediate and final reporting activity date.
Indicator origin	From the objectives of the research department and the information obtained during the meetings.
Value origin	The value can be obtained from the software. The target value can be defined by the personnel involved.

Innovation, learning and growth perspective

Name	Number of clinical researchers - NC
Formula	$NC_i = \text{sum of all clinicians that are currently developing research during year } i$
Description	The teaching activity is carried out at the same time as the assistance activity and research activity. It is important for the hospital the collaboration with the university and the formation of the clinical researchers.
Goal	The objective could be to increase the number of clinical researchers with respect to the previous years.
Target value	$NC_i > NC_{i-1}$, where $i = \text{year}$
Frequency	This indicator can be revised annually.
Indicator origin	From the mission of the hospital defined in the performance plan. [26]
Value origin	This value can be obtained with the software and the timely calculations. The target value must be defined by the personnel involved.

Name	Degree of software implementation - SI
Formula	$SI (\%) = (\text{number of users using the new software}) / (\text{total number of users that have to use it}) * 100$
Description	This indicator is aligned with the objective of increasing technological empowerment, innovation and digitalization. It measures the percentage of the total users that are using the new software tool, among the ones that should be using it.
Goal	The objective will be to keep this percentage higher than a target objective and with time, reaching a 100%.
Target value	SI > % established target value
Frequency	This indicator can be revised annually.
Indicator origin	From the objectives of the hospital and the research department, defined in the performance plan. [26]

Value origin	The calculation can be done by establishing a list of the personnel that should use the software and marking if they do or not, for finally summing the total number of users.
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Table 7: Key Performance Indicators description.

7.4. Indicators relationships:

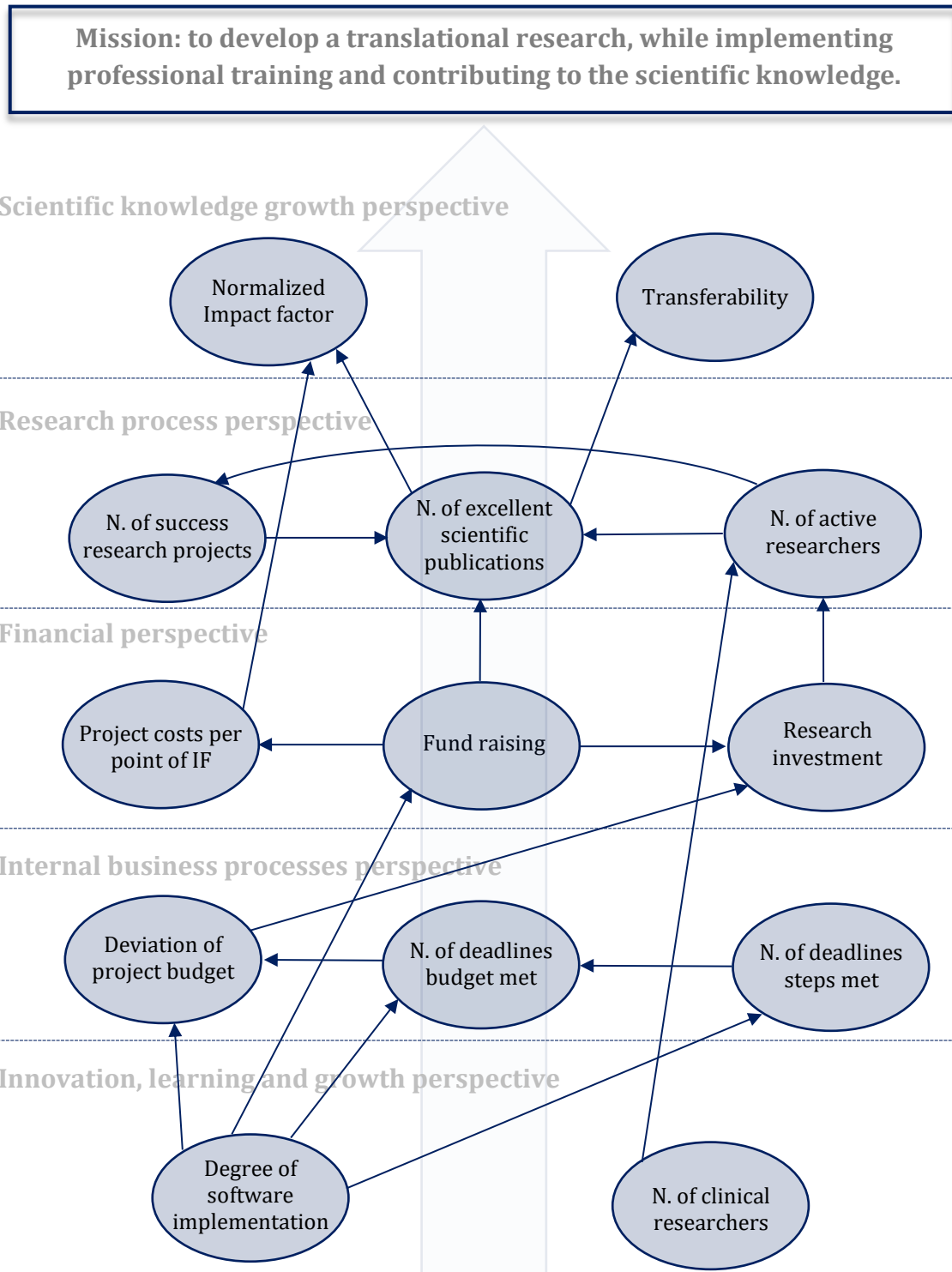


Figure 7: Key Performance Indicators relationship of the BSC.

The perspectives, objectives and indicators are not independent. The performance in one perspective will interact and influence the others. The Figure 7 shows the relationship between the indicators, having the mission of the Research Office on the top and going from the bottom to it. Each arrow going from one indicator to another, represents each relationship or influence that one indicator has on the other.

Starting from the innovation, learning and growth perspective, the Number of clinical researchers can directly influence the Number of active researchers. They can participate in different projects with researchers, helping them in the ongoing of the projects and increasing the contribution as active researchers.

The Degree of software implementation, that wants to measure the utilization of the software that is being developed, has an impact in the Number of deadlines budget/steps met. It is because the software helps to meet the deadlines, as it makes more agile the development of the projects and it has special reminders for the deadlines. It also has an impact in the Fund raising, as it has a dedicated step for this phase helping in the development of the procedure, having also a predefined template and making easier the whole process. Finally, it has an impact in the Deviation of project budget, because the more all the personnel use the software, the more it is controlled and the lower would be the deviation.

Going through the internal business process perspective, the Number of deadlines steps met influences in the Number of deadlines budget met, as it is related to the phase of development of the project and a change in one step can stop and influence the total budget deadlines.

At the same time the Number of deadlines budget met will influence the Deviation of the budget, because a direct and accurate control of the budget report will help to have it under control.

The Deviation of the budget at the same time influences the Research investment, as it can change the total financial research volume, if the budget is not met.

In the financial perspective, the Fund raising indicator influences both, the Research investment and the Project cost per point of IF. On one hand, Research investment

measures the ratio between the investment in research and the total investment in research and assistance activity. A change in the fund raising for research can impact in this ratio, changing this indicator. On the other hand, the Project costs per point of IF depends on the total financial volume of the projects of the period, which means that a change in the fund raising can change this final quantity. The Fund raising also influences the Number of excellent scientific publications, as a higher research funding will allow the possibility to produce high quality publications.

The Research investment influences the Number of active researchers. If you increase the ratio of investment in research, you will be able to have more researchers working in projects and having publications, that at the same time will be able to produce more publications and with higher quality.

The Project costs per point of IF impacts the Impact Factor. A lower cost per point of IF would mean that you are able to produce a higher IF.

Regarding the research process perspective, the Number of active researchers influences the Number of excellent scientific publications, especially if they produce publication with high IF. It also influences the Number of success research projects, as they are active researchers that are improving their capabilities and that increase the possibility of success of the proposed research projects.

The Number of success research projects, which is a measure of the success capacity, also influences the Number of excellent scientific publications. Each finished successful research project must end with a scientific publication, what means that if the success capacity increase, the possibility to produce scientific publications with a high IF increases.

The Number of excellent scientific publications directly influences the Impact Factor, as it takes into account the publications in a journal only with high Impact Factor. It also influences the Transferability, as it will take into account finished research projects which produce high value publications.

Finally, all of them have an impact on the mission of the Research Office, as they represent the contribution to the translational research, the professional training and the scientific knowledge.

8. Conclusions:

This project has been developed inside the Research Office of the IRCCS Carlo Besta (Italy). The Research Office is in charge of the management of the research projects and the relationship with the Ministry. The IRCCS Carlo Besta is recognized as centre of excellence for neurological research and treatment. It also develops the tripe mission of assistance, teaching and research.

The objective of this project has been the development of a performance measurement system, in particular a Balanced Scorecard, for the Research Office. Performance measurement systems are useful for monitoring the performance of organizations, while aligning the resources with the strategy and involving the different personnel. The Balanced Scorecards were born inside industrial organizations, in order to supplement the traditional financial measures. At the end it was composed by four main perspectives (financial, internal business process, customer, learning and growth). Doing a research into the literature, what can be found is that the Balanced Scorecard needs to be changed in order to fit into the requirement of a research hospital. These ones behave different than an industrial organization, and the perspectives and its order usually need to be changed in order to fit into the necessities and the objectives. Some examples found in the literature relate the process of applying a Balanced Scorecard for a research hospital, but it could not be found one that talks about applying it inside the Research Office of an IRCCS. Having this in mind, this project tries to give answer to the question of applying a Balanced Scorecard inside this particular department.

The methodology followed for the development of the work, has been that of working together and in parallel with a team who is in charge of the development of a software for the management of the research projects of the Research Office, and the active participation to different meetings with the personnel involved. The information obtained from interviews done by this team to the personnel and the one extracted from the different meetings, have made possible the full understanding of the objectives and important necessities of the Research Office. Also, the full knowledge of what this software can offer, and its reports are essential, as it is going to be a tool to be used together with the performance measurement system designed.

At the end, it has been designed a completely customized Balanced Scorecard for the Research Office, which is composed by five perspectives (i.e. scientific knowledge growth, research process, financial, internal business process an innovation, learning and growth) and thirteen indicators. The order of the perspective has been changed with respect to the traditional ones, adapting it to the special mission and objectives of the Research Office.

Most of the indicators have been thought to be calculated with information that can be directly reported from the software. The software allows the report of different measures, information or different values. Most of the data can be directly obtained in a format that is easy to handle (e.g. Excel) and this will facilitate a lot the calculations. Regarding also the indicators, each of them has been specifically designed and selected to help the Research Office to monitor their internal and external performance. For example, there are indicators that are also useful for the Ministry to monitor the outgoing of the hospital (for example the Impact Factor or the Project costs per point of IF) and other that have been selected to help the Research Office to monitor the internal performance (for example the Number of deadlines budget/steps met or the Deviation of the budget).

As explained before, this Balanced Scorecard has been designed to be used with the software that is being developed. This software will facilitate not only the management of the research process, but also for example the communication between the different personnel, improving the performance. It will represent a very important tool for the Research Office. This is why an indicator has been designed to measure the degree of used of the software (Degree of software implementation). Observing the Figure 7 it can be seen the importance of the implementation and use of the software. This indicator that measures the use of the software, impacts in other four indicators that measure internal and external performance. It is important the relation with the Fund raising, as it is also an indicator that impacts in many others. It can be seen also from the information of the software, as it has one dedicated step for this fund-raising process.

Another observation that can be done from this figure, is that lot of indicators interact or influence in the Number of excellence scientific publications. This is important because at the end, it is this one that impacts in the top perspective

indicators (Impact Factor and Transferability), what represent to get closer to the mission.

After the development of the Balanced Scorecard, the result of what is obtained is a system that is customized for the particular situation of the Research Office, that is thought to be used in parallel with the software, which is adaptable to changes along time (indicators and linkages are adaptable to changes, being able to add or drop any of them) and which helps to keep the internal and external performance of the Research Office updated.

Even though the software and the Balanced Scorecard are developed for the Research Office, in order to have a fully implementation it will probably need to interact with the personnel from other departments. The Balanced Scorecard provides a framework for converging the efforts and the actions of the personnel related and involved, toward a mission and an objective. So, involving the personnel at different levels of the organization, will allow to work all together toward the same direction, improving the effectiveness of the work.

Finally, due to the time constrains of this project, there are some limitations that need to be mentioned. As the Balanced Scorecard is constructed to be used together with the software, until its installation and start up this Balanced Scorecard cannot be used. As the software is still being developed, it has not been possible to test its applicability and use. For this reason, it is fundamental that the start-up of the software, and the future development would be to test the Balanced Scorecard with the data and its integration at different levels of the organization.

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Appendix I:

Clinical research IT systems.

Clinical research is a vital phase in the continuum from biomedical discovery to actual clinical practice. In the age of intelligent information systems, data sharing in a medical environment remains a challenging objective.

The management of projects involves the definition and integration of different processes such as planification, organization or administration. Some common characteristics to the general management of projects are the establishment of objectives and goals, the definition of the activities and deadlines, the management of complexity, the administration of resources or the communication and control system. Research projects generally involves human resources that allow continuity along time.

Research administration is central to the research infrastructure of an organization. Administration of human subject research is complex, involving not only the institutional review board, but also many other regulatory and compliance entities within a research enterprise. [\[12\]](#)

Existing clinical research data systems take on several different forms and functions. One of the most frequently deployed clinical research systems can be defined as a Clinical Data Management System (CDMS) which is used in clinical research to manage data of a clinical trial (i.e. an experimental interventional study conducted with human subjects), as well as other forms of clinical research such as observational, outcomes or epidemiological trials. [\[15\]](#)

Another form of clinical research system more specific to the area of interventional clinical trials, is known as a Clinical Trial Management System (CTMS) [\[15\]](#). A CTMS consists of a customizable software system to manage large amounts of data involved with the operation of a clinical trial. Such a system not only provides a data capture interface and data storage, but also provides additional functionality, such as maintaining and managing the clinical trial planning, preparation, performance; tracking deadlines, data expectations, and milestones; and reporting of clinical trials for regulatory and analysis purposes. Modules for handling trial budgeting and patient study calendars may be included in the CTMS as well. Compatibility with

other data management systems is a highly desirable feature of any CTMS or related study management software tool. Some of the goals achieved with this integration between clinical research systems and electronic healthcare data systems, is to achieve secondary data use. [\[14\]](#)

What is behind of this development is the pursuit of an integrated technology suited to streamline workflows and improve usability. CTMS allow experts easily to access centralized data and thus reducing the number of delayed trials. Clinical trial management systems are cost and time effective, as they also can be used for gathering and organizing information that can be shared to different care providers and distributed across different systems. [\[14\]](#)

Some of the **strengths and benefits** derived from the integration of these software are [\[30\]](#):

- Availability: all data and information coming from different sources are organized in one system. As such, the same level of information is made available to all members involved at the same page.
- Continuity and topicality: Since this diverse information on your trial's progress is collected all in one place, it makes the study management much more comfortable for the whole study team. Continuous checks and follow-up of study activities and documents, with regard to completeness and critical milestones, can be performed straightforwardly.
- Integrity: it provides with a comprehensive overview of your study at every step. Accordingly, it can be continuously monitored the progress of the trial and selectively control and plan the activities.
- Reactivity: as it is easy to control the trial at all times, it can be identified potential problems at early stages and can be initiated corrective actions.
- Flexibility: these systems are very flexible and can be tailored towards the specific need of the corresponding clinical trial.

Today, bundle of data pertaining directly to the core health services research mission are accumulating in large-scale, organizational and clinical information systems. Health services researchers, who holds the structure of information systems and databases and the function of software application, can use existing

data more effectively, assist in establishing new databases and develop new tools to collect data. At the same time, informaticians are needed, who can structure databases that serve the needs of health service research and who can design and evaluate applications that effectively improve health care delivery. As long as health services researchers and informaticians work in separate spheres, however, opportunities to use data from health care encounters to improve care, expand knowledge and develop more effective policies will be missed. [\[13\]](#)

Given the obvious opportunities for collaboration between health services research and informatics, a **gap** is found representing an obstacle in the integration of these systems [\[13\]](#). On one hand, it emerges the fact that not enough researchers are trained in both fields and collaboration can be difficult. Often, collaboration is impeded by the lack of common theoretic framework or vocabulary. On the other hand, the gap is physical – health services researcher and informaticians often do not work near each other. Even when informatics and health services research programs exist within the same institution, activities are carried out separately. The physical separation results in an insufficient communication. [\[13\]](#)

Most of the already existing solutions in this field, were conceived in order to facilitate the communication and real-time collaboration between the actor involved in the clinical research program, sometimes even across geographically distributed locations. Some general characteristics of these existing platforms are for example the scalability in the context of web-based interfaces to the referred platform database or the success based on methodologies and approaches used in the management of projects. [\[14\]](#)

Despite the majority of these existing solutions were conceived for the management of patient's data and its integration with the assistance of research administration, some **characteristics and requirements** can be pointed out as common with the IT system being developed for the Carlo Besta Institute, such as:

- The reduction of time and effort for clinical trial analysis.
- Efficient data management.
- Accessibility at all times.
- Usability: an application with a user-friendly interface.

- Data integration: data from other systems should be easily imported or accessible.
- Flexibility.
- Management of the projects at all levels including time, costs and resources.

Regarding the IT system to be developed within the institute, it will be important due to the fact that it will allow to implement the characteristics mentioned before, improving the experience when performing the activities that the clinical activity involves.

