

**Learning in a Belgian Hospital: Conditions of Biomedical Innovation
in the Sector of Health Sciences at the Université catholique de
Louvain**

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MEDLEARN is a research project on the conditions of biomedical innovation in academic medical centers. Three university research institutes (Université de Montréal, University of Saskatchewan, Université catholique de Louvain) cooperate in this project, coordinated by Prof. E. MONTPETIT (Université de Montréal). The project is supported by the Social Sciences and Humanities Research Council of Canada, as well as by the Research Council of the Université catholique de Louvain (Grant - FSR Jeunes Académiques).

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ABREVIATIONS

AMC - Academic Medical Center

SHS-UCL - Sector of Health Sciences at the Université catholique de Louvain

UCL - Université catholique de Louvain

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INTRODUCTION

This report is part of "Medlearn". Medlearn is a research project coordinated by Prof. E. MONTPETIT (Université de Montréal, Canada), in collaboration with Prof. D. AUBIN (Université catholique de Louvain, Belgium) and Prof. M. ATKINSON (University of Saskatchewan, Canada). Academic Medical Centers (AMCs) are often at the center of biomedical innovation. The objective of this research project is to better understand the conditions of biomedical innovation within AMCs, that is the capacity of diversified actors to work together behind biomedical research. An AMC is composed of a hospital and a faculty of medicine, both depending of an university. For this reason, an AMC has three missions: It provides not only health care services, but also education and research in the field of biomedicine.

To meet its objective, Medlearn is composed of two steps. The first step is devoted to qualitative case studies of three AMCs, respectively located in North-America, Europe, and Asia. They aim at familiarising the researchers with the nature of biomedical innovation and with the actor networks who support it in such organizations. The second step of Medlearn consists in a quantitative study of a more extended number of AMCs on the same three continents. It aims at testing the competing hypotheses retrieved from theories and on the basis of the case studies.

Being part of the first step of Medlearn, the present report is dedicated to the case study of the AMC of the Université catholique de Louvain (UCL, Belgium), officially named: "Sector of Health Sciences" (SHS-UCL). It is composed of a faculty - the "Faculty of Medicine" - and a hospital - the "Cliniques Universitaires Saint-Luc". While the other faculties of the UCL are located in Louvain-la-Neuve, the AMC (Faculty of Medicine + Cliniques Universitaires Saint-Luc) is entirely located in Woluwé-Saint-Lambert (Brussels). To our knowledge, a previous management-oriented audit of research activities was made in the SHS-UCL that only concerned the Cliniques Universitaires Saint-Luc¹. It consists of a management-oriented audit. It was ordered in 2004 by the management of the Cliniques Universitaires to Antares Consulting, a consulting firm expert in strategy, management and technology, specialized in health care, life sciences, social and socio-sanitary services (<http://www.antares-consulting.com>). The conclusions of this audit appear in Appendix 1².

The primary objective of the present report is to prepare the web survey which will be implemented in the second step of Medlearn. On the one hand, it documents the content of the questions of the survey. On the other hand, the report supports the formulation of the

¹ References: Antares Consulting, 2004, 2005a, 2005b, 2005c, 2005d.

² This audit follows another audit also made by Antares Consulting, which was dedicated to the costs and funding of university missions in the seven Belgian AMCs. It was ordered by the *Conférence des Hôpitaux Académiques de Belgique* (references: Antares Consulting, 2003a, 2003b, 2003c).

questions of the survey. Indeed, it contributes to narrow the concept of biomedical innovation, as well as to document its conditions at the macro, organizational, and individual levels (with the AMC as unit of analysis). The preparation of the report has given the authors the opportunity to meet some key-actors of biomedical innovation within the SHS-UCL. It has also provided contextual information which helps to determine to whom, how, when, and where the web survey will be addressed in AMCs.

This report has been documented by primary sources. On the one hand, a series of nine semi-directed interviews was conducted with a mix of actors having diverse responsibilities within the SHS-UCL. This mix is representative of the management, the researchers and the support services both in the Cliniques Universitaires Saint-Luc and in the Faculty of Medicine. It is also representative of all types of researches and researchers within the SHS-UCL. The interviews occurred in October and November 2008 and lasted between one and two hours (cf. Appendix 2). On the other hand, a series of documents was analysed. They were collected on several institutional websites as well as during the interviews, or sent afterwards. They consist of the documents of the audit made by Antares Consulting, organizational diagrams, reports of activities, institutional newsletters and brochures, research projects' descriptions, newspaper articles, etc.

The report is composed of six chapters. The first Chapter presents the SHS-UCL: Structures, activities, and reform projects. The second Chapter describes biomedical research in the SHS-UCL. On the one hand, it describes its legal and political framework. On the other hand, it enumerates which types of researchers conduct which types of research projects in the field of biomedicine in the SHS-UCL. Finally, it tells three representative stories of biomedical research projects which unfolded in the SHS-UCL. The third Chapter discusses the notion of "biomedical innovation", on the basis of the suggestions formulated by the interviewees. The three last Chapters analyse the conditions of biomedical research, successively at the macro, organizational and individual levels. The report ends with conclusions and recommendations for the next step of Medlearn.

Chapter 1. The Sector of Health Sciences

Untill 1968, the whole UCL was located in Leuven. In 1965, given the growing number of students in medicine, the authorities of the UCL decided to build a new academic hospital, complementary to the one of Leuven and named : Cliniques Universitaires Saint-Luc. It would be located near Brussels, in Woluwé-Saint-Lambert, a town which was judged little-served in hospital services. It holds the legal form of a not-for-profit organization. In 1968, for reasons of linguistic conflicts, the French-speaking students and personnel of the UCL left Leuven. All the faculties were transferred to Ottignies-Louvain-la-Neuve, except the Faculty of Medicine, which was transferred to Woluwé-Saint-Lambert, next to the Cliniques Universitaires Saint-Luc. Nowadays, this cluster is called the Sector of Health Sciences of the Université Catholique de Louvain (SHS-UCL) and constitutes one of the seven Belgian AMCs (Cliniques Universitaires Saint-Luc, 2008a; Haxhe, 2001).

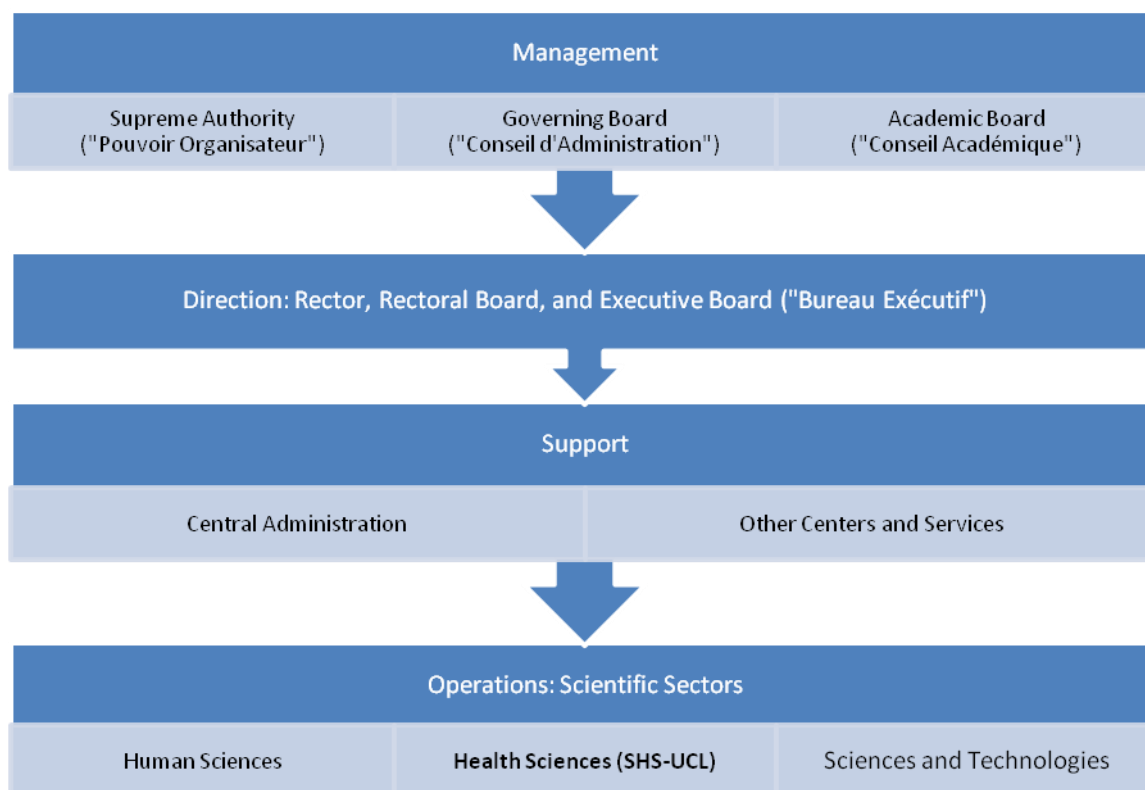
Section 1.1 describes the organizational structures of the SHS-UCL. Section 1.2 indicates the kinds and amount of activities provided by the SHS-UCL. Section 1.3 briefly exposes the two major reform projects under progress at the SHS-UCL.

1.1. Structures of the Sector of Health Sciences

The SHS-UCL is the AMC of the UCL and constitutes one of the three "sectors" of the UCL, with the Human Sciences and the Sciences and Technologies. Sub-Section 1.1.1 describes the main structures of this university. Sub-Section 1.1.2 describes the specific organization of the SHS-UCL. As mentioned *supra*, the SHS-UCL is quite classically composed of the Faculty of Medicine and the Cliniques Universitaires Saint-Luc.

1.1.1. The Université catholique de Louvain

UCL is managed by a governing board, an academic board, the Rector, the rectoral board, and the executive board. They manage and direct the general administrations, the scientific sectors, and the other centers and services of the UCL (cf. the organic and ordinary rules of the university: Université catholique de Louvain, 2008a, 2008b)



From a legal point of view, the UCL is a moral person of private law with goals of public utility.

The Supreme Authority ("*Pouvoir Organisateur*") of the UCL is religious. It includes the Archbishop of Malines-Bruxelles (President), the Bishops of the French-speaking Belgian Catholic Church, as well as three laic, co-opted, other members. They do not intervene in the "management" of the UCL, but they appoint the members of the Governing Board. They decide the organic rules and approve the ordinary rules of the University. As well they approve the charges, promotions, and nominations of the Academics, who are the only permanent researchers of the University paid on its own budget (cf. *infra*: 2.2.1.1).

The Governing Board ("*Conseil d'Administration*") is composed of the whole Rectoral and Executive Boards (*ex officio* members), two members from the UCL designated by the Academic Board, and other external members appointed by the supreme authority after consultation of the Governing Board and the Academic Board. It also includes one delegate of the Government of the French-Speaking Community, as well as a delegate of the Minister responsible for the budget in this Government. Together with the Academic Board, the Governing Board ensures the actual management of the University, under potential veto by the supreme authority (which, to our knowledge, never happens) The Governing Board is in charge of the general management of the UCL: Ordinary rules (under approval of the supreme authority), application of the law, elaboration, implementation and follow-up of the budget and the accounts, appointment of the

permanent researchers (after consultation of the Academic Board and approval of the religious authority) and appointment of the employees and temporary researchers.

The Academic Board ("*Conseil Académique*") is composed of the whole Rectoral and Executive Boards (*ex officio* members), as well as three representatives of each of the following bodies: Academic personnel, scientific personnel, employees, and students. It is chaired by the Rector. Together with the Governing Board, it ensures the management of the University. The Academic Board is in charge of the elaboration and implementation of the scientific policy of the University with regard to education and research. It coordinates the education and research policies of the diverse faculties and centers of the University. It is consulted by the Governing Board or makes propositions regarding the ordinary rules of the University, cultural and social issues, as well as about relationships with the society, other universities and research centers.

The Executive Board ("*Bureau Exécutif*") is composed of the Rector, the Vice-Rector for Academic Issues, the Vice-Rector for students-related issues, three Pro-Rectors, and the General Administrator. Collegially, they ensure the day-to-day management of the University. The Rector is appointed by the religious authority of the UCL, once elected by the members of the UCL at the universal, pondered suffrage. The Vice-Rector of Academic Issues is the Vice-President of the Academic Board, which designates him or her among the Deans or former Deans of the faculties of the University. The Vice-Rector for students-related issues is proposed by the Academic Board among the academic personnel of the University, and appointed by the supreme authority. The Pro-Rectors are proposed by the Rector after consultation of the Governing Board, then approved by the Academic Board, and finally appointed by the supreme authority.

The Governing Board includes a special commission, named: "*Medical Center*". This commission is composed of the Rector, the direction of the Cliniques Universitaires Saint-Luc (General Coordinator, General Administrator), the Director of the Cliniques Universitaires Mont-Godinne, the Pro-Rector of Medical Issues, the direction of the Faculty of Medicine (Deans), as well as some academics from the Cliniques Universitaires Saint-Luc and Mont-Godinne. It ensures the coordination of the objectives of the Faculty of Medicine and the objectives of the Cliniques Universitaires. It proposes appointments of clinical academics to the Governing Board.

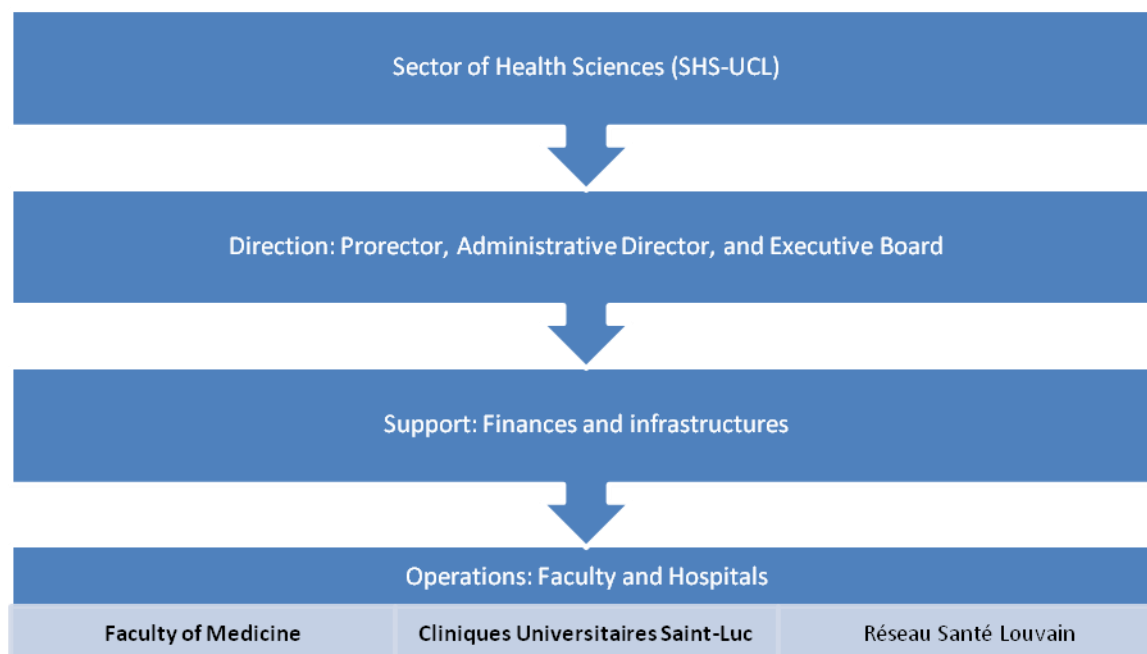
The Governing board includes another special commission, named: "*Commission of the University Hospitals Network*", which is composed of representatives of the UCL (the Rector, the Pro-Rector of Medical Issues, the Deans of the Faculty of Medicine, the General Coordinator and two academics of the Cliniques Universitaires Saint-Luc), the other member hospitals, the "Hospital Federations", the Catholic Health Insurance System ("*Alliance Nationale des Mutualités Chrétiennes*"), the general practitioners, as well as the "Association of the Services Psychiatric and Mental Health of the UCL". It proposes, coordinates, and implements the policy of the network of hospitals, named "*Réseau Santé Louvain*", and situated at the level of the SHS-UCL (cf. *infra*: 1.1.2).

The *Central Administration* provides administrative support to the scientific sectors in performing the missions of the University: Education, research, and services to the society. It includes an finances administration, a personnel administration, an administration of the holdings and infrastructures, an administration of students-related issues, an administration of international relations, an administration of education and formation, and - last but not least regarding biomedical innovation - the Administration of Research. The other general services also aim at providing support to the scientific sectors and to the management of the UCL, on more specific issues. They include services of security, human resources management, libraries, etc. They can also provide technical expertise about legal, political, or organizational questions.

The *Scientific Sectors* are composed of faculties and inter-faculty centers and institutes, which deliver education, research, and services to the society. Some of these centers are situated outside the faculties, among the "other centers and services".

1.1.2. The Sector of Health Sciences

The SHS-UCL is the Academic Medical Center (AMC) of the UCL.



The *direction* of the SHS-UCL is composed of the Pro-Rector of Medical Issues of the UCL, an Administrative Director, and an Executive Board. The Pro-Rector is in charge of the Academic coordination of the Sector with regard to the management and direction of the UCL.

The Executive Board is composed of the Pro-Rector, the Administrative Director, the Faculty Deans, the General Coordinator of the Cliniques Universitaires Saint-Luc, the General Coordinator of the Cliniques Universitaires Mont-Godinne, and an Academic Secretary of the Sector. It is in charge of the overall coordination of the SHS-UCL.

At the level of the SHS-UCL, the administrative *support* organizes infrastructures and finances of the Faculty of Medicine, under the supervision of the Administrative Director.

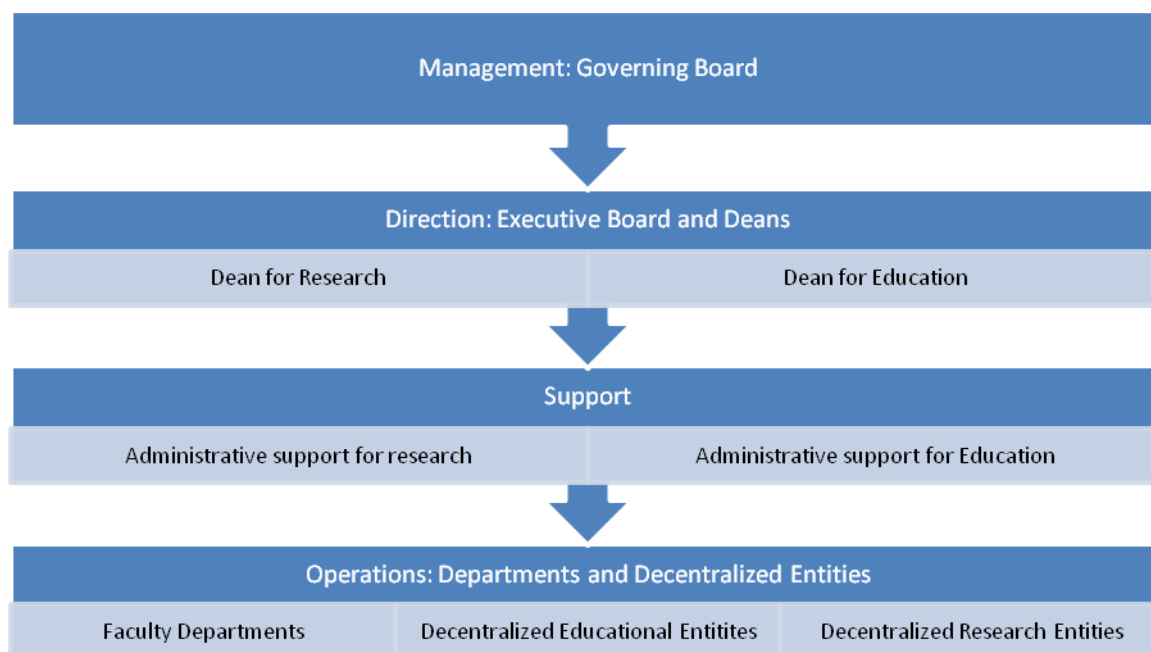
Quite classically for such an AMC, the SHS-UCL is composed of the *Faculty of Medicine*, as well as a central university hospital: The *Cliniques Universitaires Saint-Luc*. It also includes a network of other hospitals, named "*Réseau Santé Louvain*", and organized by the "Commission of the university hospitals network" (cf. *supra*: 1.1.1).

The present report will focus on the Faculty of Medicine and the Cliniques Universitaires Saint-Luc in studying the macro, organizational, and individual conditions of biomedical innovation, for two reasons. Functionally, the Cliniques Universitaires are the closest component of the SHS-UCL next to the Faculty of Medicine (research collaborations, common personnel, institutional history, etc.). Formally, this is the only hospital of the *Réseau Santé Louvain* where the members of the managerial boards are appointed by the boards of the UCL. The members of its General Assembly are the members of the Governing Board of the UCL and the members of its Governing Board are appointed by its General Assembly, on the proposition of the Governing Board of the UCL. In addition, the Governing Board of the Cliniques Universitaires Saint-Luc includes at least four and a maximum of seven members of the Faculty of Medicine of the UCL. Actually, the Cliniques Universitaires Saint-Luc are historically "The" university hospital of the UCL, while other hospitals of the network maintain weaker relationships with the SHS-UCL³.

³ Nowadays, the SHS-UCL formally comprises the Cliniques Universitaires Mont-Godinne. But the functional relationships between the Cliniques Universitaires Mont-Godinne and the SHS-UCL are similar to ones between the SHS-UCL and the other hospitals of the *Réseau Santé Louvain*.

1.1.2.1. The Faculty of Medicine

The SHS-UCL is the sole Scientific Sector of the UCL which includes only one faculty: The Faculty of Medicine.



The Faculty of Medicine is managed by a *Governing Board*, composed of all the permanent researchers of the Faculty and the Cliniques Universitaires Saint-Luc, as well as representatives of the temporary researchers, the administrative employees, and the students.

The *Executive Board* of the Faculty is similar in composition to the Executive Board of the SHS-UCL, plus the Directors and Presidents of all the Departments and Decentralized Educational and Research Entities, as well as representatives of the researchers, the administrative employees, and the students. The Administrative Director is only consulted.

Two *Deans* are specifically and respectively in charge of the research and educational issues. The *Dean of Research* can rely on the administrative support of a "Ph.D. Unit", as well as several "technological platforms" supervising the management of some special analysis equipments. He or she supervises the "Research Council of the Faculty", which gathers actors concerned with research in the Faculty: The Representatives of the upcoming Research Institutes (cf. *infra*: 1.3), the person in charge of the Doctoral Commission, the Director of the General Administration of Research of the UCL, as well as representatives of the researchers, the administrative employees, and the students. The *Dean of Education* can rely on the

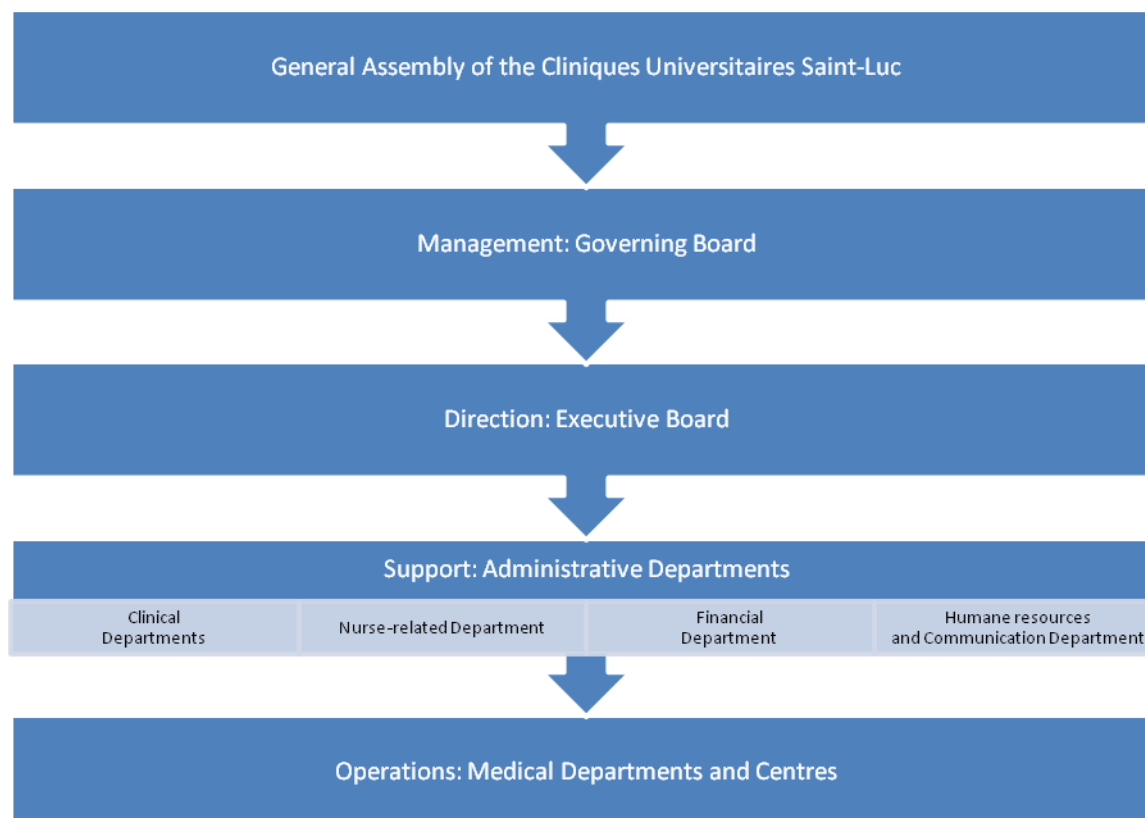
administrative support of a "Center of pedagogical development" as well as secretaries organizing study programs, courses schedules, and exams. He or she supervises the "Education Council of the Faculty", which gathers actors concerned with education in the Faculty: The Representatives of the upcoming Schools (cf. *infra*: 1.3), the person in charge of the bachelor programs, two representatives of the General Administration of Education and Formation of the UCL, as well as representatives of the researchers, the administrative employees, and the students.

Courses are organized at the level of the Faculty *Departments*. Within each Department, several Units conduct research. The Faculty of Medicine includes a Department of Biochemistry and Cellular Biology, of Microbiology, Immunology, and Genetics, of Physiology and Pharmacology, of Normal and Pathological Morphology, of Radiology and Medical Imagery, of Internal Medicine, of Surgery, of Gynecology, Obstetrics, and Paediatrics, of Neurology and Psychiatrics, of Public Health, of Dental Medicine and Stomatology, of Pharmacy, and of Physical Education and Revalidation. Except some scientific researchers, Academic and scientific researchers who perform research activities in the Units are the same who deliver education at the level of the Departments. The Departments and Units also include administrative and technical employees supporting scientists in their educational and research-related activities.

Finally, some *decentralized entities* specialize in some specific educational services or research fields. Such educational entities include an "Academic Center of General Medicine", a "Unit of Medical Science Pedagogy", or a "Center of Orientation". The three decentralized research entities are the "Institute of Cellular Pathology Christian de Duve", the Ludwig Institute for Cancer Research, and the "Interdisciplinary Center of Ageing". The two first are inter-related. From a legal point of view, the Institute of Cellular Pathology is a not-for-profit organization distinct from the UCL and the Cliniques Universitaires Saint-Luc. Dedicated to fundamental research, it gathers researchers from different units of the Faculty of Medicine. It also includes the researchers employed by the Brussels Branch of the International Ludwig Institute for Cancer Research. This Institute is again a different legal organization, but functionally integrated in the management of the Institute Christian of Cellular Pathology as well as in the International organization of the Ludwig Institute. All in all, the Institute of Cellular Pathology counts 8000 m² of laboratories and about 250 researchers. Given its specific legal status, it has the opportunity to manage research funding in autonomy (Lucas, February 2005 - March 2005).

1.1.2.2. The Cliniques Universitaires Saint-Luc

The Cliniques Universitaires are the university hospital of the UCL. They are a not-for-profit organization.



The *General Assembly* is the supreme authority of the Cliniques Universitaires Saint-Luc. It is composed of the members of the Governing Board of the UCL. Among others, the presence of Didier MALHERBE, the Delegated Administrator of UCB Belgium (a pharmaceutical company) and Michel TILMANT, the President of ING Group (a banking company) in the membership of the General Assembly is worth to be noted. The General Assembly has the responsibilities committed by the law on not-for-profit organizations ("Law of 27 June 1921 granting civil personality to not-for-profit organizations and institutions of public utility" and "Law of 2 May 2002 on not-for-profit organizations, international not-for-profit organizations and foundations").

The *Governing Board* is composed of the Rector, the Pro-Rector of Medical Issues, the General Administrator and the President of the Governing Board of the UCL, the General Coordinator and the General Administrator of the Cliniques Universitaires, the General

Coordinator of the Cliniques Universitaires Mont-Godinne, as well as some economic and social representatives of the civil society and some representatives of the academics of the UCL. Among others, the presence of Jean HERMESSE, the General Secretary of the Catholic Belgian Insurance System ("*Alliance des Mutualités Chrétiennes*"), Marc SPEECKAERT, the General Director of Sofina (an investment fund), and Philippe CASIER, representative of the religious association "*Oeuvre du Calvaire*" are worth to be noted.

The *Executive Board* includes the General Coordinator, the General Administrator of the Cliniques and the Directors of the Administrative Departments of the Cliniques Universitaires, as well as the Pro-Rector of Medical Issues. Besides its role of Chief Executive Officer in the Executive Board, the General Coordinator is specifically in charge of the Medical decisions in the Cliniques. In addition, several transversal services are put under its direct supervision: The ombudsman, the Unit of Medical Economics, the Service of Hospital Hygiene, the Religious Service, and the Pharmacy Department. The General Administrator is specifically in charge of the administrative decisions. More specifically, he is often identified as the "minister of foreign affairs" of the Cliniques Universitaires and, to a lesser extent, the SHS-UCL. In addition, several transversal services, such as Strategy, Internal Audit, Insurances, or Security, are directly under its supervision.

The *Administrative Departments* provide support to the Medical Departments in their health care and research activities. The Clinical Departments are under the responsibility of three Clinical Directors. They are medical doctors, given that the tasks of these Departments are directly concerned with the performance of the health care and research activities. They include Services of Quality, informatics, Patients Administration, Technique, Medical Information, Processes, and the management of the Surgery Service. A specific Department is devoted to the management of nurse-related issues. Finally, one Department is in charge of Finances (budget, accounts, bills, litigations, treasury, purchases, logistics) and another is responsible for personnel, human resources management, as well as internal and external communication.

The *Medical Departments* perform the health care services and conduct biomedical research. The Cliniques Universitaires include a Department of Cardiovascular Diseases, of Internal Medicine & Associated Services, of Surgery & Associated Service, of Paediatrics, of Neuropsychiatry and Special Pathologies, of Acute Medicine, of Clinical Biology and Pathological Anatomy, of Medical Imagery, of Dental Medicine and of Stomatology. The Medical Departments, each composed of several Clinical Services, form part of the hierarchical structure of the organization. By contrast, Medical Centers stand up next to this hierarchical structure. They gather specialists from several fields and from different levels of the organizational hierarchy, to interdisciplinary treat a specific disease, medical problematic or human organ. For example, there is such a center dedicated to cancer, to the fight against ache, or to the male sexual pathologies.

1.2. Activities of the Sector of Health Sciences

The SHS-UCL devotes its human, financial and organizational resources to the accomplishment of three basic missions: Education, health cares, and research.

The amount of education and health cares delivered by the Faculty of Medicine and the Cliniques Universitaires Saint-Luc can be quantified on several respects. In 2007-2008, the Faculty of Medicine educated 5396 registered students, in the framework of 147 educational programs. In 2007, the Cliniques Universitaires delivered 220 304 days of classical hospitalisation. 21 180 additional days were delivered in the Institut Albert Ier et Reine Elisabeth, the center for long-term hospitalizations of the Cliniques. 27 606 one-day hospitalizations were delivered. 13 666 dialyses and 1615 childbirths were performed. The practitioners delivered 490 981 medical consultations. To get an idea of the equipment of the hospital, it can be mentioned that it counts 23 rooms for surgery operations, 17 rooms for radiology, 10 rooms for endoscopies, 4 rooms for childbirths, 3 rooms for cardiac catheter, 1 room for interventional radiology, 1 room for *in vitro* fecundation, 4 devices of magnetic nuclear resonance, 4 linear accelerators, 4 scanners, 6 gamma cameras, 1 Pet Scan, 2 neuro-navigators, 1 lithotripter, and 2 cyclotrons.

From a financial point of view, in 2007, the operating costs of the Cliniques Universitaires stood at 385 504 269 €, while the operating receipts amounted to 396 448 183 €. Taking into account the exceptional financial operations, the Cliniques Universitaires made a net benefice of 3 350 224 € in 2007. The UCL does not hold a separate budget for the Faculty of Medicine to the attention of the public authorities.

By way of conclusion, it appears that research activities are difficult to measure, in "real" (number of projects, number of personnel, number of operations, etc.), as well as in financial terms. For example, the number of research projects is difficult to evaluate. Indeed, when having taken the granted and rewarded research projects into account, one has not counted the number of research projects conducted without specific funding, without specific internal or external communications, thanks to the financial margins of other research projects or thanks to the operating budget of the SHS-UCL. From a financial point of view, no specific accounting of research activities is held in the publicized budget of the SHS-UCL; this is written in terms of personnel, equipments, investments, interests or provisions indistinctly aimed at research, education and health cares. In addition, specific such official budgets are held at the level of the UCL and at the level of the Cliniques Universitaires, while research activities (and budgets) are implemented at the level of the Faculty of Medicine or the Cliniques Universitaires (often in collaboration, which even more dilutes costs and receipts).

1.3. Reform projects in the Sector of Health Sciences

Two reform projects in the Sector of Health Sciences are developed to enhance the research potential of the AMC: The conception of hospital-faculty departments and the *Plan de développement*.

The project of *hospital-faculty departments* would not modify the structural (statuses and hierarchy) organization within the Faculty of Medicine nor within the Cliniques Universitaires Saint-Luc, nor the charges of the personnel at the level of Faculty Units and Clinical Services. Major changes would concern coordination among education, research, and health cares, at the level of the presidents of department. Current presidents would apply for functions of education, research, or health care coordinators, as well as of President of Department. Functions would be combinable: For example, two persons could head a hospital-faculty Department, one responsible for education and research coordination, the other for the health cares coordination and for the presidency. Presidents of Units within the Faculty would debrief to the research coordinator and to the education coordinator, while Chiefs of Clinical Services would debrief to the health care coordinator. The President and the Coordinators would be appointed by the managerial boards of the Faculty and the Cliniques, after approval of a hospital-faculty departmental policy project. Meetings would gather the President and the coordinator, as well as the persons responsible for nurse-related and technical issues in the Clinical Services, for purposes of coordination. The President of hospital-faculty departments would become the interface with the boards of the Faculty and the Cliniques Universitaires. The project of hospital-faculty departments was discussed in 2003-2005 and has not been implemented yet: Faculty Departments have well been reshaped - there are nine Faculty Departments of which the educational and research-related activities are related to nine out of ten Clinical Departments. However, the coordination structures do not exist. The remaining four Faculty Departments are devoted to fundamental research and to education: Public Health, Dental Medicine and Stomatology, Pharmacy, as well as Physical Education and Revalidation. According to the General Coordinator of the Cliniques, Prof. J. MELIN, the project of hospital-faculty departments is not rival with the *Plan de développement*, given that it is concerned with coordination, while the *Plan de développement* aims at modifying the organizational structures (hierarchy and statuses) (De Nayer, 2005). It is not clear to which extent the *Plan de développement* will incorporate the features of the project of faculty-hospital departments.

The *Plan de développement* is the showpiece of the current Rectoral team, led by the Rector B. COULIE. The basic idea of the *Plan* is to dissociate the management of teaching - in "schools" - and research activities - in "institutes" - to make both activities internally more efficient and externally more visible. The research institutes would be aimed at sharing and coordinating research resources for the research centers which would compose it. Research teams, in centers or in their subdivisions, should be organized at a small scale. This should contribute to correct one of the reasons identified by some interviewees for missing some

research opportunities or failing the creation, implementation, and finalization of research projects: The lack of administrative relays between operational researchers, on the one hand, and the administrative and managerial staffs, on the other hand.

Moreover, as will be described, an important set of individual conditions for conducting research consists of the enthusiasm, the curiosity, and the entrepreneurship of researchers, as pointed by the interviewees. Hence according to them, efficient research centers should gather a small number of interrelated, enthusiastic persons. According to the interviewees, all in all, the conditions for successfully creating a new research institute consist of: A research personality which is able and wants to lead the project, some time availability for this personality to conceive and implement a research policy, the human, financial, infrastructural, technical, and other organizational resources of this research policy, and the recognition by the university authorities of the research field's specificities.

Several points regarding the implementation of the *Plan de développement* in the SHS-UCL are worth to be underlined. First, opinions are divergent about the basic principle of the *Plan*, that is whether it is relevant or not to dissociate both activities. For example, it is a "non-sense" according to some interviewees. By contrast, some others are favorable to the reform project, given that persons cannot be expert in both activities simultaneously. These interviewees advocate a modular system which would allow the distribution of teaching and research activities between persons at a certain moment as well as a longitudinal evolution of activities for one person - for example, with more research activities at the beginning of the career and more teaching activities afterwards. It is noticeable that this formalization of the distribution of activities would allow a clearer evaluation of their realization by the management.

Concretely, some interviewees pointed the slowness of the implementation of the *Plan de développement* (the principles of the project were first presented in September 2005). The current version of the *Plan de développement* schedules the creation of five research institutes in the Faculty of Medicine: The De Duve Institute (which already exists as such, as a decentralized research entity), the Louvain Drug Research Institute, the "Institute of Neurosciences", the "Research Institute Health and Society", and the "Institute of Experimental and Clinical Research". The last one would include research centers with research perimeters corresponding to the activities of the Clinical Departments (which would consist of the incorporation of the project of hospital-faculty departments or similar coordinating committees⁴).

⁴ For this reason, according to some interviewees, it is quite clear that the devising of the *Plan de développement* at the level of the UCL originates from the needs and objectives of the SHS-UCL, in which people have used to set up interdisciplinary collaborations for a long time. According to these interviewees, it is a will of "the university authorities".

Chapter 2. Biomedical research in the Sector of Health Sciences

This Chapter is dedicated to the description of biomedical research, as it is performed in the SHS-UCL. Section 2.1 highlights the legal and political framework of such an activity, in such an AMC, in Brussels. Section 2.2 identifies the institutional actors who are involved in biomedical research projects in the SHS-UCL. It also distinguishes several types of biomedical research projects. The aim of this Section is not to create or combine "typologies" but well to give some information about these types of actors and research projects. Different types of research projects require and receive different conditions and supports at the macro, organizational and individual levels. Section 2.3 tells three stories of biomedical research in the SHS-UCL. It is aimed at providing concrete examples of the conduct of biomedical research in the SHS-UCL, and illustrating the analytical discussion. These stories are quite representative. They involve different types of actors and research projects, research centers with variables sizes, and few or many external partners.

2.1. Legal and political framework

2.1.1. Legal framework

It is important to know which *competences* political entities are responsible for regarding scientific research and health in Belgium, before examining the content of the norms they have enacted.

The Federal State is responsible for establishing norms and structures regarding technical, professional and financial aspects of the health care system, including hospitals management. This role is related to the responsibility of the Federal State in designing and financing the Social Security System, including health care (as well as the salary of medical doctors in public AMCs and hospitals). Federated entities of the State (Regions and Communities) are responsible for the implementation of these norms, as well as for policies on preventive health (Communities) and curative health (Regions) (Région Wallonne, 2007). Examples of such policies for curative health are the coordination of the services of mental health, the "medical houses" or the centers of coordination of at-home cares and services. Examples of such policies for preventive health care are the promotion of healthy behaviors in the schools or the advertising campaigns against tobacco. Communities are also responsible for scientific research, including biomedical research.

The coordination of these policies within Belgium primarily occurs in the "*Conférence Interministérielle Santé Publique*", the "*Conférence Interministérielle Politique Scientifique*" as well as in the "*Comité de Concertation*" for the most important issues. The *Conférences Interministérielles* gather the policymakers of the different Federal and Federated Governments to coordinate policies around specific thematic (here: Public health and scientific research). The *Comité de Concertation* gathers the Chief and other relevant Ministers of the different governments, for the most important and/or global issues. In accordance with this distribution of competences, relevant political entities of the Belgian State are also responsible for the implementation of the European Union directives.

At the *Federal level*, Belgian AMCs must primarily respect the "Law on hospitals and other health care organizations, coordinated on 10 July 2008" and its decrees of execution. Their status is fixed at the art. 4 of the Law: "For the application of the present coordinated law, are considered as university hospitals, university hospitals services, university hospitals functions, or university health care programs, the hospitals, the hospitals services, the hospitals functions, or the health care programs which, given their proper function in the field of patients cares, clinician education, applied scientific research, development of new technologies, or evaluation of medical activities, satisfy conditions imposed by the King and are named as such by Him, on the proposition of the academic authorities of a university which disposes of a faculty of Medicine which offers a complete curriculum". These conditions are fixed in the "Royal Decree of 7 June 2004 establishing the conditions of quality for the appointment of a university hospital, university hospital service, university hospital function, or university hospital health care program". Other specific conditions to the approval of some university equipments and services are fixed in the "Royal Decree of 15 December 1978 establishing special norms for university hospitals and services". Specific rules are also mentioned in the "Royal Decree of 25 April 2002 related to the establishment and the liquidation of the budget of financial means of hospitals". Finally, regarding programming (the distribution of health cares' offer in Belgium, among others the number of beds by hospital), Belgian AMCs are specifically submitted to the "Royal Decree of 24 December 1980 establishing the maximum number of beds which is of application in university hospitals". These norms do not directly relate to biomedical research in the SHS-UCL, as such. But they are of importance for its daily production (cf. *infra*: 5.5).

Biomedical innovation is regulated by numerous decrees of the *French Community* (for example, the Decree of 19 July 1991 on the career of scientific researchers) as well as by *European directives*. The action of the European Union mainly concerns bioethics (for example, the Directive 2001/20/EC of the European Parliament and of the Council of 4 April 2001 on the approximation of the laws, regulations and administrative provisions of the Member States relating to the implementation of good clinical practice in the conduct of clinical trials on medicinal products for human use)

Besides these legal norms, biomedical research is dependent upon decisions made by the *committees of ethics*, as pointed by some interviewees. Since 1987, the Law on Hospitals has made the existence of such committees compulsory within each hospital. Their advice remained

consultative. In 1994, given the increasing complexity of the tasks of these committees, a Royal Decree of 24 September defined their roles, composition, and tasks. The Law on medical experimentation of 7 May 2004 made the positive advice of the committees binding for any research project involving human beings. Their number has also been reduced and their responsibility, increased. The "*Comité Consultatif de Bioéthique de Belgique*" provides consultative advices about problems raised by biomedical-research-related questions regarding ethical, social, and legal aspects, at the professional (in collaboration with the hospital committees), political or public levels, spontaneously or at the demand of any one. It was created by the "*Accord de coopération du 15 janvier 1993 signé par l'Etat fédéral, les Communauté française, flamande et germanophone ainsi que la Commission Communautaire Commune*". It is composed of academics, doctors, and jurists, appointed by the Federal and Federated governments of Belgium.

2.1.2. Political framework

As perceived by all the interviewees, biomedical innovation is dependent upon the "*politics*" of biomedical research. According to what results from the interviews, this does not seem to refer to the interference of public authorities in the management of the SHS-UCL, however. As mentioned *supra* (cf. 1.1.2.2), besides the internal managers, the Governing Board of the Cliniques Universitaires is well composed of stakeholders in the field of biomedicine, such as Jean HERMESSE, the General Secretary of the Catholic Belgian Insurance System or Marc SPEECKAERT, the General Director of Sofina. In the same line, the General Assembly includes Didier MALHERBE, the Delegated Administrator of UCB Belgium and Michel TILMANT, the President of ING Group. But these members do not seem to take part to the boards to influence decisions, on the contrary. The internal members must sometimes explain them what the issues are at stake behind particular decisions. External members of the Governing Board are actually freely chosen by its internal members. Regarding the Cliniques Universitaires, the management must only fulfil legal commitments, that's just it; there is a wide management autonomy, regarding public authorities. For example, the appointment of permanent researchers is actually the prerogative of the Governing Board and the Medical Center, independently of (inexistent) external pressures.

By contrast, the content of the federal norms on programming, approvals, and funding - that is: *The legal framework on hospital management* - are at the center of intense negotiations. As explained *infra* (cf. 5.5), they have strong impacts on the means for biomedical innovation within each AMC. These negotiations are viewed as being exclusively led by the management of the Cliniques Universitaires, without involving the other stakeholders, such as researchers, and more specifically by G. DURANT. With respect to this point and others, it is worth to note that G. DURANT is often designated as the person in charge of external relations in the SHS-UCL ("*Minister of Foreign Affairs*", as named by one interviewee, cf. *infra*: 4.2.1).

Another strategic resource impacted by political negotiations is the fundamental *research funding by the French Community*. This financial support is provided by the French Community to the "*Fonds National de la Recherche Scientifique*". Its board includes the Rectors of the universities of the French Community, as well as representatives of the public and political authorities of the French Community and the heads of Belgian scientific and economic authorities (for example, the National Bank or the Royal Academy of sciences). Then, this amount of money, together with the private financial support collected by the administration of the *Fonds National de la Recherche Scientifique*, are distributed by its scientific commissions to research projects, to researchers, and hence between universities.

Finally, the *policies of hospitals mergers* are also a major political issue. This issue primarily concerns the programming of health care. But, as explained *infra* (cf. 5.5), it has huge consequences for biomedical research, given the need, for its production, of "interesting" patients (with unknown diseases or with diseases for which drugs or treatments are put to the test). Several logics are implemented at different levels. They do not match each other. First, at the political level, public authorities seek to simultaneously combine local, political and confessional, overlapping logics. Each Region wants to preserve its capacities in biomedical research. Hospitals of each political or confessional tradition (socialist, catholic, liberal, etc.) also want to preserve its capacities of biomedical research.

Second, at the level of the hospitals (academic or not), each entity is desirous to hold, within its bosom, some "prestigious" and commercially interesting activities and, in the same line, research activities as well as modern equipments. This creates inadequate distributions of human, financial and organizational resources. For example, some interviewees point that the Federal State approved eight transplantation centers in Belgium while there are only three such centers in the Netherlands. Overall, this wastes research resources. Some interviewees evaluate that a rational concentration of AMC's in Belgium would only allow us to reach the level of other nations in biomedical research, given our actual potential.

Third, at the level of universities, strategies are implemented to associate with local hospitals all over Belgium, in such a way to guarantee a good circulation of patients among the AMC and its local partners, to the benefits of biomedical research in the AMC (cf. *infra*: 5.5). AMC's are rival in arranging partnerships with local hospitals to ensure that all the interesting patients (for biomedical research) of these local hospitals will be sent in the research centers of their own researchers.

By way of conclusion, generally speaking, policymakers are perceived by the interviewees as being receptive to the importance of rationalising the offers of biomedical research and health care. But, in each case (political and confessional logics, as well as hospitals' and universities' strategies - policymakers are confronted to overlapping logics. For example, geographically, rationalisation purposes could lead policymakers to merge and rationalise the different AMC's of Brussels. But it is conceived as absolutely impossible by a lot of interviewees given "sociological" (that is: Confessional) divergence with, for example, the AMC of the

"Université Libre de Bruxelles". To further complicate the formulation of political choices, the numerous relationships between the authorities of hospitals, universities, regions or localities and policymakers allow the first ones to relay their conflictual demands in the different arenas of negotiations (but prevent policymakers from making clear choices of rationalisation based on one or another criteria).

The more broadly speaking "politics" of biomedical research also includes all these inter-organizational and inter-personal relationships around financial support, access to data, patients, and equipments. But these aspects will be discussed in details in Chapters 4 to 6 at the macro, organizational and individual levels.

2.2. Types of actors and research projects

Sub-Section 2.2.1 identifies the different types of institutional actors who play a role in biomedical research in the SHS-UCL⁵. Sub-Section 2.2.2 distinguishes different types of research projects, among others given the type of institutional actors that they involve, but also on the basis of the financial supports and the objectives of these research projects.

2.2.1. Actors

Institutional actors of biomedical research can be distinguished on the basis of their structural position: Operation or support.

2.2.1.1. Operation

At the operational level, biomedical research is the result of the commitment of permanent and temporary researchers. *Temporary researchers* are assistants of the SHS-UCL-UCL, paid for educational and research-related purposes or for conducting research solely. They are employed with fixed contracts, most often the time to conduct a PhD and write their thesis. Temporary researchers can also be paid by on external funding sources, for a fixed term, in the framework of a research project, to prepare a PhD, or a combination of both. In both cases they can be statutory members of the Faculty of Medicine or the Cliniques Universitaires, which

⁵ A general presentation of the organizational structures of the SHS-UCL has been proposed in Section 1.1.

is not always representative of the time that they effectively dedicate to activities in one or another entity.

Permanent researchers have a permanent contract. They are academics or not. In both cases they can be research supervisors. They are statutorily paid either by the UCL in the Faculty of Medicine, or by the Cliniques Universitaires, or they are paid and have a scientific career related to an external funding source such as the *Fond National de la Recherche Scientifique*. Most of the permanent researchers working part-time or full-time in the Cliniques Universitaires are paid there. Nonetheless, 23 of them are paid by the Faculty, which is the result of an old system planned to disappear. Other permanent researchers of the Faculty dedicate all their time to in-faculty activities.

Biomedical research is also dependent upon the work of technical *and administrative staffs* involved in the operational management of one or another research project. These professional functions include data, equipment, or administrative management and are performed by persons with varying statuses and formations.

2.2.1.2. Support

The role of several institutional actors in the structure of the SHS-UCL is worth to be mentioned in transversally supporting biomedical research (functions not related to specific research projects).

At the level of the UCL, the role of the *Administration of Research* is to support research in the university. At the logistical level, it prepares, implements and evaluates policy choices of the boards of the university, coordinates the administrative management of the PhD, and manage research-related databases (inventories of research projects, publications, prices, dissertations, etc.). At the financial level, it searches for and spreads information about financial opportunities (prizes, competitions, funds, etc.) from diverse sources (private and public, from the local to the global level) to conduct research projects, by way of diverse communication media (posters, emails, direction solicitations, etc.). It also relates with companies and other partners and advertises research potential and production of the UCL. Finally, it supports researchers in applying for financial supports, among others by organizing meetings and conferences and producing documents to facilitate the access of the researchers to funding sources. At the legal level, it develops research procedures within the UCL, supports contract transactions with external partners, and collaborates with the Sopartec (cf. *infra*: This paragraph) for the valorisation and patenting of the research outcomes of the UCL. It also develops a regional dimension of these roles by intensifying relationships with regional commercial partners of the UCL.

At the level of the SHS-UCL and *within the Faculty of Medicine*, some administrative services also provide support to biomedical research, under the direction of the Dean of Research. On the one hand, they perform functions similar to the ones of the Administration of Research of the UCL, but specifically oriented toward biomedical research projects, in a quite redundant or more complementary way. For example, it ensures the diffusion of some prizes and funding opportunities within the Faculty. In a more complementary way, it prepares and implements the scientific decisions of the Research Council of the Faculty, regarding the academic progress of the PhDs students. On the other hand, under the supervision of the Administrative Director of the Sector, the administrative services of the SHS-UCL perform some other tasks useful to biomedical research in the Faculty. Roughly speaking, they manage the allocation and use of financial and infrastructural (among others: Rooms and equipments) of the Faculty. More specifically, within the Faculty, the role of the technological platforms can be remembered here.

At the level of the Cliniques Universitaires Saint-Luc, the most important institutional actor for the support of biomedical research is the *Unit of Medical Economics*. It is the service of reference in the Cliniques Universitaires for any research-related issue. Directly attached to the Direction of the hospital, this Unit is composed of three persons. The first is responsible for legal aspects of research contracts concluded with external partners of the hospital. The second person is responsible for the supervision of research projects regarding the internal (Committee of Ethics and other procedures) and external (law) regulatory framework. Both work under the direction of the person in charge of the Unit, which coordinates their functions as well as manages other research-management-related aspects: For example, the preparation and implementation of the research policy of the hospital or the collaboration with other services to adopt the computer program for the management of research projects and data. More specifically, the following roles of the Unit are cited:

- Negotiating research contracts with external partners;
- Controlling the legal terms of these contracts;
- Controlling the financial equity of these contracts, given the institutional costs implied by the participation for the Cliniques Universitaires;
- Assisting researchers in formatting their research projects along to the requirements of the local committee of ethics;
- Supervising the legal conformity of clinical research projects with regard to insurances and legal norms on clinical trials;
- Choosing to participate to the research project or not, given these criteria (advising the research supervisor when he or she is responsible for the project or deciding for him or her when the research project "institutionally" penetrates in the Cliniques, that is by way of formal contacts at the top of the hospital).

The costs of the Unit are financed by deducting fixed overheads on clinical research projects (the ones which are known and measurable by the management, and not the ones which are implemented (without communication) on operating costs (cf. *supra*: 1.2). It is worthwhile to note

that this Unit of three persons cannot ensure alone, for the hospital, the work provided the Administration of Research for the UCL. Research projects of an academic hospital well present some specificity in comparison with university faculties' projects. There are some common needs, however, which relate to the search for and spreading of information about funding sources or to the valorisation of research projects, for example. Nevertheless, the use of the Administration of Research's potential in the hospital is limited, however, given the tightness of the organizational boundaries between the General Services of the UCL and the Cliniques Universitaires (some members of the Administration of Research invoke the different legal status of the Cliniques from the legal status of the UCL to explain this). According to the interviewees, the Administration of Research has positively evolved toward coordinating research initiatives among the university services when convergences are noticed, however.

Still at the level of the Cliniques Universitaires, financial resources have been released to organize the status of "*research project coordinator*", responsible for the coordination of research projects. This function is most often committed to nurses. It consists in being the contact point of any interlocutor interested in some aspects of the research project. It also includes the follow-up of patients, the management of information, the administrative tasks such as encoding data on the computer program which has been implemented to manage research projects., etc. All these tasks are performed under the supervision of the supervisor of the research project. There are about 55 full-time-equivalent such positions in the Cliniques Universitaires. The stability of persons in these positions is low, however, because it does not offer any career (professional and wage) perspective. According to some interviewees, it is most often solicited by persons "who want to do something different in a meantime". This initiative participates to the institutionalization of research activities within the SHS-UCL, according to some interviewees. By contrast, they point that, fifteen to twenty years ago, the progress of research projects within the Cliniques was actually a "black box" for the management staff of the hospital.

In valorizing the results of research, the Administration of Research and the Unit of Medical Economics are assisted by the *Sopartec*, the company of technological transfer and investment of the UCL. For example, Sopartec is solicited by the Unit of Medical Economics to provide legal advices on contracts with pharmaceutical firms. As this kind of contracts are not often subjected to major modifications, there are a maximum of about five to six such contacts a year. A convention designates contact persons in each organization and regulates relationships between them at a general level. Sopartec is in charge of:

- Managing the intellectual property of the UCL;
- Transacting license contracts with industrial partners;
- Managing patents of the UCL's research products;
- Investing venture capital in "spin-offs" companies;
- Valorizing the results of research by transacting partnerships with existing companies.

The importance of the role of the Sopartec was nuanced by several interviewees. The collaborative relationships with the company would not be very dense. The amount of patents and licenses aimed at technological transfer would not be very large (investments were not discussed during the interviews). One potential explanation of these mediocre results would be cultural: There is no patenting and licensing culture of biomedical innovations in Belgium, according to some interviewees. Another explanation will be described *infra*: For several reasons, it is not interesting for researchers to patent their findings (cf. 6.1)

2.2.2. Types of research projects

Biomedical research projects can be distinguished on the basis of different criteria, with a corresponding denomination.

Academic and sponsored research can be distinguished on the basis of the funding source of the research projects. Sponsored research includes research projects supported by private companies having an interest in these research projects, such as pharmaceutical firms. The private companies can formally support one or another research project given that the results of this are useful to its industrial objectives. Or the research projects are developed with marginal financial benefits, the data collected or any other support collected in the framework of another kind of industrial contract. Academic research includes all the other studies, that is: Studies supported by commercially uninterested funding sources or by the internal budget of the SHS-UCL. Both types of research can be combined in one study. For example, some clinical trials being at the center of an industrial contract with a pharmaceutical company can be equally useful to an academic study, in such a way that some research products can simultaneously result from an academic study and a sponsored study.

Fundamental, applied and translational research can be distinguished on the basis of the institutional actors involved in the studies, as well as on the basis of their objectives. Fundamental research is developed in the Faculty of Medicine and aim at a better understanding of such or another biomedical question. Applied research is developed in the Cliniques Universitaires and aims at the production of such or another treatment, technique, drug or equipment to care patients. Translational research combines fundamental and applied research. It includes all these studies which simultaneously require, given their objectives, the involvement or researchers in the Faculty and in the Cliniques Universitaires (functionally at least, persons can be the same). These studies are implemented in one hospital service, with the support of one Unit in the Faculty of Medicine to perform fundamental research. According to some interviewees, it is a particularly comfortable position, given the opportunities that the faculty position offers (researchers, material, devices, locals, etc.), in comparison with the constraints it imposes (which are much less numerous than in the Cliniques, according to him).

2.3. Three representative biomedical studies

2.3.1. Liver cell transplantation

Liver cell transplantation is the specialty carried out by Prof. SOKAL in the Unit of Surgery and Abdominal Transplantation within the Cliniques Universitaires and the Unit of Paediatrics within the Faculty of Medicine. Prof. SOKAL is full professor at the Faculty of Medicine.

The Professor and his team try to avoid the transplantation of complete livers for diseased patients. Alternatively, they conduct stem cell research, aiming at using bone marrow, liver, and cord blood derived adult stem cells as a source of hepatocyte after in vitro differentiation.

The project sprang from an encounter and mutual help between Prof. SOKAL and a colleague from Chicago, during a symposium in the United States. Prof. SOKAL exposed his project. At this moment, he was following a patient who was candidate for experimenting this technique. The colleague proposed to rejoin Prof. SOKAL at the SHS-UCL in Belgium with removed cells as soon as he could find a relevant donor. He did it. The first attempt enabled a partial solution for the patient-candidate, a first experience of the new technique, and some first analyses of transplanted cells.

The continuation of the project was made possible thanks to successive fundings, based on its two axes. On the one hand, the research is concerned with the quality of the transplanted cells. In this perspective, the team has progressively focused their attention from mature cells to stem hepatic cells. On the other hand, the research is concerned with translational initiatives. In this perspective, the team is also interested in the development of techniques and substances for cells' transfer.

Translational research allowed to solicit different financial supports. First, Prof. SOKAL met Mr. DEWEZ (project leader at Baxter S.A., a pharmaceutical firm). This person was interested in sustaining a "First Spin-off" file with any interested researcher in the SHS-UCL. The First Spin-off program is funded by the Walloon Region to promote translational research in the scientific institutions of the French Community, in the framework of the regional "*Plan Marshall*" (Biowin cluster)⁶. After a first failure, the application was supported by Ms.

⁶ On 30 Augustus 2005, the Walloon Government presented the "*Plan Marshall pour la Wallonie*", a program for the economical recovery of the Region. This *Plan* represents an important political turn. Since the Region has these competences in its hands, it had never concentrated such an amount of financial means to stimulate the development of its companies. The immediate context in which the *Plan* appears is marked by (...) a new analysis of the causes of the Walloon economic stagnation, which will serve as a basis for a more ambitious, more concentrated strategy, for which the budget will be defined more clearly. In this way, the *Plan* mobilizes 1 billion euros spread over four years. It is articulated around five strategic axes. First of all the implementation of clusters of competitiveness on which a

MONTERRAT. It passed the second call of the program. Second, to ensure the financial viability of the new firm, Prof. SOKAL and his team searched for external investors ("business angels", "venture capital"). It did not work immediately. At stake of due-diligence, a report was commanded to evaluate the project to Arthur D. Little, a consultancy group. The report was critical to convince not only investors, but also the authorities of the UCL of the validity and the legitimacy of the project. Third, the project benefited from the financial support of Glaxo Smithskline Beecham, in the framework of a collaboration which interested Prof SOKAL and his team for one part, and one academic colleague for another part. These supports gave Prof. SOKAL and his team the opportunity to develop a drug medicine, under the "Orphan drug" status at the European Medicines Agency, which is less costly. In this perspective, positive advices of the Ministry of Public Health and by the National Committee of Bioethics were required. To this end, the acquaintance of a member of the EMEA was salutary for Prof. SOKAL: This member helped him to convince the Committee of Bioethics, which was reticent.

2.3.2. Cancer immunology and genetics

This project is carried by Prof. BOON in the Brussels Branch of the Ludwig Institute for Cancer Research. Prof. BOON is extraordinary professor at the Faculty of Medicine and is employed by the Ludwig Institute. He noted that the De Duve Institute, given its organization, is in a certain way a forerunner of the Institutes that are proposed by the *Plan de développement*. Further, it can be noticed that this reform project plans to hold the De Duve Institute, as such, in the new organization.

"The notion that the immune system might be enlisted to rid the body of cancer draws on past work at the Branch, which revealed that most human tumors bear antigens that can be recognized by cytotoxic T lymphocytes (CTLs). Some of these antigens are highly tumor-specific, while others are expressed on certain normal cells. A number of antigens have been found on many different types of tumors, suggesting that a therapeutic strategy targeting such antigens could be used to treat a wide range of cancers. The Brussels Branch continues the search for tumor antigens, and evaluates their therapeutic potential in vaccine trials of cancer patients" (Ludwig Institute for Cancer Research Ltd - Brussels Branch, 2008).

substantial amount of the new means, notably in research and development, will be concentrated. The second axis, the support to the creation of economical commercial and non commercial activities simultaneously constitutes the guiding principle and the primary objective of the *Plan*. Then comes the reduction of taxation on companies, an increased support to research and innovation, as well as an additional effort on training, particularly in languages. A new mode government is adopted, characterized by a rationalisation, a better coordination of public action, and the implementation of structural measures (Accaputo, Bayenet, and Pagano, 2006). The Biowin Cluster, dedicated to human health, is coordinated by J. STEPHEN, the General Director of Glaxo Smithkline, a pharmaceutical firm.

The project sprang from a fortuitous observation by Prof. BOON, while working in a laboratory in the United States. He came back in Belgium to develop it. It is made of successive and partially overlaid phases, implying tests on mice and tests on human persons.

Regarding support, the project benefited from "classical" funding sources at the beginning: For example from the Christian de Duve Institute of Cellular Pathology, the UCL, the Caisse Générale d'Épargne et de Retraite (CGER), etc. Quite rapidly yet, the financial and then institutional and scientific support of the Ludwig Institute for Cancer Research became salutary, notably given the tremendous costs of clinical trials. These trials were made possible thanks to the particularly cooperative attitude of the Cliniques Universitaires Saint-Luc as well as well as some AMC partners in Germany.

Prof. BOON thinks that, in a period of about ten years, a number of legal and political factors have represented new brakes against biomedical innovations. First, the lawyers of the corporate headquarters of the Ludwig Institute in the United States analyzed the clinical trials which were realized in the 1990s by the Professor and his team. They concluded that legal attacks were to be feared. Hence, nowadays, their agreement is required for any new trial. Second, from free, the scientific collaboration with other research centers around the world has become more and more expensive. Third, social insurance systems have become under financial and thus political pressure. Hence, the generosity of AMCs and other hospitals for performing clinical trials has decreased. Furthermore, the offers of fundamental and academic research centers like the Ludwig Institute must compete with more and more attractive proposals of private pharmaceutical and industrial corporations. Fourth, in the 1990s, control on trials was roughly limited to the approbation of the proper ethical committee or commission at the level of the universities. Nowadays, this control has not disappeared, but it is complemented with other structures at diverse political levels. Fifth, molecules must be added in new medicines to increase their performance (absorption speed; reduction of secondary effects, etc.), given recent research results. Molecules can be produced by patented firms only. But the more and more complex rules and financial requirements which surround this step make it less attractive for industry to realize it, mostly for medicines which investment return is not guaranteed indeed. Hence, it is more and more difficult to find appropriate molecules to be included in new medicines. Sixth and finally, all these factors were multiplied as soon as actors intervened in their respect at the European level. Together, these factors represent strong financial and temporal brakes for biomedical innovation.

2.3.3. Measurement of hepatic fibrosis

This project is carried by Prof. Yves HORSMANS in the Unit of Gastroenterology of the Faculty of Medicine and in the Service of Gastroenterology in the Cliniques Universitaires. Prof. HORSMANS is full Professor in the Cliniques Universitaires.

Currently, hepatic fibrosis is measured by way of a liver sample, analysed in a laboratory. To avoid this invasive technique and to enhance the representativeness of the measure, Prof. HORSMANS and his team proposed to use nuclear magnetic resonance.

The project benefited from classical funding sources. But the main financial issue at stake was the purchase of the equipment required for nuclear magnetic resonance. The acquisition was dependent on the announcement by several teams of their interest for the future equipment, which was the case. The decision was made to purchase it via the Foundation Saint-Luc, with the help of the National Fund for Scientific Research (fifty-fifty). Nowadays, several researchers of the SHS-UCL use this equipment at discount prices.

Regarding collaborations, there is only one team around the world which conducts similar research. This team of Rochester (New York, USA) will now put the results of Prof. HORSMANS to the test, to confirm or correct them.

Chapter 3. Definition and types of biomedical innovation

The interviewees were asked and the documents were examined to suggest possible *definitions* of "biomedical innovation". According to one interviewee, biomedical innovation can be defined as a "response to a need". In the same line, according to another interviewee, an innovation is an "improvement".

More specifically, this response, this improvement can be related to particular criteria. In this line, according to one interviewee, biomedical innovation could be defined by reference to its economical added-value. Some interviewees relate it to the "quality of life" of patients and to the improvement of "therapeutic treatments".

Quite differently, it is also proposed to define biomedical innovation according to the criteria that projects have to fulfil to benefit from funding. For example, the "*Plan Marshall*" of the Walloon Region includes criteria to grant financial support to the BioWin Cluster, dedicated to life sciences. Another example consists in the conditions which a discovery is patentable upon: It must be new, imply an inventive activity and it be susceptible of industrial application (Loi du 28 mars 1984, art. 1). On this respect, some interviewees note that there is no consensus among agencies about the definition of biomedical innovations. For example, there is no common definition among drug agencies of different nations and at different political levels.

When questioned about the definition, interviewees also spontaneously distinguish different *types* of biomedical innovation, on the basis of the following dimensions:

- The final "material" product: Substance, technique, or equipment;
- The final "scientific" Product: publication, patent, prestige, communication, etc.;
- The commercial implications of the discovery;
- The orientation of the research: Directly toward the patient or indirectly by aiming at improving information, communication, infrastructure, management, etc.;
- The place of the innovation within the research cycle: Informative or translational, or applied research.

Interestingly enough, one interviewee also points out that biomedical innovations can be distinguished along another continuum that he names "quality", "goodness", or "degree". The interview made clear that these dimensions do not refer to "types" of innovation, but well to the measurement of biomedical innovation, according to the expert judgement by, for example, the peers. More broadly speaking, one can also imagine the judgement of other kinds of stakeholders, including ethicists or the public opinion, for example.

Chapter 4. Macro support to biomedical innovation

This chapter examines which support to biomedical innovation exists in any Belgian AMC. Financial and political supports are distinguished (Sections 4.1 and Section 4.2). Each of them can (or cannot) be provided by public (Sub-Section 4.1.1 and Sub-Section 4.2.1) and private organizations (Sub-Section 4.1.2 and Sub-Section 4.2.2).

4.1. Financial support

Proportionally, the amount of financial support provided by public authorities is less important than the one provided by private sources. And this tendency is increasing, according to some interviewees: "The private sector increasingly provides money, while the public sector increasingly regulates". The financial support of the public authorities is not negligible, however, mostly for some types of research, such as fundamental research.

4.1.1. Public financial support

"Researchers need means and freedom": "Allow financial support without control to experienced researchers and you will lose the half of your money; allow financial support with control and you will lose everything", says one interviewee. Generally speaking, interviewees complain about the lack of public financial support for biomedical innovation. They also notice the constraints imposed on the access to funding sources. Regarding financial support to biomedical innovation, politicians "settle for managing a budget while preserving several particular interests". Several funding sources from the public sector are cited, however.

Fundamental research is funded by major public funds. Given its competence in scientific research, the French Community is often involved in the subsidization of these funds. It has already been underlined that the distribution of the amount of money provided by the French Community to The *Fonds National de la Recherche Scientifique* among researchers and universities is at the center of intense negotiations (cf. *supra*: 1.1.2). At this level is also discussed the distribution of the *Fonds Spéciaux de Recherche*. This amount of money is distributed to the universities. But, differently from the first funding amount, this is directly managed by each university, and not committed to such or another researcher or research project.

Applied research is funded by all public authorities (governments, administrations, agencies, etc.) at all political levels, including the French Community too. Research projects are funded by authorities when these projects involve their own political competences, most often following a public call. For example, the program Waleo which provided support to Prof. SOKAL and his team (cf. *supra*: 1.2.1) is aimed at developing industrial applications, including in the sector of biomedical research, given the competence of the Walloon Region in economy and industry. This represents an important part of the public financial support to research. For this reason, several interviewees bear witness of the difficult exercise consisting of including fundamental research objectives within the budgets aimed at applied research (for example by including the required salary for writing a doctorate thesis or for performing some additional series of clinical trials). Selection and follow-up of the projects are often committed by the public authorities to scientific committees, totally or partially composed of stakeholders (for example, university managers or representatives of public authorities), as well as of independent experts from abroad. Some interviewees highlighted the importance to "respect" the public funder (for example, by publishing the expected reports), as well as the quality of the scientific and administrative follow-up committees.

The European Union supports research through the Research Framework Programs (currently, the 7th). These programs consist in allocating a financial support to research projects, on a competitive basis. Biomedical innovation in the SHS-UCL is finally indirectly influenced by numerous European and national directives, laws, and decrees regulating a series of related fields, such as the "Law of 19 December 2008 related to the acquisition and use of humane material aimed at medical ends or at scientific research ends".

Another kind of public financial support consist in *special budgets associated with some public programs* concentrated on one or another specific theme, such as cancer or VIH. A recent example of this kind of budget consists of the "Action 29" of the "Plan pluriannuel de lutte contre le cancer 2008-2010", which consists, among others, in financing 29 projects oriented toward translational cancer research in 2009-2010⁷.

The "Télévie" is another example of such a program supporting the fight against cancer. Sustained by the public authorities (for example, the *Fonds National de la Recherche Scientifique*), *Télévie* is a program of demonstrations organized and promoted by RTL, a private television and radio broadcast corporation in Belgium. Some interviewees pointed the political stakes raised thanks to this kind of initiative. On the one hand, some diseases are pointed up to the eyes of the public opinion. For example, it is much easier to obtain donations of the public

⁷ It is interesting to note that four of the selected projects involve a research team of the SHS-UCL, sometimes with teams of other universities: Project 018 - Safe Margins in Bone and Soft Tissue Sarcomas : A Prospective Study (Prof. X. BANSE); Project 019 - B-cell Chronic Lymphocytic Leukemia (B-CLL): A Model To Test The Synergy Between Chemotherapy And New Biological Treatments In An Attempt To Cure B-CLL Patients (Prof. C. CHATELAIN and Prof. E. VAN DEN NESTE); Project 049 - Characterization of Spontaneous and Vaccine-induced Immune Responses Against Melanoma, and Analysis of their Influence on the Clinical Course of the Patients (Prof. Dr. P. COULIE, Prof. K. THIELEMANS, Prof. J.J. VAN DEN OORD); Project 051 - Functional Image-guided Intensity Modulated Therapy : Integration of Tumor Microenvironment in Treatment Planning : A Joint KUL-UCL Project (Prof. V. GREGOIRE and Prof. Dr. K. HAUSTERMANS).

for diseases such as cancer than for less-known diseases. On the other hand, positions and relationships of research supervisors with the policymakers and the coordinators at the top of these programs are of much importance to get funding for biomedical studies, given the concentration of money collected. For example, the first *Télévie*, in 1989, collected 2 014 737 €. In 2008, it provided 8 117 840 €.

Special budgets can also be dedicated to policies of biomedical research promotion. On this respect, the *Plan Marshall* has already been described *supra* (cf. 1.2.1), for example. As for applied research projects, researchers try to transfer the benefits made on research applications toward fundamental research.

Other smaller funding sources for biomedical research include *prices* for research applications and discoveries. Financial support is sometimes provided for smaller initiatives, such as a research journey in a foreign university, sometimes through a permanent invitation to tender, sometimes through a particular invitation, limited in time. Initiatives by the "*Fonds National de la Recherche Scientifique*" as well as by the Brussels Region to hold Belgian researchers in Belgium were finally noticed by the interviewees. For example, "Brains back to Brussels". Interviewees remarked that this kind of funding sources are limited in time and irregularly opened. Hence, they are of poor "quality", due to planning difficulties.

Finally, the public financial support to hospitals mainly consists of the "*Budget of Financial Means*" ("*Budget des Moyens Financiers*"), distributed by the Federal State. AMCs receive about eight percents of additional such public financial support, compared to classical hospitals, to fund research activities (when permanent researchers who are also physicians in the Cliniques Universitaires conduct research, this creates a shortfall time during which they cannot practice health cares to patients, beneficial for the hospital). Actually, the additional cost of the additional mission of AMCs, compared to classical hospitals has been evaluated to be 24% by Antares Consulting, as was echoed by some interviewees. The Budget of financial means covers 32 % of the operating costs of the Cliniques Universitaires Saint-Luc (Cliniques Universitaires Saint-Luc, 2008b, p. 44).

4.1.2. Private financial support

The largest part of financial support coming from private sources is provided by pharmaceutical companies, for sponsored research. It is aimed at clinical trials, as well as at industrial contracts with permanent researchers, to develop a technology or a substance. Other financial supports are allocated to the SHS-UCL for exclusively industrial tasks (that is: Not including research activities), including the test of developed material and devices (the SHS-UCL as "beta-site"). Money earned on this basis can be re-invested in research projects, but

also in health cares. In addition, the AMC can make its patients benefiting from these materials and devices for free or cheaply, during the tests and afterwards.

Except in the framework of promotional activities, including the funding of a chair, the organization of a scientific prize, or the funding of a research journey, private financial support is not primarily aimed at academic, fundamental research. As for public financial support, academic researchers as well as permanent researchers must ground on budget allowed to sponsored research to develop fundamental research projects. Nevertheless, according to some interviewees, researchers are even fond of this kind of financial support given the quick link between investment and benefits.

4.2. Political support

4.2.1. Public political support

Opinions are highly divergent among interviewees about the *density and quality of relationships* between SHS-UCL's actors and public authorities: From "inexistent" to "permanent", from "bad" to "good". For example, some interviewees estimate that relationships between biomedical innovation managers of the SHS-UCL and politicians are permanent. They mainly occur at the Regional or Community level, given that French-speaking actors are less favorably treated at the Federal level. Generally speaking, researchers and managers in biomedical innovation are well understood by their political interlocutors, according to the same interviewees. Just the opposite, some others estimate that relationships between biomedical innovation's actors from AMCs and politicians are nearly inexistent, at least in an institutionalized way. According to some of them, politicians do not hold the best welcome to AMCs' demands.

Some clues - sometimes pointed by the same interviewees - suggest an intermediary situation about the density and quality of the politico-professional relationships, however. On the one hand, direct relationships exist between some representatives of biomedical researchers of the SHS-UCL and politicians. For example, the Management and the Direction of the SHS-UCL sometimes meet relevant Ministers to influence funding distribution among hospitals, as wells norms content⁸. The "*Conférence des Hôpitaux Académiques de Belgique*" smoothly gathers the Belgian AMCs to share their expertise about specific issues, as well as to

⁸ On this respect, it is interesting to note that the political party of the Minister has no impact on its reception of the demands of the SHS-UCL, while historical proximities of between some universities and their AMC with some specific parties could suggest the contrary. For example, a university such as the UCL is historically closer to historically more Social-Christian parties than with others, whereas a university such as the *Université Libre de Bruxelles* is historically closer to historically left-wing and liberal parties.

promote direct relationships and lobbying, towards politicians. According to some interviewees, individual initiatives of researchers, next to policymakers, have few chances to succeed. Generally speaking, relationships with public authorities are managed by a specific administration or unit of research within AMCs and universities, as it is the case within the SHS-UCL, when it does not occur at the level of the management or the direction.

On the other hand, *formal structures* exist to organize institutionalized relationships between actors of biomedical research and policymakers. The political role of public agencies must not be neglected. For example, orientations proposed by the General Secretaris of the "*Fonds National de la Recherche Scientifique*" - formerly Ms. Simoens and more recently, Prof. HALLOIN - are highly important, according to some interviewees. In addition, the following organizations provide spontaneous, solicited, or compulsory advices to the attention of the Federal Government, regarding restrictive norms on hospitals management (which, as already mentioned, can have huge impact on biomedical research (cf. *infra*: 5.5):

- The "*Conseil National des Etablissement hospitaliers*": It provides advices about programming, approvals, and funding of Belgian Hospitals; it is composed of experts or stakeholders in the administrative, medical, nurse-related, or health-insurance-related management, appointed by the Minister of Public Health;
- The "*Structure Multipartite*": It provides advices about crucial aspects of hospitals policy: It is composed of representatives of the medical doctors, the hospitals, the insurance-health-system, the "*Institut National d'Assurance Maladie-Invalidité (INAMI)*", the "*Conseil National des Etablissements Hospitaliers*", the "*Centre Fédéral d'Expertise*", the "*Inspection des Finances*", and the "*Commission de Contrôle du Budget*"⁹;

Besides these relationships, one must not neglect the support (or the obstacle) which can be provided by public authorities *by modifying the legal framework of biomedical research*. Among others, these modifications can result from relationships with biomedical research actors. To give only one example, one can refer to the European regulation on Medicinal Products for Paediatric Use. The implementation of this regulation has without doubt a positive impact on the activities of a center such as the Paediatric Clinical Investigation Center, of which the activities are focused on sponsored research and clinical trials (cf. *infra*: 5.4). Indeed, this regulation imposes specific clinical trials for the use of some drugs on children, while it was not the case before 2007 (Cliniques Universitaires Saint-Luc, n.d.).

The public authorities can also contribute to biomedical research *by making AMCs more visible*. This includes a wide set of tools, from taking their needs into account in any negotiation or projects with any other private or public, domestic or foreign actor, to specific interventions, such as an official visit of a Minister in a research center. Finally, some interviewees also notice

⁹ The General Administrator of the Cliniques Universitaires - Guy Durant - has been identified *supra* as the "minister of foreign affairs of the Cliniques Universitaires and, to a lesser extent, the SHS-UCL (cf. 1.1.2.2). In this framework, it worthwhile to note that he is currently President of the *Conférence des hôpitaux académiques de Belgique*, President of the Section of Funding within the *Conseil National des Etablissements Hospitaliers*, as well as responsible for the Working Group on "Justified Admissions" within the *Structure Multipartite*.

that public authorities could beneficially promote collaborations between AMCs and the pharmaceutical sector.

4.2.2. Private political support

Private firms have their own network of political lobbying, to promote their commercial interests. However, instances exist where AMCs indirectly benefit from this lobbying, if it is aimed at promoting clinical trials or industrial contracts in which they are involved.

More direct initiatives can be taken by private firms, however. For example, a group formed by four pharmaceutical firms - the "G4": Glaxo Smithkline, Janssen, Pfizer, and UCB - once approached the *Conférence des hôpitaux académiques de Belgique* to suggest a common, "political" partnership. Roughly speaking, they proposed to activate their own network of political lobbying towards public authorities, in exchange of more industrial contracts and clinical trials in Belgian AMCs, which is considered as a "virtuous circle" by some interviewees. The firms presented a positive "systemic" approach of sponsored research, according to them: Biomedical innovation to the benefits of patients, and patients to the benefit of biomedical innovation (cf. *infra* the importance of the capacity of patients inclusion: 5.5). In the same line, some other interviewees judged that relationships between private companies and AMCs are "win-win": AMCs offer private companies the opportunity to test and sell their products, while private companies offer AMCs the most up-to-date technologies and the possibility to buy them, sometimes at discount prices.

Chapter 5. Organizational supports and impediments to biomedical innovation

This Chapter examines which supports and impediments are identified at the organizational level to biomedical innovation, specifically in the SHS-UCL.

The SHS-UCL, as an organizational framework that supports biomedical research, provides the general infrastructure, services, and salaries of technical and administrative staffs, as well as of researchers. It pertains to research supervisors to find relevant resources and relationships to fund salaries, material, and other costs of research projects, assisted by the SHS-UCL (cf. *infra*: 6.2.1) and the macro support of public and private institutions (cf. *supra*: Chapter 4). Then, the supervisors are also ultimately responsible for all the content-related, as well as financial, technical, and legal aspects of the projects and contracts. This is different in North-American AMCs, where the administration is often large enough to manage the search for external research credits, according to some interviewees.

Some other interviewees point that research supervisors work at the best place to ask the best questions and provide the best answers, however. This is even more particularly the case of permanent researchers in the Cliniques, which are actually confronted to the patients and their diseases (as underlined in the Antares report). For this reason, permanent researchers are often the best lobbyists to defend research projects, according to the same interviewees.

Individuals are very important in biomedical research, to such an extent that professional relationships with external partners (other research centers, hospitals, private companies, etc.) are most often lived as "personal" than as organizational or institutional, according to some interviewees. This general organizational framework, combined with the intellectual freedom of researchers, made some interviewees claiming that the SHS-UCL is like a multitude of small businesses ("*Petites et Moyennes Entreprises*"). When considering this general level of analysis, some organizational patterns are already more or less conducive to biomedical innovation.

At a general, organizational level, some "political" initiatives of the management of the SHS-UCL, which financially or otherwise support biomedical research, can be illustrated here. For example, a dinner was organized at the initiative of the Rectoral team, aimed at past or future creators of "spin-offs" companies, to make them visible, to congratulate them, and to promote collaboration and experience sharing among them. When organizing journeys abroad, the rector invites relevant research supervisors to join him. On these occasions, contacts of researchers with foreign scientific institutions, commercial companies, or public authorities are facilitated by the Rector. Quite astonishingly, some permanent researchers notice that relationships between the researchers of the SHS-UCL and its Rector are probably more dense

abroad, during official missions, than usually at home. At a higher level, these journeys provide the opportunity for the management of the UCL, the research supervisors of the SHS-UCL, as well the policymakers and directors of public authorities to get closer, the first acting as a mediator between the two last, as is illustrated by the interviewees.

Five other more specific issues influencing biomedical innovation potential in the SHS-UCL can be discussed at the organizational level: The modes of decision making in the Sector (Section 5.1), the organization strategy regarding this activity (Section 5.2), the relationships between the Faculty of Medicine and the Cliniques Universitaires (Section 5.3), the financial arrangements made to support biomedical research projects in the Sector (Section 5.4), as well as the relationships fostered by the SHS-UCL with other Belgian Hospitals in the framework of this kind of projects (Section 5.5).

5.1. Decision making

According to some interviewees, the SHS-UCL suffers from a "*réunionite aiguë*" (an "acute meetings disease"). Except for global decisions, permanent researchers are most often systematically involved in decisions at the level of their Unit or their Department. The UCL is quite specialized in creating a multitude of councils, committees, groups, etc. in charge of discussing diverse issues. This implies the participation of permanent researchers to numerous meetings, related to the health care and research activities, as well as to administrative, technical, and managerial issues, while the SHS-UCL's managers could have them in charge. Some temporary researchers (assistants and scholars, for example) sometimes attend these meetings too. The time taken by these meetings, their preparation, and their follow-up cannot be devoted to biomedical research as such, even though the necessity of such conciliations is recognized, to a certain extent.

The multitude of decision places also raises power-related questions. On the one hand, permanent researchers who more and more involve themselves in these places have less time to conduct research and to find external research fundings. On the other hand, they hold the good position to orientate internal funding towards their own projects or related research fields. In the same line, they can influence the organizational strategy towards external funding sources to promote their own research field.

A seemingly related issue consists of the impact of the "reputation" of a research field as an important factor to be integrated in such decision places. Researchers conducting studies in some fields such as cardiovascular diseases seem to find more open doors to decision places within the SHS-UCL than specialists in other fields, such as paediatrics. The first fields would be culturally and financially more strategic than the second ones. For example, cardiology is much valorized from these two points of view. By contrast, paediatrics is not very reputed among

academics, but it has the humane favors of the top managers of the SHS-UCL (among others, the external members of the governing boards) and the public funding sources, as well as in the public opinion. Combined with the scientific reputation and the financial attractiveness of research fields, the previous organizational responsibilities of persons play an important role for accessing to decision places in the SHS-UCL.

The multitude of discussion and decision places homogenizes the choices at all levels. But it also contributes to homogenize refusals for research proposals or other kinds of initiatives, and hence the power of some (persons, research fields, etc.) on others too.

Finally, it can be noted that all members of the executive boards of the SHS-UCL are academic persons, that are researchers who stopped or decreased their research activities to take managerial tasks in charge, instead of expert managers.

5.2. Biomedical research strategy

Strategy and reforms at the level of SHS-UCL as well as at the level of the Cliniques Universitaires seem to be decided at the level of the UCL, in the Governing Board or in the Medical Center. More specifically, decisions regarding university affairs and fundamental research are made at the level of the UCL, while decisions regarding hospital affairs and sponsored research are made at the level of the Cliniques Universitaires. But, as explained *supra* (cf. 1.1.1.2 and 1.1.2), persons who actually make decisions at the level of the Cliniques Universitaires are also members of the Medical Center and the Governing Board of the UCL. As described by some interviewees, external members of the Governing Board of the Cliniques Universitaires act as experts in the financial and managerial fields. They give advices regarding budget management. Besides, internal managers must often explain them what the other (medical, research-related, etc.) stakes of the decisions are, as described by some interviewees. For these reasons, there is coherence in the management of the SHS-UCL. At the other side of the coin, some other interviewees point that the management of the SHS-UCL (concentrated in Woluwé-Saint-Lambert) by "Louvain-la-Neuve" (that is: By the management and direction of the UCL) does sometimes not take into account the specificities of the Sector given remoteness.

The strategic plan of the SHS-UCL is to combine the services of proximity of the Cliniques Universitaires, while improving the role of AMC of reference in French-speaking Belgium and around the world. To contribute to the second role, one of the major components of the management's strategy is to focus resources on selected, strategic research fields, that is: "To capture some market shares". According to some interviewees, it could be useful to take the analysis of Antares into account for selecting relevant research fields. This selection would allow to match personal initiatives to the institutional strategy of the SHS-UCL. On this

respect, some interviewees notice that these research fields have not been selected yet by the direction of the SHS-UCL.

5.3. Faculty-hospital relationships

Faculty-hospital relationships are not institutionally "organized" in the SHS-UCL. At the managerial level, they are *de facto* ensured by persons who commonly take part to the governing and executive boards of the faculty, the hospital, and the UCL. At the operational level, they are primarily ensured by researchers who hold responsibilities in both organizations. From a legal and financial point of view, the Cliniques are a not-for-profit organization distinct from the UCL. For this reason the acts and accounts of both institutions must officially be distinguished. Actually, aspects such as personnel, finances, legal and infrastructural issues, together with research-related questions are indeed managed separately. There is seemingly no will (or possibility, or authorization?) from anywhere to join the management of these dimensions for the Faculty of Medicine and for the Cliniques Universitaires, for example at the level of the UCL. Even the *Plan de développement* does not seem to be directed toward such an objective. According to some interviewees, there is no tension between the management of the UCL and the Cliniques Universitaires with regard to strategic or biomedical-research-related issues. By contrast, some other interviewees point tensions between the Cliniques and the Faculty with respect to the distribution of resources.

Generally speaking, relationships between researchers of the Cliniques Universitaires and researchers of the Faculty of Medicine are good. Sometimes, fundamental researchers can denigrate the nobility of the job of their colleagues, given the constraints to which they are submitted. The inverse criticism is formulated by permanent researchers implicated in the Cliniques Universitaires who estimate themselves to be better positioned to ask the relevant scientific question, due to the contact with patients. These dissensions are judged marginal by the interviewees.

5.4. Financial arrangements

Some ways of financial support to biomedical research at the level of the SHS-UCL have already been described *supra*. They consist in the infrastructure and the salaries of permanent researchers paid by the SHS-UCL (cf. Chapter 4), the research-related services provided by the administrative staffs and the Sopartec, as well as the investments made by the Sopartec (cf. 1.2.1.2). In the same line, an indirect support provided by the SHS-UCL at the individual level, to the research supervisors, is their PACI status which will be described *infra* (cf. 6.2.1).

Besides, the SHS-UCL provides financial support for the acquisition of special materials, equipments. On this respect, the SHS-UCL sometimes takes in charge the negotiations with one or another private or public funding source to benefit from some support. For example, the recent acquisition of nuclear magnetic resonance has been funded by the SHS-UCL for one half, and by the FNRS for the other half. This kind of purchase is more favourably consented when several research teams ask for it, which was the case for the nuclear magnetic resonance.

General costs as well as special equipments are financed with the general budgets of the SHS-UCL, that is, the budget of the Cliniques Universitaires as well as the budget of the Faculty of Medicine. In the Cliniques, some of the benefits from the health care services are institutionally transferred to research activities, together with the general overheads deducted on previous research projects. Besides, the use of the financial surplus produced by research projects in the Faculty of Medicine and the Cliniques Universitaires is committed to academic and clinical research supervisors who, at their level too, try to transfer benefits from sponsored research to academic research (as explained *supra*: 4.1.1). For example, a research center such as the Paediatric Clinical Investigation Center- coordinated by Prof. E. SOKAL - yields more money than it costs, given that it focuses on sponsored research and clinical trials quite exclusively. This represents an important amount of money, according to some interviewees. This amount could be used to reach some objectives of the organizational research strategy. However, there is no such a strategy in the SHS-UCL, according to the same interviewees. Generally speaking, there is no institutional control of the SHS-UCL on the activity of the researchers and services. As indicated by some interviewees, this control should be based on objective measures of the activity of the researchers and services. For example, at the organizational level, an analysis of the global impact factor of each service could be performed every three years. This represents a huge and complex work, however.

The contribution of the "*Fondation Saint-Luc*" can also be underlined. It centralises the financial patronage in the Cliniques Universitaires. Its historical role, since 1976, is to promote the education of the students and researchers of the UCL by funding study journeys and other educational projects of limited scale. In this task, the *Fondation* strives to only spend interests of its financial capital, while trying to increase it. Since 2004, the objectives of the Foundation have been enlarged to the funding of a limited number of multidisciplinary research projects, however. The "*Déjeuners scientifiques*" regularly gather the research projects' supervisors and contributors, to thank and inform them for and about their contribution. By way of examples, the research projects supported in this way in 2008 were concerned with: Psycho-neurosciences, gynaecology, obstetrics, cardiology, neurosurgery, paediatric, liver diseases, cancerology, and blood diseases.

In the same line, at the level of UCL, the "*Fondation Louvain*" funds research projects to which the Faculty of Medicine can be associated (for example, about the Alzheimer disease), as well as academic chairs, educational projects, and cultural projects. But these are to a lesser extent directly related to biomedical research, generally speaking (among others: Given the existence of the *Fondation Saint-Luc*).

5.5. Relationships with other Belgian hospitals

Relations between the SHS-UCL and other hospitals in Belgium hold a great attention from the SHS-UCL authorities. As mentioned *supra* (cf. 1.1.1), any Belgian hospital must respect legal rules regarding programming. Programming rules regulate the distribution of the health care offer around Belgium, among others the minimum and maximum number of beds and nurses in each hospital. In turn, the authorized number of beds limits the minimum and maximum aggregate amount of money that can be asked to patients for services. In turn, this limits the personnel (among others: Researchers) and investments that can be hired and incurred into the hospital.

Programming rules are discussed at the level of the *Conseil National des Etablissements Hospitaliers* (cf. 4.2.1), among others. This limitation is also related to the "inclusion capacity" of an AMC, that is: Its capacity to include potential patients into research protocols and clinical trials. Hence, while the stake for small classical hospital consists of attracting as many patients as possible, an AMC like the SHS-UCL has to insure the best possible turnover of "interesting" patients, to optimize its inclusion capacity (more new patients means more potential interesting patients for research protocol) as well as the number of beneficial care services that can be carried out (beds are occupied anyway, hence it is important to optimize the number of care service per bed).

In this context, upstream relationships with local and regional classical hospitals are strategic. For the Cliniques Universitaires, these hospitals represent a potential provision of interesting patients around Belgium. Hence, it is important to conclude agreements with these hospitals to get the exclusivity on patient transfers for research purposes or to practice specific, technologically dense care services. These hospitals also represent a potential professional environment for the vocational training of students from the SHS-UCL. In turn, these local and regional classical hospitals benefit from the support of the SHS-UCL, at several regards (among others: Promises of investments).

Downstream, it is also strategic to make arrangements with hospital of medium- or long-during stays, to welcome patients under monitoring, who do not need advanced care services anymore or who do not have an interest for a research project or clinical trials. In these hospitals, technological investments can be less dense and costly.

Agreements with upstream and downstream partners can take many forms, from smoothly coordination (for example, with the Hôpital Psychiatrique du Beau Vallon) to organizational absorption (for example, with the Institut Albert Ier et Reine Elisabeth, notably in exchange for one place in the Governing Board of the Cliniques Universitaires to the former owners of the Institut, the *Catholic Oeuvre du Calvaire*). A specific network of hospitals has been created under the initiative of the Cliniques Universitaires in this sense: The "*Réseau Santé Louvain*". In the same line, services are developed to ensure some health cares at

patients' home, such as the dialyses at home or the post-birth services with the "*Maternité à Domicile (MADO)*".

Chapter 6. Individual motivations to biomedical innovation and support

This Chapter examines motivations to biomedical innovation at the individual level. In Section 6.1, it identifies them. In Section 6.2, it scrutinizes which support is provided at the organizational and macro levels to these individual motivations.

6.1. Individual motivations for biomedical innovation

Intellectual motivation consists of the researcher's feelings such as "enthusiasm", "curiosity", and "entrepreneurship", as named by the interviewees. Such feelings are fed by the newness and diversity of research tasks. They justify why it is more relevant to group a small group of researchers in a research unit (as should be the case in the *Plan de développement*, cf. *supra*: 1.3), to make it efficient. These are important individual conditions to conduct research. They were often cited as necessary conditions, that is to say: Other individual conditions are often not sufficient enough to create and maintain vocations, without intellectual motivations.

The *financial motivation* primarily refers to the salary. Indeed, it is very difficult for researchers to benefit from secondary financial advantages of their intellectual production. On the one hand, the salary itself does not evolve according to the research products. On the other hand, the only way to associate one's own name to the financial benefits of a research product is to patent it. Patenting requires huge financial and personal investments, as well as time, however. According to some interviewees, all in all, individual researchers and even small research teams within AMC's cannot make personal profits from patenting; only the big pharmaceutical firms dispose of a sufficient time horizon to make such financial calculations. In addition, only some academic research projects give the researcher the privilege to associate his or her own name to the findings. Other profitable activities exist to financially benefit from research activities. They include the creation of a private firm ("spin-off") to commercialise the research products. They also include the private medical practice, that is: The AMC does not pay any salary for these care services and the patients directly pays the doctor, working as free agent at home or within the AMC, taking advantage of one's "aura" as specialist in the field. But these activities do not provide financial motivations to conduct research *within* the SHS-UCL as they involve, if not less time availability for research as such, at least partly continuing this activity out of the SHS-UCL.

Cultural motivations refer to social recognition of research activities. These refer to the personal prestige of the researcher within society as a whole. More specifically it also relates to the intellectual recognition by the peers.

Material and contextual motivations relate to the development of a professional environment conducive to researchers' performance. This includes the natural environment, the organizational running, the place of the organization within society, job flexibility, transportation facilities, familial advantages, inter-personal relationships, etc.

6.2. Support to individual motivations

6.2.1. Organizational support

A major measure of the SHS-UCL at the individual level consists of the "*Projet Académique Clinique Individuel (PACI)*". This statutory framework insures the permanent researchers working in the Cliniques Universitaires that 3/11 of their time can be devoted to academic-research-related activities, while the other 8/11 must be devoted to health care services. In turn, these permanent researchers must submit a series of objectives that they will aim at accomplishing in these 3/11. These objectives can include the creation of a "spin-off" company, for example. More classically, it is concerned with research themes, publications, or the formation of temporary researchers. The calculation of the /11 is made at the level of the services, given the number of PACI that each of them includes. From the point of view of the management, this measure actually represents a financial effort made the SHS-UCL, given that the salary of physician-researcher within AMCs is the same as in other hospitals, while they do not devote their whole time to directly profitable health care services, unlike in other hospitals. According to some interviewees, this measure indeed represents a net wage revalorization, in effect. Interviewees noticed that this framework was actually enforced long before its formalization under the PACI.

By contrast, this current formalization is only formal and on paper, for at least three reasons identified by the interviewees. First, the individual pattern of this framework is nuanced by its implementation at the level of the services; within services, permanent researchers are free to charge some members of more health care services to provide some other members some additional free time for conducting research. Second, the content of the proposed objectives is not really submitted to a formal approval by the management. Third, the (non-)accomplishment of the objectives is not accompanied with rewards and sanctions. Anyway, there is no actual evaluation of the fulfilment of the objectives. It must be noted that the academic freedom of permanent researchers plays a role in their demands for autonomy as well

as in the difficulty for the management and the direction to formulate and control individual objectives¹⁰.

The research strategy of the SHS-UCL - that is: Focusing resources on selected, strategic research fields, as mentioned *supra* (cf. 5.2) - has also impacts on individual motivations. Indeed, while the intellectual freedom is a condition for enjoying research enthusiasm, curiosity, and entrepreneurship, formatting supported research fields at the organizational level - which will be organizationally but also financially promoted - *de facto* limits this freedom. In the same line, interviewees perceive increasing administrative and financial constraints on research projects which, combined with a limited salary (cf. *infra*: 6.2.2), do not support intellectual motivations. They argue that, in this context, getting the advantage of the intellectual freedom requires such a personal willpower that it demonstrates the importance of intellectual motivations in conducting biomedical research.

Regarding the research strategy of the SHS-UCL, some interviewees make "moderate" suggestions. On the one hand, current students interested in research activities should be directed toward selected research fields, strategically, financially interesting for the SHS-UCL, that is: The "party line" should be inculcated early, to avoid organizationally and personally painful reorientations of the research interests. By contrast, older, confirmed researchers could be stayed away from these strategic changes: They are experts in their research field. Letting them conducting research projects in their field preserves the potential of unexpected research findings in any domain. According to the interviewees, this would combine an answer to the concentration of resources of biomedical research while avoiding organizational changes detrimental to individuals. Generally speaking, however, the SHS-UCL has little power on its researchers to implement and enforce any organizational strategy, including such research strategy, according to the interviewees. And, again, the statutory academic freedom warranted to permanent researchers plays a role in this context.

Supports and impediments provided by the PACI status and by the research strategy of the SHS-UCL relate to personal and financial motivations of the researchers. As identified by the researchers, *several initiatives have been taken in the SHS-UCL to sustain the material and contextual motivations of the researchers*. They include a leasing plan to provide cars to the permanent researchers and members of the hospital management. They also include all the components of the global institutional strategy for human resources at the level of the UCL: Modern equipments, buildings renovation, natural framework, advantages in some stores and on financial products such as insurances, familial advantages, continuing education, etc.

¹⁰ The academic freedom is statutorily granted to permanent researchers to perform their professional activity with such or another orientation, relevant in their eyes. According to some interviewees, this creates such an important employment security that any permanent researcher has the choice to "settle" or to continue "having fun" in his or her career; it seems highly exceptional that a permanent researcher receives any sanction of any degree from the direction of the SHS-UCL, and only in cases of total professional inactivity (which does not prejudice of the actual professional activity of permanent researchers in the SHS-UCL and hence the actual necessity of such sanctions).

From a cultural point of view, motivation is organizationally sustained by publicizing research products of the researchers, in the Cliniques Universitaires as well as in the Faculty of Medicine. This includes prizes, awards, advertises on poster within and outside the SHS-UCL, mentions in the reports of activities, etc. The management of the SHS-UCL aims at repeating, diffusing and constantly distilling these initiatives throughout the AMC, according to some interviewees. According to them, there is a high creativity of the management in this domain. In another but related line, without denying these initiatives, some interviewees noticed that researchers suffer from a lack of internal, informal recognition by hierarchy, however. For example, when a research product is realised or when a step of a research project has been overcome, direct congratulations are rare from the hierarchy and the SHS-UCL management, while it may be important at a "symbolic" level.

In conclusion, the administrative support provided by the institutional actors described *supra* (cf. 1.2.1.2) can be mentioned again here. It must be noted that this support participates to the institutionalization of research activities in the SHS-UCL. This puts constraints on the work of research supervisors. But this support is substantive for them. In addition, it includes warranties (for example, insurances against professional mistakes with patients or legal protection in front of pharmaceutical firms) which are more and more important nowadays. The interviewees judge that, for these reasons, the research supervisors are not prompt to step out of this institutional (restrictive and supportive) framework.

6.2.2. Macro support

From a financial point of view, the salary of researchers is "dumb" (that is: Really low). For this reason, the salary could not be an important motivation for them to conduct research, according to some interviewees. As described by them, the "deal" is to accept this salary in exchange of intellectual freedom (intellectual motivation). As noted *supra* (cf. 6.2.1), this intellectual freedom is already increasingly limited by strategic, financial, and administrative constraints. Given their "dumb" salary, this context could lead some researchers to leave Belgium to get foreign AMCs, where salaries are much higher (for example, in the United States). Initiatives have been taken at the public level, including "Brains Back to Brussels", a program of the Brussels Region. It consists of research grants, primarily intended to Belgian or foreign young researchers, established abroad. It covers salary, travel, and research costs for five years in Brussels. Another one, "Ulysse", is a program of the FNRS (depending of the French Community). It grants a research mandate to Belgian or foreign senior researchers, established abroad. It covers the salary, travel, and research costs, as well as the salary of potential employees. All in all, attracting researchers from foreign research centers is not the major problem compared to the competition with other potential employers, according to the interviewees. The major threat comes from private hospitals in Belgium. To illustrate this, one of the (not to say the) only departure from the SHS-UCL due to another employer's salarial

concurrency is the one of Dr. POILVACHE, who left the Cliniques Universitaires to practice medicine in the "Center Hospitalier Inter-Régional Edith Cavell", a Belgian private hospital. These hospitals are able to pay much higher salaries to their doctors because they do not conduct research and practice a huge number of care services each day. Moreover, these hospitals are free to set tariffs, contrary to public hospitals.

Despite questions on this subject, interviewees did not provide any illustration of governmental or administrative public initiatives specifically aiming at improving cultural, material, or contextual conditions of biomedical research. Nonetheless, it can be noticed that public programs to sustain research projects, such as Brains back to Brussel, Ulysse, or any other public funding initiatives in general, include the promotion of cultural motivations of researchers. Indeed, they often ask the recipients to take part in conferences, to produce public reports and practical applications of their findings, visible to their peers and the public. However, as noted by one interviewee, in the case of organizational as well as national support to cultural research motivations, publicizing research results sometimes raises questions about the research's confidentiality.

To conclude, it can be highlighted that individual motivations themselves can sometimes contradict macro and organizational initiatives to promote biomedical research. Cultural motivations can sometimes turn into "personal" motivations, when the social prestige of one person takes a lot of place in his or her motivation to conduct research. In this line, some interviewees express doubts about the actual will of researchers to commit administrative and managerial research-related tasks to specialists (for example, in the framework of the future, or more directly in the current institutional structure). Convergent with this remark is the claim of one permanent researcher: If he was authorized to do it, he would prefer to manage all the financial, administrative, managerial, and technical aspects of the projects he promotes. In the same line, the individualization of the promotion of the research projects and their financial support sometimes creates jealousy among research supervisors in the SHS-UCL. For example, when one supervisor receives a lot of financial support from external sources, some colleagues can be prone to lock internal support in the SHS-UCL, which is made possible by the homogeneity of decision making in the SHS-UCL, as mentioned *supra* (cf. Chapter 5).

CONCLUSIONS

As part of the first step of Medlearn, the primary objective of this report was to discuss the notion of biomedical innovation and to identify as much of its conditions as possible at the macro, organizational, and individual levels, based on primary sources (interviews and documents) from the AMC of the UCL. Some hypotheses about the conditions of biomedical innovation in AMCs had already been suggested before the beginning of the case studies of Medlearn. By way of conclusion, some of them are discussed a first time here.

Two hypotheses directly point the networked capacity of diversified actors to work together behind biomedical innovation. The first suggests that biomedical innovation occurs in diversified networks of actors who hold complementary resources (ideas, expertise, money, commercial assets ...). The second proposes that biomedical innovation occurs where actors in diversified networks are capable of bridging their differences of opinion and work together (perhaps behind a common frame). The report presents clues congruent with these hypotheses. To take only two examples, the innovation story about liver cells transplantation (cf. 1.2.1) shows how two professionals are able to share their complementary resources (interesting patients and technique under development). Another example consists of the research centers created in the SHS-UCL, gathering researchers from different disciplines and/or hierarchical positions. Other illustrations appear in the report (cf. 1.1.2.2, for example).

At the organizational level, little evidence supports the hypothesis that biomedical innovation occurs once a sufficient level of trust is reached among the research network, particularly between AMC members and biotechnology firms. Quite the opposed, the description of the Unit of Medical Economics reflects a high degree of formalization of the relationships with commercial partners, for example (cf. 1.2.1.2).

At the individual level, the probably most evidenced hypothesis in this report is that biomedical innovation occurs where leaders and entrepreneurs are capable of mobilizing diversified networks of actors. The role of research supervisors, given the autonomy that one commits them and the initiatives they take, is really important. Related to this, but not as much illustrated in the report, it can be argued that the following hypothesis is correctly formulated: Rather narrow networks constitute themselves inside AMCs grouped around shared core beliefs (with competing coalitions within AMCs and scarcity of interactions between them). Some remarks spontaneously formulated by some temporary researchers during the study of the SHS-UCL seem to suggest that research supervisors, whatever the hierarchical and networked organizational positions of stakeholders, have a strong power on them in conducting their biomedical research projects.

Regarding the support to, as well as the environment of biomedical innovation, a first hypothesis suggests that biomedical innovation occurs where the government is capable of providing adequate support. While it seems clear that public financial support is open-arms

welcomed by research supervisors, they also criticize the quality of this support. In addition, no evidence was found that the cultural, political, or any other support provided by public authorities is a necessary condition for conducting biomedical research projects (cf. 6.2.2). In the same line, the hypothesis suggesting that biomedical innovation occurs where a non-governmental actor (for example, a foundation) is capable of providing adequate financial support is well evidenced in this report, if this support is understood as one support among others: The composition of the financial macro support (cf. 4.1) shows that this kind of support is not sufficient for all projects of all or one type of research, and sometimes even not sufficient one research project (often, combination of funding sources). The two hypotheses suggesting that biomedical innovation occurs where it pays to innovate or where culture values performance are challenged in this report. Illustrations appear in Chapters 5 and 6 that this cultural valuation does not seem to be important for biomedical research to be effective, at least to a certain extent.

Finally, it could be first suggested to take into account the position in the AMC of the individuals investigated during the second part of Medlearn. Indeed, this position can influence their subjective perception of the issues discussed in this report. For instance, as illustrated by some interviews, researchers and management of the SHS-UCL can share common views about some objectives and some patterns of the *Plan de développement*, while nourishing the certitude that the other parts deny all their own demands each others.

Second, some hypotheses could be enriched by distinguishing an organizational level and an individual level of analysis. Regarding the two first hypotheses pointing the networked capacity to work, for example, it seems that stakes are different when the collaboration involves the SHS-UCL with external organizations, different organizations within the SHS-UCL, individuals within the SHS-UCL or with external partners, etc¹¹. And, to combine this with the first remark, one could imagine that collaborations at the individual level need more institutionalization when they occur within the AMC than when they occur with an external partner because, in the first case, they require the distribution of a fixed amount of resources between the actors, which is illustrated by the examples of the liver cells transplantation (informal collaboration with a foreign colleague, cf. 2.3.1) and the creation of research centers (formal organization of the relationships between the researchers within the SHS-UCL, cf. 1.1.2.2.).

¹¹ On this respect: 6, Goodwin, Peck, and Freeman, 2006.

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APPENDICES

APPENDIX 1 – ANTARES REPORT¹²

The objective of this Antares audit was to analyse the research environment and activities in the SHS-UCL, and to suggest a strategic plan in this domain. Data were collected by way of questionnaires and semi-directed interviews, submitted to the researchers, the SHS-UCL management staff, the support services, and external experts. Data were also retrieved from internal documents of the SHS-UCL, and from external documents of public agencies, universities, other AMCs, biomedical firms, etc. The results were discussed and approved by a "Strategic Council" of the audit. The analysis of the research environment and activity was organized around ten points. They appear in Table A2.1.

Table A2.1: Analysis of research within/around the Cliniques Universitaires formulated by Antares Consulting

1. Research is present in the institution but we do not hold the required information to assess its degree of importance.
2. Research is *de facto* drawn in profile in the Cliniques Universitaires but this situation is not the result of a will.
3. Research in the Cliniques Universitaires is the result of the work of some key persons.
4. The development of research in a selective way to increase its efficiency is a heavy trend.
5. Actors do not share a common model and vision of research.
6. There is neither specific organization nor specific management model for research.
7. The legal and legal context (intellectual property rights, European Directives, their national transposition) is crucial for the activity of research.
8. Research in the Cliniques Universitaires is not accompanied with a human resources management plan proper to this activity.
9. The Cliniques Universitaires could adopt a more proactive logic in the search for funding.
10. The partners related to UCL in the field of research have not set up a collaboration network.

Source: Antares Consulting, 2004.

The audit drew six strategic conclusions in a SWOT matrix (Strengths, Weaknesses, Opportunities, and Threats), which inspired the Table A2.2.

¹² References : Antares Consulting, 2004, 2005a, 2005b, 2005c

Table A2.2.: SWOT matrix of research within/around the Cliniques Universitaires designed by Antares Consulting

	Threats	Opportunities
Strengths	facing concurrence and concentration of funding by leaning upon research profiling within the Cliniques Universitaires	promoting a valorisation culture of research to benefit from the whole potential of its investment return
Weaknesses	<ul style="list-style-type: none"> reconsidering the management and organization of research in order to professionalize and favour its development reconsidering the research model to better define the coherence between health care and research activities 	<ul style="list-style-type: none"> modifying the individualist culture of research in order to promote internal collaborations and partnerships with other actors of research modifying the approach of clinician essays in order to develop the role of prime contractor and guarantee financial resources related to this activity

Source: Antares Consulting, 2005b.

On the basis of the SWOT matrix, a strategic map, and then 14 initiatives were designed. These initiatives were scheduled to be implemented in the following years. They appear in Table A2.3..

Table A2.3.: 14 initiatives for research within the Cliniques Universitaires suggested by Antares Consulting

1. Human resources plan, specific to research
2. Mentoring program to learn from other researchers in the institution
3. Glossary of key terms of research
4. Information system for research
5. Spaces et equipments program and rules of shared use
6. Appropriate governance mode and legal structure
7. Alliances and collaboration policy
8. Research profiling policy
9. Common support services
10. Follow-up criteria for research projects
11. Hospital-faculty collaborations
12. Commercial and marketing plan for research
13. Symposium about research valorisation and its investment return
14. Promotion of translational research

Source: Antares Consulting, 2005c

Ten conclusions were drawn at the end of the audit. First, the audit provided some quantitative data to suggest that the global positioning of the HS-UCL in research is high. In the same time, it demonstrated that the information required to measure the criteria of this positioning is often not available. Hence, "research is present in the institution but we do not hold the required information to assess its degree of importance".

Second, the audit made clear that there are asymmetries in the activities of the centers within the HS-UCL. But there is no parallelism of these asymmetries between the research activities, the health care activities, and their perception by the management of the HS-UCL. Hence, "research is de facto drawn in profile in the (HS-UCL) but this situation is not the result of a will".

Third, the audit identified some common characteristics of the services which are strong in research activities. "These services are directed by a dynamic and charismatic leader who initiated research activities in the service and favour its development by a proactive attitude. These leaders built a "project" around research in their service and defined a vision of the development of this activity. In these services, a team management of research exists what about the time dedicated by everyone to this activity as well as what about the distribution of the available resources. These services have a research tradition and, thanks to their efforts, they dispose of funding. They have integrated to the service the required support activities. The leaders of these services develop the clinician and fundamental research and favour the translational research. It must be noted that they share the common vision that it is important to have a strong clinician activity". Hence, "research in the (HS-UCL) is the result of the work of the key persons".

Fourth, the audit documented that funders of research concentrate their resources on certain themes. In parallel, research centers around the world define priority domains. Hence, "the development of research in a selective way to increase its efficiency is a heavy trend".

Fifth, translational research is crucial for any AMC. Indeed, "the clinician researcher has to know the results of fundamental research as well as clinician problems". "Translational research aims at allowing a maximum of hypotheses coming from fundamental research to be translated into solutions clinically tested, in relatively brief delays. The development of translational research allows to involve all the actors of the research value chain in a collaboration dynamics. In addition, given its nature, translational research allows to develop close collaborations among varied domains (materials, computing, medicine) to realise multidisciplinary projects. Moreover, by its strong orientation towards results, it more easily enjoys from industrial, and thus public, funds. But "actors do not share common model and vision of research". The UCL and the HS-UCL have different types of research as well as well as different conception of this activity. The HS-UCL management gives priority to health care services whereas clinician researchers would like more time dedicated to their researches. Finally, among researchers, the interest for research variable and the purpose of this activity is differently perceived.

Sixth, the audit identified six strategic functions on the research chain: Strategy and choices, human resources policy, values and ethics, management guidelines, resources allocation, and results valorisation. The audit identified seven support function on the research chain: Legal support, technical support, fundraising, information system, technological platform, project management support, and communication. The researchers do not ask for an aid in strategic function, but well in support functions, mostly in services which are weak in research activities. Hence, "there is neither specific organization nor specific management model specific to research".

Seventh, the audit documented that "the legal and legal context (intellectual property rights, European Directives, their national transposition) is crucial for the activity of research".

Eighth, "research in the (HS-UCL) is not accompanied with a human resources management plan proper to this activity". For example, despite the number of clinician researchers in the institution, there is no specific status for clinician researchers exclusively dedicated to research. Moreover, within the existing statuses, there is no incentive mechanism for doing research nor there is an institutional career management favouring research profiles.

Ninth, having compared the potential and actually used funding sources, the audit concluded that the Cliniques Universitaires do not exploit all of them nor do they are proactive enough with regard to the already used sources.

Tenth, "the partners related to UCL in the field of research have not set up a collaboration network". On the one hand, the Cliniques Universitaires have not set a collaboration network with their natural partners. For example, several actors related to the UCL are also active in research: The Faculty of Medicine (in the same place) and the Cliniques Mont Godinne. In Woluwé-Saint-Lambert, two other actors develop similar research activities: The Institut de Pathologie Cellulaire (IPC) and the Ludwig Institute. On the other hand, extra-muros collaborations are essentially based on interpersonal relationship more than on an institutional will. For example, there exists few collaborations with other Belgian AMCs. Moreover, the involvement in European and International partnership is basic.

APPENDIX 2 - INTERVIEWS

Date	Person	Responsibilities
18/09/2008	Ms. Bleus	<ul style="list-style-type: none"> In the Cliniques Universitaires: Member of the Service of Communication
19/09/2008	Ms. Kinard	<ul style="list-style-type: none"> In the UCL: Member of the Administration of Research (in charge of the medical research projects)
15/10/2008	Prof. Deneff	<ul style="list-style-type: none"> In the SHS-UCL: <ul style="list-style-type: none"> - Pro-Rector of Medical issues - Member of the Executive Board In the Cliniques Universitaires: <ul style="list-style-type: none"> - Member of the Governing Board - Member of the Executive Board In the Faculty: President of the Executive Board In the Foundation: Member of the Governing Board In the UCL: Member of the Medical Center
27/10/2008	Prof. Horsmans	<ul style="list-style-type: none"> In the Cliniques Universitaires: <ul style="list-style-type: none"> - Associated Chief of the Service of Gastroenterology - President of the Department of Internal Medicine and Associated Services In the Faculty: in charge of the Unit of Gastroenterology
28/10/2008	Prof. Boon	<ul style="list-style-type: none"> In the Faculty: <ul style="list-style-type: none"> - Director of the Brussels Branch of the Ludwig Institute for Cancer Research - Member of the Board of Directors of the Christian de Duve Institute of Cellular Pathology
28/10/2008	Prof. Gianello	<ul style="list-style-type: none"> In the SHS-UCL: Member of the Executive Board In the Faculty: <ul style="list-style-type: none"> - Dean of Research - Member of the Executive Board In the Foundation: <ul style="list-style-type: none"> - Member of the Governing Board - President of the Scientific Board In the UCL: Member of the Medical Center
28/10/2008	Prof. Durant	<ul style="list-style-type: none"> In the Cliniques Universitaires: <ul style="list-style-type: none"> - Secretary of the Governing Board - Vice-President of the Executive Board - General Administrator In the UCL: Member of the Medical Center
07/11/2008	Dr. Van Hassel	<ul style="list-style-type: none"> In the Cliniques Universitaires: in charge of the Unit of Medical Economics
13/11/2008	Prof. Sokal	<ul style="list-style-type: none"> In the Faculty: in charge of the Unit of Paediatrics