

# DESIGNATING EUROPEAN CANCER INSTITUTES:

## 'TOWARDS A PROFESSIONAL TOOL FOR QUALITY IMPROVEMENT'



*'A QUALITATIVE STUDY ON THE CHALLENGES AND CRITICAL FEATURES OF A DESIGNATION SYSTEM FOR EUROPEAN CANCER INSTITUTES WITH THE FOCUS ON DEVELOPMENT AND IMPLEMENTATION'*

Gijs Hesselink University of Twente, 2008

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**MASTERTHESIS IN 'HEALTH SCIENCES'**

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*"To classify is human"*

*Bowker & Star, 1999, 'Sorting things out'*

## EXECUTIVE SUMMARY

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The growing cancer burden and a great unused potential for making advancements in cancer care and research on an international scale, urges policymakers to take extra measures. In view of this need, the 'Organisation of European Cancer Institutes' (OECI) pleads for more harmonization between cancer institutes in Europe through common used methods that enable the comparison, evaluation and synchronization of their cancer activities. Subsequent to the introduction of an accreditation project, the most recent proposed initiative is to develop and implement a system in which European cancer institutes can be designated.

Although this initiative appears to be very promising at first sight, two major problems currently occur in the development and implementation of the designation system: (1) the challenges and features for developing the right categories, criteria and review-methods are unclear (2) there is insufficient understanding of the social-political context and what consequences it might have for the development and implementation of the designation system. A qualitative research has therefore been performed in order to get a better understanding of the system-technical and social-political aspects in developing and implementing the designation system and to provide subsequent recommendations. Data has been gathered with the help of a literature review, interviews, observations and many informal conversations. The analysis of data in the field has been supported by theoretical concepts, considerations, relevant aspects of existing examples similar to this designation initiative.

Findings from the theoretical and field research indicate that the development and implementation of the designation system are mainly challenged by the complex context. Translating it from theory into practice appears to bear several hazards along the way. From a system-technical point of view these hazards mainly concern the practical applicability of the system, with regard to demographic, legislative, administrative and language differences. Social-politically it is the complex social setting that initially triggers conflicting and strategic behavior and therefore challenges the required acceptance and commitment among stakeholders to the system. These hazards can be related the best to what Bowker and Star (1999) in theory call a 'divergence between the symbolical and material side'; *the overarching purpose of designation diverges with the practical situation in which a designation system has to be developed and implemented.*

The big managerial challenge for the future is therefore to find a balance between the overarching purpose of the system and a 'satisfying' basis that is applicable and worthy enough to be loyal to for all parties. From a system-technical point of view, this means that in the development of categories, criteria as well as the review methods a balance has to be found between the level of abstraction and rigidity - for having an effective purpose on a supranational scale- and the level of specificity and flexibility -for anticipating to the daily, complex practice in which cancer institutes have to be designated. A first draft of the designation system based on this thought is presented in the appendix. From a social-political point of view, it requires an extra effort in realizing a more constructive, harmonized setting as well as in clarifying and promoting the system's added value to reach to required consensus and commitment.

## **FOREWORD**

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This thesis is the final product of the master research on the challenges and critical features of developing and implementing a designation system for European cancer institutes. The research has been conducted and reported over a period of five months in light of the master-program 'Health Sciences' the University of Twente, Enschede.

During my bachelor period in 'Public administration' and a previous master program in 'Organization, Culture and Management' I developed a great fascination for management and policy issues related to the quality of healthcare. Although quality of healthcare has improved radically throughout the last century, developments such as the rise in chronic diseases are confronting the sector with serious challenges. From a managerial point of view this requires new perspectives on how health services should be organized. The way these new perspectives are introduced and how they are implemented often strongly depends on a complex and social-political dynamic reality. Contextual differences and varying social perceptions towards a new organizational development for instance can have huge frustrating consequences. This can make management in healthcare difficult but at the same time very interesting to study, especially on an international scale.

Based on this thought I did not hesitate when in December 2007 the opportunity occurred to apply for the master assignment concerning 'A study on the designation of European cancer institutes'. This designation initiative is a perfect example of introducing a new organizational perspective in healthcare along with the inherent managerial difficulties of developing and implementing it the right way. This thesis may make readers more aware of the practical challenges that are confronting this designation initiative and offers them insight in how to overcome these challenges in the best possible way. Together with a number of concrete recommendations it may contribute to a successful development and implementation of a designation system for European cancer institutes in the near future.

In this foreword I would like to thank in the first place all the respondents. They formed the foundation of my research by sharing their perspectives and concerns with me. Without their effort and cooperation this thesis could not have been realized. Secondly, I would like to thank in particular the 'Steering committee members of the OECI Accreditation Work Group'. As this accreditation project is closely linked to the OECI designation initiative, they formed an important and easy accessible source of data by supplying a lot of information, advice and feedback during the last few months. Special thanks go out to my supervisors, professor van Harten and professor van Rossum, for their advice and feedback and for offering me the opportunity to graduate on this very interesting subject. This study has taught me a lot about the social-political and technical aspects of introducing new quality-improvement perspectives and methods in a highly professional and international environment! Last but certainly not least, I want to thank my parents, brother, sister and my dear girlfriend. Your support in all possible ways was irreplaceable and extremely stimulating these past years of study.

Gijs Hesselink  
Hengelo, 11 juli 2007

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# **1 INTRODUCTION**

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Europe is currently facing a growing cancer burden, affecting both the survival and quality of life of human beings. At present, with more than 3 million new cases and 1.7 million deaths each year (Ferlay et al., 2007), cancer represents the second most important cause of death and morbidity in Europe following cardiovascular diseases (Coleman et al, 2008). Causes for this increasing incidence can be found in a wide range of social and epidemiological factors such as the result of an aging, a growing population and unhealthy lifestyles (e.g. Ferlay et al., 2004). In the rise of the cancer problem different countries and regions in Europe show marked differences in the speed and direction of trends in cancer incidence and mortality rates.

Along with the growing cancer burden the activities in cancer care and research have become more complex and challenging. Causes can be found in: rapid advances in technology and knowledge which make new breakthroughs more complicated, improved diagnosis and treatment with improved survival rates, and the longer survival of patients with a chronic cancer disease (Coleman et al, 2008). The growing and more complex demand for improvements requires in that respect a new paradigm of collaboration; multi-disciplinary working has become the keyword and sharply contrasts with the traditional, single oriented cancer research and -care approaches from the past. Professionals with highly diverse skills working together and the sharing of resource allocations on a micro-, meso- and macro-level are perfect examples of this.

Although substantial organizational progress has been made in the last decennia, European cancer institutes are still facing an increasing number of cancer cases. Next to the well working national health systems, an effective organization of cancer care and research activities on a supranational, European level can significantly contribute to these challenges in the fight against cancer. This thesis involves a study on one of the most recent initiatives that is aiming to improve this supranational organization, being the development and implement of a designation system for European cancer institutes.

The next chapter will outline the context of the current situation of cancer care and research in Europe and the central subject with its problems. The design of the research will be central in the third chapter. Respectively the purpose, relevance, questions and the method of the research will here be formulated and discussed. The theoretical position will be formed in chapter four. Since the designation of European cancer institutes, from a social scientific point of view, can be seen as an act or form of classification, it will here be placed in a broader classification-perceptive. All relevant considerations and examples that facilitate the data analysis from this perspective will be outlined here. In addition it will also examine a few theoretical concepts for analyzing the social-political context of this designation initiative. The thesis will finally ends with the presentation of the results in chapter five and subsequently the conclusion in chapter six.



## **2 CANCER CARE AND RESEARCH IN EUROPE**

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### **2.1 INTRODUCTION**

Nowadays new organizational policies in healthcare are at first sight often considered as very promising. However, the potential promise becomes difficult to realize when it comes to the implementation of it. Based on a first round of informal talks with some respondents and an initial literature review, this seems to be the case in designating European cancer institutes as well: theoretically a very competent and effective plan, but hard to realize in daily practice. For a better understanding of this contradiction it is important to get a better insight in the context it is situated. In short, this chapter therefore elaborates the current situation of cancer care and research in Europe along with the new organizational perspectives and developments that recently have been introduced. Based on this contextual sketch the problem definition and general cause for this research will finally be defined.

### **2.2 UNUSED POTENTIAL TO IMPROVE**

At present European cancer care and research have a lot of potential to improve quality. The spectacular progress in novel, powerful technologies and research discoveries in the last decades have brought new opportunities to improve diagnostic methods and treatment. On a macro-level the opportunity exists to use this potential in a better way if forces are more effectively bundled. This can be done by the sharing and dissemination of innovations, knowledge and other important resources on an international scale. However, from the organizational point of view, this potential has so far largely been remained unused.

The most important explanation for this can be found in the insufficient European coordination and collaboration of activities. At the moment cancer care and research at this level is too fragmented and lacks coherence. Main examples are: the gap between basic research and clinical treatment, duplication of research efforts, the lack of a global defined set of quality standards, and the access to knowledge and information that at present is unequally shared throughout Europe (OECD, Accreditation Workgroup, 2008). Although huge efforts have already been made, the coordination and overall improvement in cancer activities are still insufficient and are in need of further improvement on a European scale, in particular regarding the translation of research into care.

An additional explanation are the relatively modest cancer research expenses in Europe. In comparison with the United States and some countries in Asia, the European expenses are considered to be relatively modest (Sullivan, 2005). Although the current quality of cancer research and care in Europe is adequate, further improvements are possible here as well.

It is a collective challenge to bring both research and care to a higher level, requiring initiatives on a supranational level. This is needed both from the public health and the economic point of view.

## 2.3 TOWARDS QUALITY IMPROVEMENT

The growing cancer burden in combination with an unused potential to improve, makes it necessary to take extra measures on the European level (Commission of the European communities, 2007). Several well respected persons, organizations and studies in the field of cancer care and research have already anticipated this by developing new coalitions and introducing new organizational approaches. A recent example in this is the collaboration between public health institutes in the EU, which resulted in the Coleman report 'Responding to the challenges of cancer in Europe' (2008). The report overviews the current epidemiology of cancer in Europe, including a discussion of the major risk factors of cancer in Europe, and provides new policies to tackle them. For instance the 'Comprehensive cancer plans' are discussed as a new approach to cancer control. Another example was the launch of the 'Eurocan+plus Project', called for by the European Parliament in October 2005. The project consisted of a coalition of prominent actors in the field of cancer research, aiming to study the feasibility for coordination of national cancer research activities in Europe and to provide recommendations for improvement (Eurocan+plus, 2008). Recently this project ended and has been followed up by the Stockholm Group (2008). Parallel to this it has been decided to work together within this group towards the creation of a collaborative platform, comprising leading 'Comprehensive Cancer Centers' and 'basic/preclinical Research Centres' in Europe (Ringborg, 2008). Such a platform is believed to be ~~the~~ new organizational approach for reaching a 'critical mass' and sustainability, that is necessary to innovate and deliver high quality in all areas of cancer research (Ringborg, 2008).

Next to those previous examples the 'Organisation of European Cancer Institutes' (OECI) is one of those organizations that is also looking for better, organizational ways to improve quality of cancer care and research across Europe. As a growing network of over more than 60 cancer institutes, the OECI organizes activities in several workgroups for developing concrete affordable and realistic solutions to effectively combat cancer in the EU (OECI, 2008).

### 2.3.1 NEED FOR HARMONIZATION

In view of the need to bring cancer care and research as a whole to an international, more qualitative and competitive level, the OECI pleads for more harmonization between cancer institutes in Europe (OECI, 2008). Besides the opportunity of reaching a 'critical mass' (meaning all resources that are needed to translate basic research discoveries into a clinical setting for the diagnosis and treatment of cancer patients), this effort leads to many other advantages. It provides the opportunity to synchronize, compare and evaluate cancer activities throughout Europe and will therefore speed the process of discovery and research of cancer. This will be a direct benefit to the public. This way of 'phrasing' cancer activities is crucial and urgently needed in order to integrate and foster the many already existing efforts and initiatives. Additionally it creates an international overview for patients and other stakeholders to recognize and select institutes in a more effective and efficient way.

In order to pursue harmonization, the OECI initiated in 2002 an accreditation project with three main objectives (OECI-AWG Steering Committee, 2008):

- to develop a comprehensive accreditation system for oncology care
- to set an updated database of cancer institutes in Europe, with exhaustive information on their resources and activities
- to develop a 'labeling' tool, dedicated to designate European cancer structures.

### 2.3.2 EUROPEAN DESIGNATION SYSTEM

With the first accreditation pilots in 2007 a start was made in the effort to reach more harmonization. These developments in accreditation have recently urged the OEI to develop and implement a system to which European cancer institutes can be designated as well. Such a system must create a platform in which synchronization and benchmarking of cancer activities will be possible on an international scale. Additionally it must be a tool for cancer institutes to ensure and improve their quality standards. By putting effort in gaining a designation status the idea is that they will be stimulated in disseminating knowledge and in forming coalitions with other institutes that are designated as well. This allows cancer institutes to benefit from each other and reach to a critical mass in cancer services.

Keyword in the designation of European cancer institutes will be the level of *comprehensiveness*. The philosophy behind comprehensiveness is: if all relevant competences, skills, resources and tools concerning cancer care and research are brought together and integrated, it will lead to an outcome that is larger as a whole, than the sum of its parts (Ringborg, 2008). Comprehensiveness, in that sense, can be seen as the new basic principal for how cancer activities institutionally should be organized. It focuses therefore on infrastructural requirements that enable the integration of cancer services into:

*“A continuum from basic through preclinical and clinical research to structured implementation and evaluation of new diagnostic and treatment methods in routine care” (Ringborg, 2008).*

The OEI sees the designation of cancer institutes on this relative level of comprehensiveness along with their level of performance, as the perfect way to ‘phrase’ cancer institutes through one single, harmonious method.

## 2.4 PROBLEM DEFINITION

As mentioned before, the increasing impact of cancer in Europe and the potential to improve strongly asks for a new collective approach towards a more harmonized policy on a European level. It has become more and more clear that cross-national standards and shared values are necessary in order to improve cancer research and care. While serious efforts are made to realize this by means of a European designation system, two major problems occur in the development and implementation of such a system.

### 2.4.1 SYSTEM-TECHNICAL ASPECTS

So far there is not much knowledge about designating the total sum of cancer services on a European scale. This leads to the first problem:

*‘It is not completely clear what the system-technical challenges and features are in the development of the designation system’.*

With this is meant more specifically the challenges and features for developing appropriate categories, criteria and review-methods. It is expected that theoretical considerations and existing information of other examples similar to this project could be very useful. Also further research is

required for obtaining a complete impression of the relevant issues that are in particular accountable for designating European cancer institutes.

#### **2.4.2 SOCIAL-POLITICAL INFLUENCES**

Although a designation system may seem very effective and promising on paper, it will be difficult to realize it. It will even be doomed to fail if little attention will be paid to the social context in which the system has to be developed and implemented. Social-political differences and the dynamics between the stakeholders involved in the designation initiative can for instance have negative influence at moments when consensus or collaboration are required. Moreover, a better understanding of this social-political context would help a lot in identifying managerial preconditions as well, for instance on how to gain more social acceptance and commitment to the system amongst stakeholders. At the moment insight in these social-political influences is lacking. It forms the cause of the second problem:

*'An insufficient understanding of the social-political context and the subsequent managerial consequences (in terms of limitations and preconditions) in developing and implementing the designation system on a supranational level'.*

### 3 RESEARCH DESIGN

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#### 3.1 INTRODUCTION

Now that the central object of this study, the context in which it is situated and the relating problems are outlined, this chapter will discuss the design of this research. Respectively the objective, question(s), and methodology of this research will be brought to the attention.

#### 3.2 OBJECTIVE

The purpose of the study is to provide a better understanding of the system-technical aspects and the social-political influences in developing and implementing a designation system for European cancer institutes. By gaining insight in the system-technical challenges and critical features, the first part of this research has the objective to:

*provide an initial draft of the system*

By focusing on the broader social-political context, the second part of the research has the objective to:

*explain how the social-political context affects the development and implementation of the designation system*  
*formulate social-political recommendations.*

With the achievement of these objectives (the initial draft of the system will be presented in the appendix) the study has a significant contribution on theoretical and practical grounds. Both will be discussed in their 'scientific' and 'social' relevance.

##### 3.2.1 SCIENTIFIC RELEVANCE

From an organizational perspective the designation of cancer institutes illustrates an act of classification: cancer institutes are referred to a certain category based on a (mostly normative) defined set of characteristics. With the emerging need to manage global challenges, such as the growing cancer burden, scientific attention for such methods of classification arises in many organizational studies, in public management as well as in managing non-governmental organizations (NGO's). Despite the fact that much is already known regarding acts of classification from this scientific point of view (e.g. Durkheim & Maus, 1963; Taylor 1995; Bowker & Star, 1999), little is actually known about the organizational impact of internationally classifying non-governmental, health organizations. The scientific relevance of this study situates therefore in its small contribution to fund a scientific framework in this area.

##### 3.2.2 SOCIAL RELEVANCE

From a social point of view, the development and implementation of an effective designation system for European cancer institutes is not an easy task. It has to deal with different interests, languages, legislations, cultural habits and traditions.

By exploring and describing several important system-technical challenges and with the initial draft version, insight is offered into how the system, technically, can be developed effectively. Moreover, it is a starting point for initiating and stimulating a discussion on the future development of the content of the system. Combined with the insight in the social-political effects and some concrete managerial recommendations, the study contributes to a further successful development and implementation of the designation system. With the system's overall purpose of quality-improvement in European cancer care and research in mind, it eventually serves a social purpose.

### 3.3 RESEARCH QUESTIONS

In order to achieve the set objectives and to provide a solution to the defined problems, the decision has been made to formulate two research questions. Together they will make this research complementary.

#### Question 1

The first question tries to provide an answer to the technical aspects in the development of the system:

---

*'What are the challenges and the critical features for designating European cancer institutes from a system-technical point of view, especially based on the (relative) level for comprehensiveness?'*

---

Based on this question the following sub-questions are:

- A. *What relevant aspects of classification can be extracted from literature and what relevant examples of classification do exist in the field of cancer services?*
- B. *What challenges occur in the development of the designation system?*
- C. *What features are essential to overcome these challenges?*
- D. *What should a draft version of the system look like?*

An answer to sub-question A will be given in the first part of the following theoretical chapter (4). The same will be done with sub-questions B, C, and D in the first part of the results chapter (5).

#### Question 2

The second question concerns the social-political context and its influences on the system:

---

*'How can a designation system for European cancer institutes successfully be developed and implemented from a social-political point of view?'*

---

Based on this second question the following sub-questions are:

- E. *What theoretical concepts do exist for analysing the social political context?*
- F. *Which are the relevant stakeholders and how are they positioned?*
- G. *What are the dynamics within the social political context of the designation system and what are the consequences, in terms of limitations and preconditions?*
- H. *What managerial recommendations can be offered?*

An answer to sub-question *E* will be given in the second part of the theoretical chapter (4). The same will be done with sub-questions *F*, *G* and *H* in the second part of the results chapter (5).

### 3.4 METHODOLOGY

This paragraph explains the way how research was conducted during the last few months. Respectively the chosen strategy will be discussed, the way data have been analyzed and finally what data-resources have been used.

#### 3.4.1 A QUALITATIVE STUDY

First of all, a qualitative study will be conducted with respect to both research questions. The choice for this strategy is mainly based on the argument that:

*“a qualitative study is most appropriate when relative new domains have to be analyzed that aren’t studied before”  
(Hart et al., 1999).*

With the designation of European institutes, on their total pallet of services, a relatively new domain is entered in Europe that never has been analyzed before. In that respect a qualitative case-study is the most appropriate for exploring new, and yet unknown technical domains of designation.

Additionally, the perceptions and actions of important stakeholders, that are often influenced by cultural, governmental and demographical differences, play an important role in how the designation system will be developed and implemented as such. This study therefore requires an in-depth case investigation in these social-contextual factors. In that respect a qualitative approach is the most appropriate once again for gaining a proper understanding of the behavior of stakeholders involved, and for providing a correct explanation of their consequences for designation, throughout a theoretical and empirical way (Grix, 2004; Czarniawska, 1992). In order to identify concrete results this means that social patterns, trends and relationships will be related to theoretical concepts and vice versa.

#### 3.4.2 FRAME OF ANALYSIS

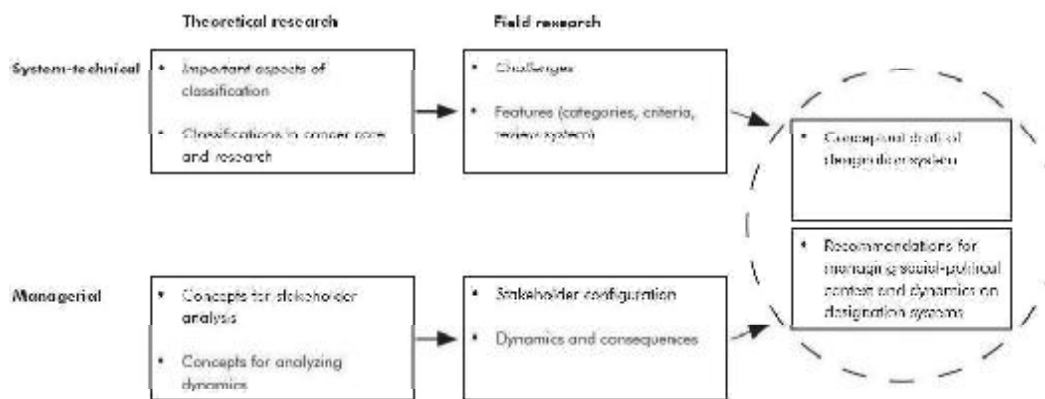
In line with the structure of the research problem, object and questions, the frame of analysis has a system-technical and a social-political approach. Both approaches include a theoretical- and field research (see figure 1). The integration of both approaches will finally result in: the provision of a conceptual draft of the system (which is referred to in paragraph 5.4 and presented in section D of the appendix entitled as ‘A system for designating European cancer institutes’), and the formulation of some general and concrete recommendations on how to cope with the social-political influences on the development and implementation of the designation system. This will be presented in paragraph 5.8 and will be once again reflected on in the conclusion.

The *system-technical approach* of this study focuses on the (practical) challenges and critical features for developing the designation system. First of all by conducting an initial literature review and a small number of interviews on what theoretically might be relevant for analyzing the process of development, and what examples in cancer care and research already exist. Together they offer a first set of considerations on what is, or might be relevant for the content of the system (see part I of the theoretical chapter). The analysis of these considerations, in combination with the data from

interviews and many informal conversations in the field research, have resulted in the identification of several system-technical challenges and critical features for a European designation system (see paragraph 5.2 & 5.3).

The *social-political approach* has its focus on the influences of the social-political context on the development and implementation of the system. Initially by conducting a theoretical research on concepts that help in explaining the position and role of stakeholders as well as the dynamics that occur (see part 2 of the theoretical chapter). Based on the data gathered in the field research, these concepts helped in analyzing and explain the social-political context and its effects on the designation system (see paragraph 5.6 & 5.7).

Figure 1. Framework of analysis



### 3.4.3 DATA RESOURCES

Data has been gathered with the use of several resources. The different data-collections have been compared and verified with each other in order to improve the validity. This is also known as 'data-triangulation'. Qualitative case-studies, like this study, often use 'triangulation' in order to realize a profound, in-depth analysis and to get a valid and plausible view of the current situation (Geertz, 1973; Grix, 2004). A common used mixture of data-resources, that also has been used in this research is: a literature- and document study combined with the use of interviews and observations.

#### Literature review

A literature study has primarily been performed in order to demarcate the study: how does this designation system have to be considered in a broader organizational perspective of classification and how can it be positioned against other existing examples? Moreover, it offers a theoretical framework to facilitate the system-technical and social-political analysis for answering the research questions of this study.

Literature with respect to cancer care and research has mostly been reviewed in the documentation of scientific journals such as 'Tumori, Journal of experimental and clinical oncology' or 'Molecular Oncology', through medical databases like 'Medline', 'PubMed' and on websites of for example the



OECI, the US 'National Cancer Institute' (NCI) and the Eurocan+plus project. Combinations of the following key-terms have been used:

*classification, categorization, designation, comprehensiveness, accreditation, cancer care, cancer research, cancer centers, cancer institutes.*

In addition, some important documents have been reviewed after referral or delivery by others. In that respect one could think of reports, policy-plans, questionnaires and notations related to for instance the OECI-accreditation project, the NCI-designation project and others. Finally lots of scientific books have contributed in reviewing the main underpinning theories and concepts relevant to this research. Those were concepts related to classification, the stakeholder theory and organizational decision-making. An overview of the used literature resources can be found in the 'References' at the end of the thesis.

### **Interviews**

A second important resource type has been the data from respondents. Through formal interviews and informal conversations with important stakeholders and based on their narratives (Bate, 1997; Kunda, 1992), insight has been gained the system-technical aspects and social-political influences on designation. Respondents made it possible to enrich this insight with citations and practical examples. Moreover it had a positive role in interpreting complex, scientific information and it provided new possibilities (Grant, 2004) for gaining further useful contacts or other resources.

Interviews have been performed based on semi-structured questions (see section B of the appendix). The questions related to the system-technical part have been developed with regard to the (theoretical) considerations out of the literature review and on the draft version of the system developed so far. The questions related to the managerial part were mostly referring to the theoretical concepts for explaining the social-political context. The choice for a semi-structured interview plan has been made to narrow the topics down, while on the other hand space was left open for other relevant input. It consequently allowed a certain degree of flexibility during the interview, which made it possible to pursue unexpected lines and directions of research during the interview (Grix, 2004). Additionally the draft designation system, which was developed parallel to this research, formed an important source of gathering data through the interviews. It created the possibility to address concrete feedback to the formulated system elements or to detect other remarks that otherwise might have been forgotten.

Regarding the relative short research period, most interviews were forced to do by telephone or on group-basis. In the beginning the fear existed that it would decrease the chance of gathering valuable, 'sensitive' information. Looking back, it didn't affect the data outcome in a negative way. In fact, on occasion group interviews generated dialogues between group members which offered new insights and other relevant data.

### **Observations**

Finally observations have also been done, considering that social-political dynamics are well detectable in the interactions between different actors. The focus hereby was on how stakeholders (inter)act to the designation initiative on a social platform. Observations were done according to Czarniawska's (1992:197) perspective on observing:

*"(...) allowed to be around, look, and ask, but (...) not required to act in the organizational drama".*

Given the relative short research period the opportunities to observe such a setting were limited and more observations would subsequently have increased the validity. Nevertheless, the EuroanPlus project meeting in Amsterdam, the end of March 2008, and the OECI general assembly in Genoa, the end of May 2008, have given substantial data to draw conclusions from.

#### **3.4.4 RESEARCH POPULATION**

The research population consisted generally spoken of actors who are involved in the development and implementation of the designation system in one way or another (see appendix). Most relevant actors in this population were directors, managers, specialists and researchers of several cancer institutes in Europe. Many of them were representatives of professional, European associations or alliances in the field of cancer care or research as well. Furthermore the population existed of a representative of the EU and a representative of a patient-organization. In addition, there were contacts with experts in the field of designation cancer care and research outside Europe. This resulted in an interview with the director of the NCI 'cancer centers program'.

All in all 15 persons were interviewed (see section A of the appendix). It must be said that many informal conversations, especially held during the OECI general assembly in Genoa, contributed a lot to the collection of relevant information as well.

## 4 THEORETICAL FRAMEWORK

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Before going into the results this chapter discusses several theoretical perspectives, experiences and concepts related to the system-technical and social-political aspects of designating European cancer institutes. Together they form the framework for analyzing the data gained during the field research. In line with the structure of the research this chapter is separated into: a section concerning the system-technical considerations for developing a designation system for European cancer institutes (part I) and a section with managerial concepts for analyzing the social-political context in which the designation system has to be developed and implemented (part II).

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### *Part I:*

### *System-technical considerations for developing the designation system*

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#### 4.1 INTRODUCTION

Central in the first part of this chapter will be the answer to sub-question A. Literature will be discussed on what theoretically is known about classification so far and how this is relevant for the development of a proper designation system. In addition, examples related to classification in cancer care and research will be discussed. The focus hereby will be on the aspects that are transferable to the development of this designation system. Together they might contribute to the discovery and formulation of technical challenges and features.

#### 4.2 IMPORTANT ASPECTS OF CLASSIFICATION

As said before, the designation system is regarded as a form of classification. To better understand the process and structure of the system's development it is therefore important to know how 'designation' is situated in the broader theoretical perspective of 'classification'. Subsequent to this it allows to link relevant theoretical aspects of classification to the development of the designation system.

##### 4.2.1 DESIGNATION AS ACT OF CLASSIFICATION

Because the study on the designating of European cancer institutes has largely been related to the concept of 'classification' so far, it is important to clarify this relationship in more detail with the help of some prominent definitions out of literature.

The term 'classification' in this study is related to two activities that, in practice, are permanently connected to each other (Durkheim & Maus, 1963). First of all, it refers to the construction of a category, also known as 'categorization'. The following two definitions are well applicable to this process:

*" (...) ordering or arrangement of objects into groups or sets on the basis of their relationships" (Johnson-Laird & Wason, 1977: 187)*

*" (...) understanding what some thing is by knowing what other things it is equivalent to and what other things it is different from" (MacGarty, 1990: 1).*

Parallel to the process of categorization, social scientists provide a broad range of definitions on the term 'category'. The following definitions covers the other similar ones well by describing it as:

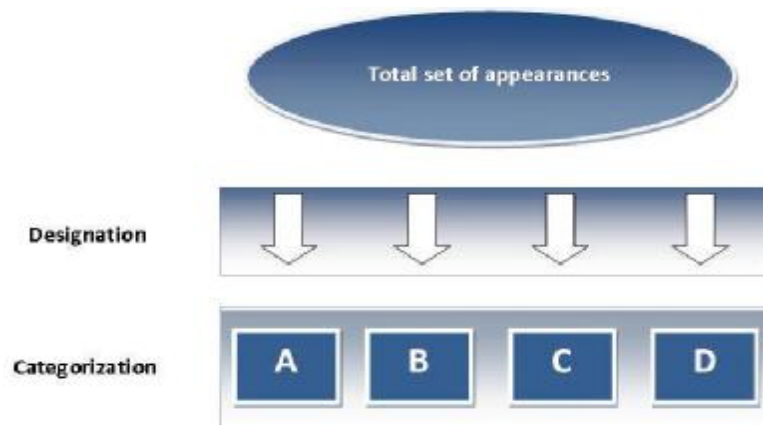
*"A set of things or creatures or events or actions (or whatever) treated as if they were, for the purposes at hand, similar or equivalent or somehow substitutable for each other" (Bruner & Amsterdam, 2000: 26).*

These definitions of 'categorization' and 'categories' can be linked to the topic of this study when European cancer institutes are perceived as a collection of organizational appearances, including infrastructures, processes, and performances, that can be categorized. To put it more concrete: they can be understood as groups or sets on the basis of similarity.

Classification secondly involves the identification of certain appearances and referring or 'labelling' it into a certain category. This is also known as 'designation'. In their definition of classification Durkheim & Mauss (1963: 4) capture both processes of 'categorization' and 'designation' well by describing it as:

*"(...) to arrange appearances in set groups which distinct from each other".*

Figure 2 Classification process



The designation of European cancer institutes can therefore be seen as a classification process as it involves (1) *the arrangement or referral of those institutes (in terms of infrastructures, processes and performances)* into (2) *specific set types that represent a particular group*. The actual designation is therefore only a fraction of a larger process that has to be understood. This whole process is illustrated in figure 2. According to this perspective, the following aspects of classification can be linked to the development of the designation system.

#### 4.2.2 ‘CLASSICAL’ AND ‘PROTOTYPE’ APPROACH OF CATEGORIZING

The designation of European cancer institutes involves a process of categorization. Literature provides in this respect two divergent approaches (e.g. Taylor, 1995; Bowker & Star, 1999; Douglas & Hull, 1992; Bruner & Amsterdam, 2000). Both approaches are relevant for understanding the development of categories in this particular study in a better way.

The first approach, known as the ‘*classical approach*’, has its origins back to Aristotle. He described categories in terms of the sufficient amount of similar characteristics which determine whether a certain appearance belongs to a certain category or not (Taylor, 1995). According to this approach categories have *clearly defined boundaries*; whether a certain appearance belongs to a certain category is obvious and undoubted.

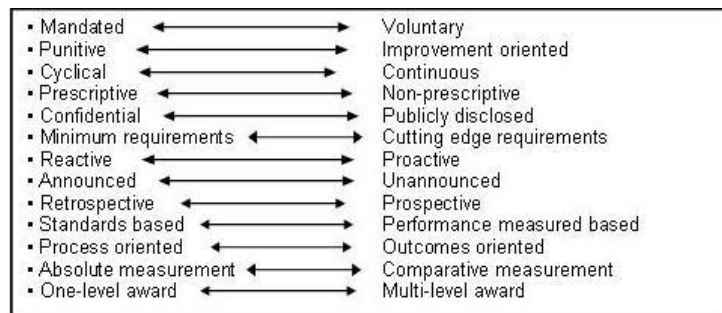
The opposing approach, studied and elaborated for the first time by a psychologist named Rosch (1978), is known as the ‘*prototype approach*’. This approach is originated out of observations of how people use classifications in daily practice. Rosch demonstrated in her study that the designation to a certain category is assessed by comparing the appearance that has to be designated with a prototype of the category that one sees as exemplary. In her study Rosch (1978) saw her hypothesis validated that belonging to a certain category has a more gradual character and is not a matter of definitive conformation or rejection. Categories don’t have strictly defined, but ‘*fuzzy boundaries*’. For that reason it is difficult to formulate relative, on-first-sight, simple categories with strict boundaries (Wittgenstein, 1992). Categories are considered, in contrary to the classical approach, to be built more on ‘familiar characteristics’ than on a specific and permanent set of absolutely similar characteristics (Wittgenstein, 1992: 51-52).

An important concern for the categorization of European cancer institutes is if it should apply to a ‘classical’ or ‘prototype’ approach. Categorization according to the first approach leaves no questions to whether a cancer institute belongs to category A or B as strictly defined boundaries will make that very clear. However, prototype categories might be more appropriate considering the often complex and unique characteristics of activities in cancer care and research.

#### 4.2.3 ASSESSMENTS IN CRITERIA

The designation of cancer institutes into categories cannot be done without the formulation of specific requirements. Literature review however shows that there is not one single common framework for developing such proper criteria. Yet different explicit or implicit models exist with accents on different features. With the purpose to perform a normative evaluation on the requirements, the ‘designation criteria’ are not so much different to the concept of accreditation criteria. In fact, both are developed to improve quality (e.g. Comparative study of hospital accreditation programs in Europe, 2008). The ‘*13-dimension-model*’ (figure 3) of the ‘Joint Commission International’, that compares a set of contrary features for international accreditation criteria, gives in that respect a good global overview of the different assessments that have to be made in the development of proper designation criteria. For instance, should they be process or more outcome oriented, and should they focus on absolute or comparative measurements?

Figure 3. Features of accreditation, (Joint Commission International, 2005)



So, in order to develop proper criteria for the designation system several features have to be assessed. Two major assessments will be further examined.

### Purpose

Classification criteria furthermore are considered to have an external and internal function. Internal when organizations primarily use it for self-assessment or improvement of their own specific structure, processes and performance. In that respect they are not meant for the general public, but only for professionals and policy-makers in the organization itself (Berg & Schellekens, 2002). Criteria have an external function when they are generally used for to control or compare different organizations for instance on quality (Berg & Schellekens, 2002). In the formulation of criteria one should reflect on the existence of these different purposes; by formulating more detailed to serve the internal function and being more broad when it comes to the external function.

### Types

Another consideration in the development of this particular system is that there are different ways to type criteria. A common used typology is that of Donabedian (1980). He makes the link to indicators, which can be divided into types of *structure*, *process* and *outcome*.

The *structure-indicator* measures elements of structure that make activities possible. The term structure refers to the preconditions for providing services such as personnel, facilities and financial capacity. *Process-indicators* refer to the primary process with organizations; it measures relevant aspects of activities in the provision of services. Process-indicators are relevant when there is a strong relation between the process of activities and the corresponding outcome. The *outcome-indicator* finally focuses on the outcome of services. Although they can offer a perfect indication of the performances, they have to be interpreted very carefully. Results are often influenced by processes from outside, which can not always be controlled (Casparie & Hommes, 1997).

#### 4.2.4 DIVERGENCE BETWEEN SYMBOLIC AND MATERIAL SIDE

Even though the formulation of categories and corresponding criteria seems to be clear from a theoretical point, the practical applicability often appears often from being a self-evident process. The question that rises with respect to designating European cancer institutes is what challenges system-technically there might be and what causes can be identified for that.

In their book *'Sorting Things Out: Classification and Its Consequences'* (1999) Bowker and Star shed light on the intense battles which are often fought and have to be overcome before acts of classification become accepted and institutionalized. They argue that most challenges are related to the inherent divergence between the symbolical and material side of classification (Bowker & Star, 1999).

The designation of cancer institutes is considered to be symbolic in the sense that it has a very abstract purpose: in the end it must make theoretical sense outside a specific environment, on a European scale. Secondly, it has a material side in the sense that this designation process has to be allocated or pointed to things or people in their daily, local and complex setting: this requires effort and investment. Bowker and Star (1999) make a point by stating that the symbolical and material side of the classification often conflicts when a high level of abstraction of the classification scheme contrasts with the tangibility of daily practice: a gap evolves between the symbolic and material side that is difficult to close. In other words, there is no one-to-one relationship between the material and symbolic side of classification. Bowker and Star have demonstrated this with the analysis of several classification-examples in which the functionality of classifying is challenged by the complexity of daily practice.

This divergence between the symbolical and material side of classification is also applicable to the designation process central in this study. It can be said that the development of a designation system will most probably bear huge challenges concerning, in the first place, the comparability of European cancer institutes. The current complex situation of cancer care and research in Europe makes it hard to formulate absolute categories and criteria that are appropriate for making those comparisons across Europe. Like many professional organizations, each cancer institute is unique to a certain extent and differs from others, especially in an international context. If these differences aren't taken into account in the formulation of categories and criteria, the chance is high that it will damage the *practical applicability*: made comparisons then don't have a correct meaning anymore and designation becomes illegitimate or irrelevant.

The development of the designation system furthermore has to cope with intrinsic social-behavioral effects as well. Intended or unintended, they ultimately challenge the designation process from an objective and legitimate point of view. This can be understood with the internal and external reflection as well as the benchmark possibilities that such acts of classifications bring along. Despite the intention to improve and to learn from each other, the risk exists that these well-intended purposes lead to uncertainty: a feeling of constantly being monitored or the idea that the results don't reflect the real status of the organization. This might feed the temptation for acting resistant to this form of classification or to manipulate reality by influencing results or stressing aspects that are less relevant than the results that in fact really do matter. This social-psychological process, to avoid that the own cancer institute scores badly in comparison to others, is referable to theories of cognitive dissonance (e.g. Burris et al, 1997) and street-level bureaucracy (Lipsky, 1980). In general this leads to strategic behavior such as withdrawal of important information (Hofstee, 1980) or 'gaming the numbers' (Berg & Schellekens, 2002; Hoogwout, 2004) in order to present themselves in what they desire or see as correct. Psychologist Stone illustrates this social-behavioral challenge to acts of classification well by the following metaphor:

*"People, unlike rocks, respond to being measured" (1990: 177).*

The impact of social-behavioral effects stresses the importance of developing an internal added value into the system for cancer institutes that are to be designated. In addition, an objective and profound evaluation of the results might reduce such social behavior as well.

Last but not least, the development of the designation system might also be challenged by bureaucratic features (de Walcque et al, 2008; van Tol, 2005) or when criteria are too open for interpretation. A time consuming, unclear or multi-interpretable list of criteria that has to be assessed by the cancer institutes themselves, in a context where time is precious, will increase the possibility that data will be incomplete, wrong interpreted and therefore less plausible and valid.

#### **4.2.5 STRATEGY**

In order to overcome conflicts between the symbolical and material side, it is essential to realize that it requires the art of continuous balancing between theory and practice. According to Bowker and Star such acts of classification have to bear the inherent ambiguity of the symbolic and material side as much as possible (Bowker and Star, 1999). For that reason classification systems need 'boundary infrastructures' (Bowker & Star, 1999: 296-297, 313-314). With respect to the development of the designation system it means that categories, criteria and review methods have to be defined balancing between flexibility -so that all parties can use it and satisfy their claims at the material side- and the robustness of the system, enough to maintain a common and legitimate identity across all European cancer institutes at the symbolic side.

### **4.3 CLASSIFICATIONS IN CANCER CARE AND RESEARCH**

Continuing on the theoretical aspects of classification, this section discusses several examples related to classification in the field of cancer care and research. This to identify relevant experiences and practical considerations for the development of the designation system.

#### **4.3.1 COMPREHENSIVENESS**

Literature review indicates 'comprehensiveness' as a frequently used denominator for classifying cancer care and research in practice. Many entities in the field of cancer care and research are using the term 'comprehensive' in order to stress a certain quality-assurance (e.g. 'Comprehensive Cancer Network'; 'Comprehensive Cancer Centers'; 'Comprehensive Cancer information'). Yet, there seems to be no consistency in the meaning of this terminology. Several features of comprehensiveness are now being discussed, in order to assess what this term here actually means.

##### **Multidisciplinary and –interdisciplinary approach**

In practice 'comprehensive' predominantly refers to a multidisciplinary and interdisciplinary approach: being the combination and integration of different competences, skills, resources and tools that are needed for an optimal cancer research and treatment process (NCI, 2004). As the following examples will illustrate, these multidisciplinary and translational characteristics are mainly expressed in infrastructural requirements.

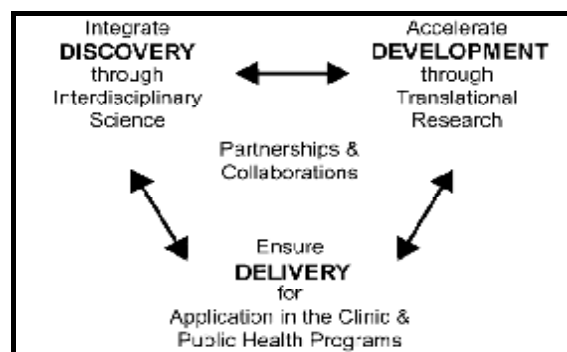
One of the first links between comprehensiveness and a multi-/ interdisciplinary approach can be found in the 'Callman-Hine' report (1995). Responding to the significant regional variations in cancer treatment and outcomes, and to a lower survival rate of cancer patients than in most other European countries, in 1995 the United Kingdom urged a restructuration of the national cancer



services on comprehensive standards. Main interpretation of comprehensiveness by the Callman-Hine taskforce was to create a state of the art provision of cancer care by the integration of three levels of cancer care: from primary, non cancer-related care up to the treatment based on high expertise (Callman-Hine, 1995:7). Although its focus, thus, was mainly on the improvement of cancer care provision by a '*coordinated integration of different levels in cancer care*', the Callman-Hine report used the term comprehensiveness as one of the first to classify institutes on the integration of different disciplinary levels in cancer services.

Another interpretation of comprehensiveness as a multi-/ interdisciplinary approach can be found in the designation program of US cancer centers by the 'National Cancer Institute' (NCI). In the NCI report of 'Policies and Guidelines relating to the Cancer Center Support Grant' (2004), 'comprehensive' first and foremost refers to the integration of cancer research into the direct provision of cancer treatment. According to the NCI it stands for the infrastructure of centers that enable the coordination and cooperation between different disciplines in research and in treatment: '*from discovery, development to delivery*' (NCI, 2004: 2).

Figure 4. Comprehensiveness as a multi- and interdisciplinary approach (NCI, 2006)



In line with the NCI's interpretation of comprehensiveness, other collaborative networks in the field of cancer research, such as the Stockholm group, underline the importance of an interdisciplinary infrastructure for translating research into care. A '*translational cancer research continuum*' (Ringborg, 2008) where all research components, from basic to clinical outcome are fully integrated, is hereby widely seen as the cornerstone of comprehensiveness. Point of remark hereby is that this interdisciplinary approach involves a bi-directional exchange of results between basic and clinical science (NCI, 2006), such as illustrated in figure 4.

#### Constant improvement and innovation

A second important feature when is referred to comprehensiveness, is the constant effort for improvement and innovation. It generally relates to an adequate infrastructure that guarantees a continuous effort at making progress in cancer research and treatment (OEI, 2007; NCI, 2004). In this perspective literature initially stresses the important role of high expertise and education (e.g. NCI, 2004). Highly qualified personnel, training and other educational activities are seen as intrinsic elements in the effort at the maintenance of innovation and quality improvement. Secondly, it refers to the monitoring of new developments in research and treatment and if these are applied

correctly. Resources for quality control, such as protocol-reviews and monitoring systems, play an important role in this respect (NCI, 2004).

#### **Leading and coordinating role**

A last major element that ‘comprehensiveness’ refers to is the leading and coordinating role in cancer care or research activities (NCI, 2004; OEI, 2007). Activities in the area of prevention, external dissemination of knowledge and innovation are considered to be comprehensive, infrastructural requirements as well and may therefore not be forgotten.

#### **4.3.2 CATEGORIES**

Up to now cancer institutes have been categorized in various ways. A few of these categorizations will be discussed here for obtaining an impression of the most common, distinct categories and their subsequent features.

##### **‘Cancer Unit’**

The first significant category deducted from the literature is the ‘Cancer Unit’. Although many concrete indications for a ‘Cancer Unit’ don’t exist or at least strongly vary, the following features are generally applicable for this type of category.

According to the Callman-Hine report a ‘Cancer Unit’ can be seen primarily as a clinical facility in large or medium sized hospitals, and having formalized collaborations with other hospital services:

*“ (...) it should be an integrated part of the hospital” (Callman & Hine, 1995: 8).*

In reporting the requirements of a ‘breast cancer unit’ (2004), the EUSOMA and EORTC refine this by arguing that a ‘Cancer Unit’ doesn’t necessarily need to be a geographically single entity. The separate buildings however must be within a reasonable proximity, sufficient to allow multidisciplinary working and to let all diagnostic procedures take place at the first consultation (EUSOMA & EORTC, 2004: 345). Treatment might therefore be given in two or more different settings. But as long as it is provided by the same multidisciplinary team, to the same protocols, and through a single dataset, it can be designated as a ‘Cancer Unit’. The size of such a ‘Cancer Unit’ has to be adequate for supporting clinical multidisciplinary oncology teams along with sufficient expertise and facilities to manage the commoner cancers (e.g. breast or lung). Exact indications for this lack or vary depending on the type of cancer treatment that is being given.

Consistent with the view of the EUSOMA and EORTC an important feature of a Cancer Unit is the care provision of particular cancer diseases in all its stages - from screening to the care of advanced disease. Occasionally the patient may need to be sent to an associated institution for addition treatment, but is essentially followed-up at the particular ‘Cancer Unit’ (EUSOMA & EORTC, 2004). Moreover here it is stressed that a ‘Cancer Unit’ has the management of its own budget, covering all the work of the unit.

Finally, literature argues that a ‘Cancer Unit’ has a limited degree to none educational and research activities. A specific indication of this limited degree of education and research is nonetheless unclear or strongly varies (e.g. Callman-Hine, 1995; EUSOMA & EORTC, 2004).

##### **‘Cancer Clinic’**

A second category is the ‘Cancer Clinic’. Although the name is frequently used for many cancer institutes, specific indications for designating a ‘Cancer Clinic’ lack in literature. Nevertheless it can

be said that, based on examples found in practice, a 'Cancer Clinic' like the 'Cancer Unit' refers to a clinical facility or hospital department having formalized collaborations with other hospital services. With practically the same similarities as the 'Cancer Unit' it distinguishes itself mainly in a larger degree of capacity for patients and the amount of oncologic specialization.

#### **'Cancer Center'**

A major category, familiar in many categorizations, is the 'Cancer Center'. According to the Callman-Hine report (1995) a 'Cancer Center' distinguishes itself from a 'Cancer Unit' by the additional range of more specialized services. 'Cancer Centers' deliver a sufficient range of multidisciplinary cancer treatments to encompass the common cancers within their immediate geographical locality. In addition, they deliver treatment programs for less common and rare cancers and those treatment regimens which are too specialized, technically demanding or capital intensive to be provided in the 'Cancer Unit' or 'Cancer Clinic'. 'Cancer Centers', in that respect, distinguish themselves in the provision of specialist diagnostic and (radio) therapeutic techniques (Callman & Hine, 1995).

Contrary to the Callman-Hine report, the NCI makes a more clear distinction by adding research as an important feature for being a 'Cancer Center'. In the designation of US 'Cancer Centers', the NCI (2004) considers the necessity of:

*"having a scientific agenda that is primarily focused on basic, population sciences, or clinical (cancer) research, or any two of the three components".*

According to the NCI, the 'Cancer Centers' scientific base is mostly developed within a single institution. Although a network of different hospitals nowadays might be unavoidable to obtain adequate expertise for the provision of care and research, the integration of facilities and activities under one sufficient administrative identifiable structure is considered to be an essential feature of a 'Cancer Center'. Moreover, the NCI (2004) stresses the important role of community outreach and education as intrinsic 'Cancer Center' requirements.

The NCI additionally states that some 'Cancer Centers' are focusing on certain scientific or clinical areas of cancer (e.g. only fundamental research or breast tumors). The scientific and clinical diversity of 'Cancer Centers' is therefore a significant feature as well.

#### **'Comprehensive Cancer Center'**

In the classification of 'Cancer Centers' a categorical distinction can be made on the level of comprehensiveness. The recognition of this 'higher' level is also known as the 'Comprehensive Cancer Center' or 'CCC' (e.g. NCI, 2004; OEI; 2008).

Like in the other categories is also illustrated, the boundaries of a CCC are difficult to define specifically. Features have become controversial or at least ambiguous regarding the broad interpretations and different accentuations that exist in a CCC. Fine examples are the different interpretations of a CCC by the OEI and NCI. They describe a CCC respectively as a center that:

*" (...) brings together all competences, skills, resources and tools needed to optimally care for the patient, and (...) also be competent for and capable of conducting basic and translational research and for providing advanced education to cancer professionals" (OEI, 2008).*

*" (...) exists of a culture of discovery, scientific excellence, multidisciplinary and trans disciplinary research and collaboration in the field of cancer, that is translated into direct benefit for to patients, their families, the general public and the agencies that serve them" (NCI, 2004).*

Although it seems difficult to define specific indications for a CCC in a set of different interpretations, some general important features still can be identified. In comparison to the regular 'Cancer Center', a CCC distinguishes itself in the combination of the earlier mentioned ideas on comprehensiveness. First of all by multi- and interdisciplinary activities from research to treatment, a strong focus on constant improvement and innovation, along with the dissemination and coordination of knowledge. A CCC has in that respect a high level of infrastructure using the full potential of a continuum of basic, translational and clinical research and clinical facilities and activities. Together this enables a direct provision of an extensive variety of cancer care, tailored to the individual patient's needs (NCI, 2004; Eurocan+plus project, 2008). Just like the 'Cancer Center' the integration of facilities and activities under a sufficient administrative identifiable structure is seen as a required feature of a CCC as well (NCI, 2004). Finally, with regard to its innovative, leading and coordinating role, the broad range of activities in the area of prevention, education plus the external dissemination and monitoring of knowledge and innovation are considered to be important features as well (NCI, 2004).

#### **'Centers of Excellence'**

Although cancer institutes aren't formally categorized on this particular level, some carry the status of 'excellence'. 'Excellence' in this context generally stands for their proven performance at a high level in the field of cancer research and care. 'Excellence' however hasn't been indisputable and a commonly used indication for designating doesn't exist yet.

#### **4.3.3 CRITERIA**

Literature shows several examples of criteria as well. A few relevant examples will here discussed more in detail.

##### **NCI designation-criteria**

Maybe the most well-known example of criteria are the ones used for designation of 'Cancer Centers' in the NCI report 'Policies and Guidelines relating to the Cancer Center Support Grant' (2004). The formulated set of these 'designation-criteria' are based on the NCI vision that centers, although they exist in many different organizational settings and with considerable diversity in their size and complexity of their research-emphases, can be judged by the same (scientific, organizational and administrative) requirements.

The NCI designation-criteria for a CCC are mostly focused on the infrastructural requirements. The NCI report describes this as:

*" (...) a sufficient breadth and depth of scientific infrastructure with adequate and appropriate facilities dedicated to each of the centers' research areas, external orientation and cooperation and the integration of laboratory, clinical, and prevention, control and population research areas into a single interdisciplinary and trans-disciplinary enterprise across departmental, educational, and institutional boundaries" (NCI, 2004).*

An important issue of the present NCI designation system is the shift from more 'smart' criteria in the past towards more 'expert driven' criteria. Even though this makes objective evaluations difficult, disputes on the designation-decisions of the NCI board deciding on the CCC status were rare so far

(NCI, 2008). Most criteria can furthermore be regarded as demanding features for being a CCC, more fit for open and subjective interpretation than being normative, objective requirements.

Adopting those criteria in the designation system for European cancer institutes could in this phase harm the legitimacy, and consequently the rating given to a particular institute. On the contrary, space for open interpretation is also required in order to measure the quality of performance and make outcomes more assessable and comparable when the nature of the criteria asks for this. One could think of the examination of complex requirements (such as the organizational stability and focus on cancer) or the identification of exceptional capabilities that distinguishes the institute from others. Both might be relevant for gaining a certain qualification. Moreover, the NCI focuses mainly on the criteria for (translational) research activities since in the United States the clinical activities are separately accredited by criteria of the Joint Commission of Accreditation of Health Care facilities (JCAHC). The NCI designation criteria aren't therefore substantial for designating European cancer institutes as this requires clinical criteria as well.

#### **OECI accreditation: criteria for comprehensiveness**

The OECI accreditation system exemplifies a second relevant set of criteria. Based on Canadian, French, Swedish and Dutch accreditation systems, the OECI initiated an accreditation project in defining consensual quality standards and criteria for European cancer care and research in 2002. By doing so their aim was to provide a tool for assessing cancer institutes on their performance and relative level of comprehensiveness, as well as to make quality improvements by self-reflection and benchmarking possible (OECI, 2008).

The accreditation system, divided into a quantitative and a qualitative section, consists of a broad set of infrastructural and performance criteria focusing on the resources and capacity of cancer institutes to improve the quality of their research and care processes. The accreditation criteria largely focus on measurement of the level of comprehensiveness. This to:

*"(...) allow the identification of structures where accelerated developments of innovative treatment or high clinical research is feasible" (OECI, 2008).*

The difficulty that the OECI accreditation currently has to cope with is the definition of clear criteria that allow a proper measurement on a supranational level. Relatively large differences in national regulations, traditions and habits made it complicated so far to develop a complete and robust set of criteria appropriate for the measurement of cancer institutes all across Europe. Moreover, the project has to deal with the challenge of formulating appropriate criteria in which cancer institutes themselves are able to assess their infrastructures and performances in a right and objective way. These challenges on the criteria have to be taken into account in the development of a designation system as well.

#### **Specific criteria**

Although a system that designates European cancer institutes is non-existing as we speak, yet a variety of organizations have developed several criteria for performance improvement or designation purposes in their own specific cancer care and research area.

The ‘Network of core institutes’ (NOCI), that was launched by the European Organization for Research and Treatment of Cancer (EORTC), have for instance developed criteria mainly for biologically driven clinical trials. This set of criteria has to realize:

*“top quality both in trial design and trial conduct, top logistics for collection of tissues, creation of real as well as virtual tumor banks, engagement of top laboratories as well as top clinical institutes, that offer both good accruing power into clinical trials as well as the necessary infrastructure, both at the clinical research level and on the basic science / translational research level” (EORTC, 2008).*

Another organization, the European Society of Breast Cancer Specialists (EUSOMA), have, in line with their certification process of Breast Cancer Units, developed a set of criteria as well. Outlined in a questionnaire they are a mix of closed, open and output criteria focusing on the comprehensiveness and multi-disciplinary working of specific ‘Units’ in breast-cancer. Pretty similar to this, the ‘European Society of Medical Oncology’ (ESMO) uses evaluation programs for certifying *“the level of up-to-date knowledge, skills, and general competence of medical European oncology”* (ESMO, 2008). Other professional organizations like the ‘European Society for Therapeutic Radiology and Oncology’ (ESTRO) and the ‘European Society of Surgical Oncology’ (ESSO) are using pretty similar criteria or guidelines primarily focusing on these specific professional domains.

The added value of these examples situates in the possibility of gaining more explicit indications for developing designation-criteria on specific research and clinical domains as such. However, regarding the fact that these examples are primarily focused on quality-assurance in their own professional or specific cancer domain they don’t fit in the measurement of trans-disciplinary infrastructures or broader institutional requirements.

#### 4.3.4 REVIEW SYSTEM

Various classifications, like the NCI designation program and the EUSOMA certification, contain a formalized review system in which particular types of cancer institutes are reviewed via a set of criteria. Although not much information is available on such review methodologies, the well-documented review systems of the NCI (2004) and EUSOMA (2006) figure as appropriate examples for obtaining a first impression in the features of a review process.

##### NCI designation

The review methodology by the NCI can be seen as a two-step process (NCI, 2004). In the first step peer review, by questionnaire and site visit, determines whether the center fulfils the mostly open scientific and interactive requirements for gaining the ‘Comprehensive Cancer Center’ status. If so, a second stage review is more concerned with the programmatic relevance and professional outreach and education. Applied cancer centers all undergo peer review by full site or limited site visits, by site visit teams, depending on the significance of change compared to their earlier status or when it is requested by a cancer center director. This is done to avoid ambiguous results and to guarantee an objective review. In addition to the guaranteeing of objectivity and reliability, the review system stresses the importance of some standards of conduct involving how to avoid and deal with suspicion of conflict of interest and the preservation of confidentiality. For instance applicants are forbidden to contact any review members about the review, and formal complaint procedures exist when conflict of interest appear to be the case or when institutes disagree with the designated status (NCI, 2004).

After considering the written report of the delegated site visitors in the NCI 'Initial Review Group' (IRG), a chartered review committee provides a final merit evaluation and recommendation for designation in a summary statement. The formal attribution of designation lies with the 'National advisory body' (NCAB) and the IRG as they determine whether to provide the cancer center a supportive grant and whether to designate the center as comprehensive (NCI, 2004).

#### **EUSOMA certification**

The EUSOMA review methodology is pretty similar with the use of peer review by a questionnaire and site visits (EUSOMA, 2006). Based on the evaluation of the results from the questionnaire and the site visit, the visiting review team will draw up a preliminary review report along with a recommendation on the certification status. Subsequently, the certification board considers this and determines the certification status by approval or disagreement with the given recommendation.

Just like the NCI this review system encompasses similar standards of conduct for increasing the objectivity and legitimacy. A remarkable point in this review process is the distinction that the EUSOMA makes in an 'initial certification', being the capacity that is needed to meet the required features of a Breast Unit according to the EUSOMA guidelines, and the full or 'conditional certification', that based on appropriate performance indicators and outcome measures in five years after initial certification is granted (EUSOMA, 2006).

#### **4.4 SUMMARY**

To summarize the first part of the theoretical frame and to answer sub-question A, the following can be said. By placing 'designation' into a broader perspective of 'classification', several theoretical aspects can be discussed that are relevant for developing an appropriate designation system. Together with various examples of classification in cancer care and research it resulted in several considerations.

The theoretical notion that formulating absolute and uncontested categories with strict boundaries have to be considered more as an illusion, is underlined by examples and experiences in practice. Indications for this are: the ambiguous meaning of 'comprehensiveness' in cancer care and research, and the often broad, vague and differently defined demarcations between different categories of cancer institutes made so far. Although several features of different cancer institutes are discussed, it must be concluded that at an international level no uniform agreed definitions exist on what a 'Cancer Unit/ Clinic', 'Cancer Center' or 'Center of Excellence' is, and what it takes for institutes to be 'comprehensive'.

The difference between theory (the symbolical side) and practice (the material side) in classification can be recognized in the practical difficulties of measurement as well. Differences in national regulations and the infrastructural complexity of cancer research and care activities often make comparable, visible measurement and eventual designation difficult. Moreover the discussion on the normative or more interpretable character of criteria, that in a sense both are required, demonstrates the practical challenges to objective and legitimate measurement. With regard to the risk of unwanted, strategic and manipulating behavior in the self-assessment phase, it is also important to provide criteria with the possibility for cancer institutions to reflect and to improve their current status.

Practical hazards finally play a role as well when cancer institutes are being designated through a review process. The major question that occurs is how to guarantee objectivity, expertise and acceptance at the same time? Although information is scarce in this particular area of classification, the well documented review systems of the NCI and EUSOMA form an appropriate example in obtaining a first impression in the critical features of a review system for designating European cancer institutes.

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**Part II:**  
*Managerial concepts for analysing the social-political context*

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#### **4.5 INTRODUCTION**

The first part of this chapter made most of all clear that the effectiveness of a designation system depends on how technically is dealt with the practical (material) side in which designations happen. The effectiveness also depends on another important, practical factor: acceptance and commitment amongst its stakeholders. The process of developing and implementing the designation system is probably influenced a lot by the setting in which it is situated. Managerial considerations for how a designation system should be introduced and implemented in the social-political context are therefore essential in order to be effective. Before going into the results this second part of the theoretical chapter therefore provides a few concepts for analysing this social-political context. This section will start with the stakeholder theory, to identify and map relevant stakeholders. Secondly, various concepts are combined for explaining the 'stakeholder-dynamics' and their consequences in terms of potential barriers or preconditions.

#### **4.6 STAKEHOLDER IDENTIFICATION**

The analysis of the social-political context starts with the identification of relevant stakeholders. This paragraph therefore initially calls for a normative identification theory, to explain why certain entities should be considered as stakeholders and why others not. Secondly, it examines a descriptive stakeholder 'mapping' theory, in order to identify which stakeholders play a significant role and require managerial attention (also known as salience).

##### **4.6.1 DEFINITION**

The identification of relevant stakeholders is in reality more complicated than one would expect at first. 'Who is in fact a stakeholder and who is not' goes far beyond the use of one single perspective or approach. An indication for this can be found in the huge variety of articles and numerous books that are written on the stakeholder theory over the years (e.g. Freeman, 1984; Clarkson, 1994; Mitchell et al., 1997). On the other hand, the leading point of view is the shared purpose of all stakeholder theories, that is to address *'The principle of Who and What Really Counts'* Freeman (1994). This section will examine the literature on this question so far: who is a stakeholder and what is a stake?

Reviewing stakeholder literature offers a wide variety of 'stakeholder' definitions (e.g. Stanford, 1963; Freeman, 1984; Donaldson & Preston, 1995). All of them recognize a certain relationship between individuals or groups with a stake and a certain organization form (Thompson et al., 1991: 209). The term organization in this context has to be seen as a more broadly defined concept, varying from a firm (Mitchell et al., 1997) to a certain policy or project that requires managerial attention. In this study it refers to the development and implementation of a European designation system for cancer institutes. Moreover, there is not so much disagreement on what kind of entity a stakeholder can be:



*“persons, groups, neighbourhoods, organizations, institutions, societies and even the natural environment are generally thought to qualify as actual or potential stakeholders” (Mitchell & et al, 1997).*

The existence and the nature of the stake, “that what counts”, is mostly the discussion and ultimately deciding in what actually constitutes a stakeholder. In general a distinction can be made between a *narrow* and *broad view* (Windsor, 1992). A short consideration on those two views will help determine how stakeholder can be identified most appropriately in this particular study. A classic definition of a stakeholder by Freeman is based on a broad empirical perspective:

*“(...) any group or individual who can affect or is affected by the achievement of the organization's objectives” (1984: 16).*

According to Mitchell (et al., 1997) this classic definition is thought to be insufficient for identifying and analyzing stakeholders in this study as it leaves the notion of stake and the field of possible stakeholders unambiguously open. To be more precise, the focus will not only be on the ones that really do matter to the designation project. To define stakeholders more effectively several scholars have applied the narrow view. It attempts to define stakeholders more focused on their direct relationship to the organization's core interests (Mitchell et al, 1997). In general this is done by the search for a *normative core of legitimacy*. The adjustment of risk, in terms of something that can be lost, to denote the stake appears thereby a frequently used way of defining stakeholders in that respect (Clarkson, 1994). Next to a legal, moral or presumed claim based on legitimacy, there is a second component to define to those with a stake in this particular view. This is the *ability to influence* the organization in terms of behavior, direction, process, or outcomes (Brenner, 1993 & Starik, 1994). Critical aspects of both views are considered to be necessary for a comprehensive identification of relevant stakeholders in the designation project. Whereas the narrow view attempts to emphasize the *legitimacy of their claims*, the broad view emphasizes their *ability* to influence the designation project, even if there aren't legitimate claims at all (Mitchell et al., 1997: 862). The working definition for identifying stakeholders in this study is therefore:

*“(...) entities with legitimate or illegitimate claims, or those who are able to affect or are affected by a designation system for European cancer institutes”.*

#### 4.6.2 CONFIGURATION

However pointing out the relevant stakeholders in the designation project is not enough. In order to actually understand the social-political influences, more insight is necessary in their behavior and amount of influence. The configuration of the relevant stakeholders by their status or position is a first step in this. Theoretically this configuration at first involves a rough separation between ‘active’ stakeholders, having an actual and dynamic relationship with the organization and, in contrast, respectively ‘facilitating’ or ‘latent’ stakeholders, being those that (directly or indirectly) are influenced or able to influence the organization (Clarkson, 1994: 90). It is expected to recognize such a configuration in the development and implantation of the designation system as well.

In that respect Mitchell (et al., 1997) argues that the ‘field of stakeholders’ has to be analyzed by their relative (combined) possession or attributed possession of three sorts of attributes. These attributes will now be explained briefly.

### Possession of attributes

The first attribute comes down to the stakeholder's *power* to influence others. Although power may be a tricky term to define (Salancik & Pfeffer, 1974: 3) since many different definitions on power exist (e.g. Weber, 1947; Etzioni, 1964; Draft, 2004)), it generally comes down to the following description, being:

*The ability of an actor to impose its will on others and to influence their behaviors'.*

Etzioni (1964: 59) suggests a logic for more determining specific types of power in the organizational setting, based on the resource used to exercise power: *coercive* power, based on the physical resources of force or restraint; *utilitarian* power, based on material or financial resources, and *normative* power, based on symbolic resources. With respect to this study, the power-attribute is thus useful to indicate the stakeholder's ability (by the extent it has or can gain access to coercive, utilitarian, or normative means) to impose its will on others that are related to the designation project.

The second attribute, *legitimacy*, generally refers to the accepted and expected structures or behaviors of stakeholders. Legitimacy refers in that respect to two types of criteria: one is based on the social nature in terms of independency, objectivity and expertise, also known as 'informal legitimacy'. The other one stands for the rational, positive basis in terms of legality, also known as 'formal legitimacy'. The definition used in this study, by Suchman (1995) recognizes both natures of legitimacy:

*"a generalized perception or assumption that the actions of an entity are desirable or appropriate within some socially constructed system of norms, values, beliefs, and definitions" (1995: 574).*

Though legitimacy is closely connected with power, as they create authority when combined together (Davis, 1973; Weber, 1947), they have to be considered as two distinctive attributes as well. To illustrate this, an entity may have legitimate standing in society, but without the power to impose its will on others, it will require little managerial attention (Mitchell et al., 1997). With respect to this study, the legitimacy-attribute is thus useful to indicate if stakeholders have a social-institutional accepted standing in the designation project which legitimizes their actions.

The final, third attribute, *urgency*, stands for the degree to which a stakeholder calls for immediate attention. With respect to this study, the urgency-attribute is useful to indicate if the designation project urges stakeholders to call for immediate attention, which often influences their behavior in terms of strategically using the other attributes of power and legitimacy. The degree of urgency can be identified in two conditions (Mitchell, 1997):

- the claim has to be an actuality, and is therefore time-sensitive
- the claim has to be important to the stakeholder.

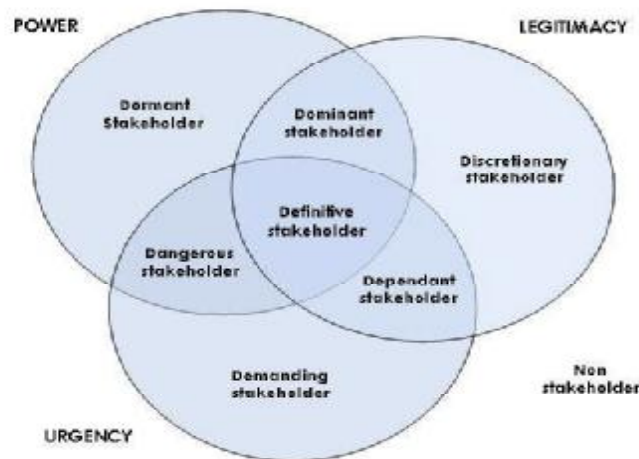
### Managerial salience

The relative possession or attributed possession of all or some of the three attributes not only helps to explain different types and positions of stakeholders, but also the distribution of managerial salience: for instance, some legitimate stakeholders with no or less influence are expected to behave differently and require another kind of managerial attention than stakeholders with a lack of

legitimacy but with a lot of power. The degree of urgency can also be added here as a consideration, as it often leads to strategic behavior. The necessity of acknowledging this is important, especially with regard to the consequences that a misperception of or inattention on the claims of stakeholders can have. Underestimated resistance or recognition of the facilitating function of stakeholders could mean the start of a failing designation project.

With Mitchell's (et al., 1997) stakeholder-model (see figure 5) it will be possible to gain more insight in how managerially should be dealt with the multiple stakeholder positions in the designation project. According to the model, stakeholders are divided in the appearance from various combinations of the attributes: power, legitimacy and urgency. Based on these combinations seven types are conceptualized: three only possessing one attribute, three possessing two attributes and one possessing all of these attributes. The entities with no power, legitimacy or urgency in relation to the organization are not considered

Figure 5. Stakeholder salience typology (Mitchell, 1997)



Based on this model of analysis, Mitchell (et al., 1997) presents a theory of stakeholder salience:

*"Stakeholder salience will be positively related to the cumulative number of stakeholder attributes, perceived by managers to be present" (1997: 873).*

Figure 5 illustrates the typology of the stakeholders' salience. Besides the opportunity to characterize stakeholders very precise, a global configuration is possible as well in salient, expectant and definitive stakeholders. The low salience classes identified by their possession or attributed possession of only one of the attributes are called '*latent*' stakeholders, since they are expected to be managerial irrelevant. With limited time, energy and other resources to provide managerial attention, managers may well do nothing about these stakeholders and may not even go as far as to recognize their existence. The moderate salient stakeholders, identified by their possession or attributed possession of two attributes are called '*expectant*' stakeholders, as they are stakeholders who expect something, but also as the ones where something can be expected from. Meant by that

is that the combination of two attributes leads from a passive (latent) to an active stance. The level of engagement of these stakeholders is likely to be higher and ‘matters’ to management as they have the attributes to do so, for instance to act strategically or facilitating. Stakeholders with the combination of all three attributes are called ‘*definitive*’ stakeholders. Managers have a clear and immediate mandate to attend to and give priority to that stakeholder’s claim.

## 4.7 STAKEHOLDER DYNAMICS

The previous paragraph has given theoretical insights for identifying relevant stakeholders, their positions and subsequent salience in the designation project. The managerial endeavour of designating European cancer institutes goes however beyond that: the relations between stakeholders are in light of the designation project, given social and political circumstances, often not static but in movement. Further theoretical investigation is therefore needed to understand the dynamics that occur in the stakeholder configuration and how can affect the development and implementation of the designation system.

### 4.7.1 ORGANIZING IN A COMPLEX SOCIAL SETTING

To understand the root of the dynamics one firstly has to comprehend the complex setting in which the designation system has to be developed and implemented. What does this setting characterize and what consequences does it have?

#### **Conflicting interests and ambiguous meanings**

Designating European cancer institutes requires an organization of policy on supranational level. Actors with different backgrounds are urged to cooperate and come together, which makes organizing complicated at the same time (Noordegraaf, 2004). The designation project has to deal with a variety of interests and ambiguous perceptions. In such a blurred and equivocal social setting it is difficult to have a controlled overview. Uncertainty and risk preferences hereby arise and, above all, collective action and consensus are required but difficult to reach.

#### **Bounded rationality**

The variation in meanings and interpretations of information and facts suggest that one objective and comprehensive reality, that everyone shares and assesses their actions on, doesn’t exist. Stakeholders are constrained by their limited cognitive capabilities and unable to comprehend all the information that exists. Thus they create their own reality on a selected set of (information-) resources. Their actions may therefore be less than completely rational in spite of their best intentions and efforts to do so (March, 1994). Such a view, known in the academic field as ‘*bounded rationality*’, is a major concept in explaining dynamic organizational settings (e.g. Jones, 2001; Simon, 1976; March & Olsen, 2004).

In view of this ambiguous setting with conflicting interests and a bounded or limited rationality, stakeholders are constantly struggling between satisfying and maximizing their own interests or ambitions. This ultimately leads to a dynamic platform where stakeholders are often strategically driven.

#### 4.7.2 ‘PARTIES IN A SYSTEM’ APPROACH

As social-political dynamics mostly take place tactfully, they are almost invisible and hard to conceptualize. The ‘*Parties in a system*’ approach of social-organizational expert Mastenbroek (1996) however forms a proper conceptual frame for analyzing them. Deviated from the theoretical perspectives of Abbott (1988) and Lammers (1983), Mastenbroek integrates two perspectives:

the ‘*system-perspective*’, that sees the organization as a socially coherent entity with a common purpose

the ‘*parties-perspective*’, that sees the organization as a collection of multiple entities with their own interests.

Mastenbroek (1996) considers organizations as networks of groups and individuals in which the relations between these groups and individuals are characterized by elements of both perspectives. The designation project fits perfect in this perspective since it is based on a cooperation between stakeholders that all strive for a better overall quality of cancer care and research in Europe, but that also bears differing and contested interests. In this lies fundamental principle for analyzing the dynamics: the tension between conflict and harmony in developing and implementing a designation system. On one hand there is the dependency on another to serve the common goal, but on the other the will to pursue own interests as well. Sociologist Gastelaars (2006) relates this perspective to the concept of classification again by stating that:

*“where certain forms of standardization are organized, such as classifying different categories, discretionary space for negotiation and struggle for influence automatically occurs” (Gastelaars, 2006: 171).*

#### 4.7.3 INTERFERING ATTRIBUTES

These processes of tension between conflict and harmony can be illustrated well by two conceptual aspects of the parties-in-a-system-perspective, namely the tension in *information orders* and in *power-dependency relations* among stakeholders (Mastenbroek, 1986; Heimer, 1985). As central attributes for identifying and explaining the dynamics these will be further explained.

##### Information orders

The designation system can be considered as a system that contains an ‘information order’ to process and evaluate data relevant for decision-making purposes (Heimer, 1985; March, 1994). The development and implementation of such an information order can be very difficult as it is a scarce resource that at the same time need sufficient grounds to be agreed upon. Stakeholders have to deal with the will to expand their own influences versus the importance of reaching consensus for the common interest. Therefore most of the time the information is disputed and subjected to the question whether the information is satisfying for the stakeholder or if action is needed to increase the influence on the current use of information. Heimer (1985) speaks in this context of ‘satisfying’ and ‘maximizing’ stakeholder behavior that can be explained in two ways: rationally and social-psychologically.

First of all stakeholders can be seen as rational entities who consider each other as a means for production and think in ‘*logic of consequences*’ (March, 1994); they need each other’s performances in order to realize a common achievement or production. The information that describes the structure of communication patterns, the ways of deliberation, the decision-making

procedures of how other aspects of this common production should be organized, often lead to frictions when they appear to conflict with the interests and preferences of stakeholders from a rational point of view (Mastenbroek, 1996). This is expected to be the case with designating European cancer institutes as well. Central tension that causes in this respect are own (professional) preferences and interests of the stakeholders versus the information that is used in the designation system, being the formulation of categories, criteria and review methodology.

The social-psychological point of view regards stakeholders as entities that are driven by rules of appropriate or exemplary behavior (March, 1994). March and Olsen (2004) call this in their same entitled paper 'the *'logic of appropriateness'*:

*"Actors seek to fulfill the obligations encapsulated in a role, an identity, a membership in a political community or group, and the ethos, (routine) practices and expectations of its institutions. Embedded in a social collectivity, they do what they see as appropriate for themselves in a specific type of situation" (March and Olson, 2004: 3).*

Alternatives and preferences aren't calculated here as such as in the ideal rational world, but are rather placed in the perspective of: "What kind of situation is this?", 'Who or what am I?', and 'What is the appropriate thing to do given who I am (March, 1994)?' This means that stakeholders are expected to not only have intuitive associations in the shape of personal feelings of sympathy and antipathy towards others, but also to carry positive or negative feelings directed to a set of shared rules and identities that exist within the information that is ought to be followed (March, 1994).

The logic of appropriate behavior is expected to be an explanation of the dynamics in this study as well. Especially since it is related to a highly professional network of stakeholders, where identity, the way of performance and ethos are considered to be very important (van Delden, 1992; Weggeman, 1992). One of the expectations for instance is that stakeholders are very sensitive to a situation where their identity doesn't correspond, or in their view, is 'inappropriate' with the information used to designate cancer institutes. This could lead to various dynamics and consequences for the designation project such as heavy resistance. Central tension in this respect is therefore what stakeholders believe as appropriate or 'what makes sense' versus the prescribed or desired rules and identities of the designation system.

### **Power versus dependency**

The degree of power versus dependency is an important resource for dynamics as well. In the power-dependant relationship stakeholders are characterized by the extent in which they determine or direct each others behavior (Mastenbroek, 1986). Whereas power is defined as the capability to influence the behavior of others, dependency is the other way around: one is dependant of another. According to Mastenbroek (1986) dependency occurs when:

he or she perceives the activities of the other as important  
the alternatives of these activities are minimal

The greater the level of dependency, the more the behavior will be influenced by others. Stakeholders, generally speaking, are therefore trying to reinforce their capabilities for optimizing their power and keeping the level of dependency as low as possible. This dynamic process is expected to be the case in the development and implementation of the designation system as well. Stakeholders with negative thoughts on the system will probably lack the system's importance and

look for the capacity to opt for other alternatives in one way or another, whereas stakeholders with a positive opinion will try to do just the opposite.

#### 4.8 SUMMARY

The identification of stakeholders and their managerial salience appear to be a productive strategy for managing in a more effective way as attention is given to 'those Who, and the things That really count' (Mitchell et al., 1997). The stakeholder theory has therefore been chosen to identify the relevant stakeholders and their different positions 'in the field' related to the designation project. Analyzing the possession of all or some of the three key attributes according to Mitchell's salience typology model makes this possible.

Stakeholders however are often not static, but in motion. Given the complex social setting in which the designation project has to be developed and implemented, that can be considered as the fundament for the dynamics, further insight is needed in the social-political patterns, processes and actions. Although such 'dynamics' are hard to conceptualize, the 'Parties-in-a-system' approach by Mastenbroek (1996) offers a solution by analyzing the tension in *information orders* and in *power-dependency relations* among stakeholders. The analysis of these attributes focuses on the assumption that there is a constant tension between cooperation/ consensus (for the common purpose) and competition (for the individual interests). The dynamics therefore have to be analysed in social-political patterns that are recognizable in the social tension of these attributes: what kind of climate dominates, which tensions do occur, and how does this affect the development and implementation of the designation system in terms of preconditions or potential limitations.

## 5 RESULTS

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This chapter presents the results of the field research that has been conducted on the development and implementation of a designation system. The results are the outcome of a profound literature review, interviews and observations that have taken place in the period from February 2008 till June 2008. Based on the two-folded character of the research so far, it has been decided to separate the results into a system-technical and a social-political part as well. A short reflection and overview of the results, where both parts are integrated, will finally close this chapter.

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### *Part I: System-technical aspects*

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#### 5.1 INTRODUCTION

Central in the first part of this chapter are the results on the technical aspects of the designation system. It concerns the answer to the following three sub-questions of this research:

- B. *What challenges occur in the development of the designation system?*
- C. *What features are essential to overcome these challenges?*
- D. *What should a draft version of the system look like?*

The results, which are mostly descriptive and prescriptive, will respectively be presented in following paragraphs 5.2, 5.3 and 5.4.

#### 5.2 CHALLENGES

Field research showed several practical hazards in the development of an appropriate system for designating European cancer institutes. In line with what Bowker and Star already argued in the literature, the functionality of the designation system seems to be challenged by the complexity of cancer care and research in daily practice. In fact, this is made even more difficult as this designation takes place at an international level. Subdivided into three important challenges, the practical hazards will be discussed in this paragraph.

##### 5.2.1 DEFINING APPROPRIATE CATEGORIES

First of all, the categorization of cancer institutes into an appropriate and uncomplicated format seems to be more difficult than one first expects. The following restraints to the categorization process were identified.

##### **Diffuse and contested definitions**

The categorization of cancer institutes is hindered by the multiple and varying definitions that in the literature exist. Examples of this have already been given in the theoretical framework. An important



aspect that makes the current categorization even more diffuse is the use of different, often self-made titles by cancer institutes of being for instance a ‘Comprehensive Cancer Center’. The meaning of these titles is unclear as no common (international) standards are used and further explanation often differs or even lacks.

In addition to the current lack of transparency in the categorization process, the formulation of appropriate categories is slowed down as well by the contest on which elements exclusively should be included in the definition of a particular category. Political, legislative and social differences on a national level but also the differences in professional perceptions can be seen as the cause for this. An example that occurred in this respect was the firm opinion of epidemiologists that epidemiology should be an essential element in the definition of a ‘Comprehensive Cancer Center’. Others however saw it more as an element that is subordinate to the larger formulation of the category (Eurocan+plus meeting, March 2008). Another example can be found in the discussion on including the dissemination or ‘community outreach’ of knowledge and population control in the definition of a ‘Comprehensive Cancer Center’ or not. In the performed interviews the relevance of these particular activities was approached differently by representatives of cancer institutes and governmental agencies on a national and European level.

#### **Ambiguous categorial boundaries**

The categorization of cancer institutes furthermore turns out to be difficult due to ambiguous categorial boundaries. Whether a certain cancer institute belongs to a certain category is often unclear, doubted and multi-interpretable. A certain institute may for instance have a sufficient (infrastructural) capacity to be comprehensive or perform on levels of excellence, but only in one or a selection of specific cancer areas such as breast-, lung- or colorectal cancer. Should the cancer institute then be interpreted as a ‘Comprehensive Cancer Center (of excellence)’, since it has the required infrastructural capacity, or not regarding the focus on one or more specific cancer areas?

Another ambiguity that occurs in the formulation of categories is the ‘relativity of comprehensiveness’. Cancer institutes, for instance, with a huge capacity may pass the requirements for the status of a CCC but are performing, in terms of comprehensiveness, equally or even less compared to institutes who don’t reach the requirements of a CCC, but are specialized in one or particular cancer areas.

With ‘comprehensiveness’ as a central starting point for designating European cancer institutes in mind, the restraint of ambiguity in categorizing European cancer institutes has therefore been illustrated well by respondents in the frequently heard question:

*“When is a cancer institute really comprehensive?”*

#### **5.2.2 FORMULATING CORRESPONDING CRITERIA**

Along with the categorization of cancer institutes, the formulation of appropriate criteria is confronted with several restraints as well.

##### **Comparative measurement**

Contextual differences make it difficult to formulate a comparable and uniform set of criteria on a European level. One of the respondents indicated this by saying:

*\* (...) it is the difficulty finding an overarching model because existing national models are very different”.*

A first factor can be found in demographical differences. The population basis of patients for a cancer institute and the concentration of different types of cancer vary regionally or per country. This influences the development of comparable criteria for cancer institutes on a European level in a negative way.

A second factor can be found in the huge administrative differences across Europe. There are numerous variations in how institutes are organized nationally. For example, the organizational form of the Swedish 'Karolinska' cancer institute, which is a department of a larger University Hospital and not only dedicated to cancer, strongly varies with the major French cancer institute 'Gustave Roussy', where care and research activities are fully dedicated to cancer. Moreover, there is the sensitivity of regulative differences in cancer care and research across Europe: various quality-assessment initiatives on cancer care and research for instance already exist nationally and regionally. These are strongly fragmented and lack an integrated vision on a supranational, European level. Specific examples of this are the initiatives by the national federation of French Cancer Center ('Fédération national des centres de lutte contre le cancer') and the Italian league against cancer ('Lega Italiana per la Lotta contro i Tumori'). These national criteria might seriously harm European comparability as they are not compatible with each other at the European level.

Last major administrative difference is the disparity in funding of cancer care and research in the European member states. Whereas in most northern countries cancer research is mostly funded by 'research groups' or 'research councils', that are providing financial support for the various cancer institutes in those countries, in most southern countries those national 'research councils' are not so much funding agencies but instead receive money directly from the national ministries to support cancer research in their own laboratories.

Language is the third factor that challenges the formulation of appropriate criteria for comparative measurement. What already came to light in the OECI accreditation pilots and workshops is that language problems often lead to wrong interpretation of criteria and ultimately to outcomes that aren't fit for comparison. These language problems are:

- insufficient understanding of the English language (in which the criteria are formulated)
- multi-interpretability of criteria
- unfamiliarity with specific terminology in the formulated criteria.

### **Complex requirements**

The nature of cancer care and research, especially with the increasing linkage to the principles of comprehensiveness, has made certain requirements become more abstract and therefore difficult to measure. For instance, how to measure concrete requirements for translational research when it is intertwined with the activities and infrastructure for basic and clinical research? Or, how to measure a sufficient identifiable entity when more and more cancer institutes only virtually exist due to a growing geographically distribution of coordinated cancer care and research activities?

Another difficulty in measurement is that many of those activities are integrated into larger health institutions across Europe and therefore difficult to extract. Surgical, radio-therapeutical and medical infrastructures for instance exist in many European hospitals, but are not dedicated to cancer alone. With those virtual cancer institutes it is much more difficult to be sure that only those patients with cancer will be measured:

*“A lot of patients are coming in cancer centers after the diagnostic has been done elsewhere, like in an other hospital or private practice. They are referred after the diagnoses with cancer has been set. (...) So, you have to be very precise in the definition of parameters”.*

Many activities in cancer institutes are furthermore difficult to measure since they can only be measured and assessed properly over a longer period of time. Clinical trials for example often cannot be assessed in an instant moment or in a couple of days and therefore difficult to measure a specific moment of time. The complexity of cancer research and care make it therefore hard, not only to formulate a set of straightforward and clear criteria, but also to formulate criteria that can be assessed in a relative short period of time.

Developing proper criteria, thus, tends to be very complex and difficult for reviewers and for cancer institutes themselves to overlook and to understand the actual requirements. Consequently this increases the chance of wrong interpretations or assessments. It might eventually lead to liability issues and even a false designation. The challenge therefore is to formulate an uncomplicated set of criteria and to avoid bureaucratism. Simplification of the criteria format has therefore been forwarded in many interviews as one of the major tasks.

### **Feasibility**

Finally, in the formulation of corresponding criteria many cancer institutes seem to fear that it will rest on a utopian model where requirements aren’t feasible for them to reach. This point was well illustrated in the following quotes:

*“Practically none of the European cancer centers covers all facets of cancer care and research. The real comprehensive cancer center and CCC of excellence are for that reason more an illusion than practical reality”.*

*“We must stay realistic in the formulation of criteria and keep the requirements feasible for the largest group of institutes, (...) otherwise the perfect will be the enemy of the good”.*

The criteria will probably lose a lot of the acceptance and commitment if the requirements aren’t realistic for most European cancer institutes to meet. Creating feasible criteria is thus essential for the vitality of the system.

### **5.2.3 CREATING A RELIABLE AND LEGITIMATE REVIEW SYSTEM**

Third major challenge to the development of an appropriate designation system concerns the creation of a reliable and legitimate review system.

#### **‘Conflict of interest’**

A first restraint in that respect is the risk of ‘conflicts of interest’. The designation of cancer institutes is intended to be mostly based on peer-review. This means that the evaluation will be done by other experts in the field of cancer care and research. Objectivity turns out to be a constant item of discussion during interviews and observations, because with peer-review the risk will increase that reviewers (professionally, financially or personally) might be associated with the institute that has to be reviewed.

*“It must be said again that it is important to avoid that anybody who can have an interest or is or might be in a position that his or her views can influence the process (...) and the danger exist for a neutral opinion (...) should not be sitting in those review boards”.*

A biased and subjective review will damage the reliability and legitimacy of the system. The challenge is to avoid that.

#### **Ambiguity and diffusion in review procedure**

Another aspect is how to cope with the threat of inconsistency in review and designation procedures. Differences in the methodology easily occur when reviews have to be done in different settings and when there must be instantly reacted to unique situations. It seems for instance quite logic that a relative large cancer institute, with a great focus on clinical breast cancer activities, requires a different composition of reviewers than a smaller cancer institute with less attention for clinical activities but more on the fundamental research.

Such inconsistency won't be a serious threat if reasons exist to deviate from the normal procedure. However, as it is argued in various existing review systems (NCI, 2004; EUSOMA, 2006), significant differences in the review and designation procedure are becoming a serious threat when clear motives for deviation lack. For instance, when review time-schedules are extremely varying and significant differences are noticeable in the compositions of review members or in the review/designation procedure of two, almost similar cancer institutes. Then it affects the uniformity in the designation of cancer institutes in a negative way and will leave space open for others to question the objectivity of the review system.

#### **Authority in review process and designation decisions**

The designation of European cancer institutes will at first be based on a voluntary cooperation by cancer institutes themselves. This makes the ability and (formal and informal) legitimacy for one certain institute, like the OEIC, to designate European cancer institutes quite fragile: why should cancer institutes comply with such system? The challenge therefore is to obtain enough authority, or in other terms sufficient power and legitimacy, in the review process and designation decisions.

### **5.3 FEATURES**

Regarding the previous mentioned challenges it seems almost impossible to develop and implement an effective European designation system. Fortunately, field research and the earlier mentioned considerations from the literature review made it possible to suggest some important system-technical features as well.

#### **5.3.1 CLEAR STRATEGY FOR DESIGNATION**

First of all the development and implementation of the system has to start with a clear strategic approach on designating European cancer institutes. This strategic plan is founded on the benefits that designation has to offer. The following elements are hereby essential.

##### **Comprehensiveness as frame of reference**

The designation provides the possibility to assess and reflect the quality of cancer institutes on a structured and equal basis. The designation system therefore primarily a central focus; a frame of reference based on a set of minimum, common standards on which all European cancer institutes can be designated. Secondly, this designation process must provide auditable recommendations for cancer institutes to improve. Comprehensiveness in cancer research and/ or care forms in that respect a perfect frame for designating European cancer institutes: it offers the possibility to evaluate and recommend them on the relative level of the following general (infrastructural) requirements.

a single integrated entity: the institutional activities must be sufficiently identifiable from a physical, legal, financial as well as from an administrative point of view

effective performance: there have to be sufficient cases to allow effective performance in cancer care and research

multi-disciplinary working: there must be sufficient infrastructure to enable the coordination and cooperation between different disciplines in research and in treatment

translation from cancer research to care: there must be sufficient infrastructure to integrate research activities in a continuous process with the direct provision of an extensive variety of cancer care that is tailored to the individual patient’s needs

education and quality control/monitoring: there have to be sufficient activities directed towards learning, maintaining and improving the professional, organizational and relational quality of cancer care and research

external dissemination of innovation and knowledge: there have to be sufficient activities in the area of prevention, education, and other ways of external dissemination of knowledge and innovation in cancer care and research.

#### **Important role for peer-reviews on site**

Designation secondly offers, next to the accreditation initiative, possibilities to map how is being dealt with quality-improvement on a daily basis. Besides a general questionnaire, an objective and accurate measurement will depend a lot on a proper review or audit procedure. The NCI experiences with designating comprehensive cancer centers and the experiences with the OECl accreditation project so far show that peer-reviews at site turn out to be necessary in order to assess the quality of performance properly:

*“Site visits are crucial to see what’s really going on. (...) They often reveal new crucial information that otherwise wasn’t discovered”.*

*“Peer reviews on site also allow you to see how a cancer institute is dealing with quality improvement on daily basis”.*

Moreover, infrastructural requirements are often hard to measure absolutely and need extensive on-site reviews as well in order to penetrate more into the detailed and complex requirements and to make better assessments at the wide range of requirements.

Only the question then rises which general criteria fit the questionnaire and what should be left for the peer-reviews on site. Another possible hazard will be the investment of voluntary time of reviewers as on site visits absorb relatively a lot of time. A stepwise time procedure that is clear defined would be an option to manage this.

#### **A ‘top-down’ and ‘bottom up’ approach**

Although cancer institutes should be designated on the previous requirements, it shouldn’t be done with the idea of recognizing comprehensiveness on the strict requirements or on the total picture that has to meet comprehensive standards in a perfect way. Being completely comprehensive in all facets of cancer research and care is for nearly all cancer institutes impossible, in fact more a utopia. A proper designation system has the possibility to arrange nuances where comprehensiveness is recognized in specific cancer areas as well or in institutes that nearly meet the total picture of comprehensiveness.

Cancer institutes therefore have to be designated by a mix of a top-down and bottom-up approach: both are separate strategies of information processing and ordering, but can be used together. Starting with the basic focus on comprehensiveness the system will break down in designating cancer institutes on the features in the detailed sub-areas. On the other hand, it is also necessary to preserve the oversight and to avoid a designation system with too many different types of cancer institutes. Resembling cancer institutes, with specific comprehensive features on a detailed sub-area, will therefore be linked to more general defined categories again but with the notice of their status on that specific area. For instance, a cancer institute with all necessary comprehensive features in the field of breast cancer should be designated as such like: 'Comprehensive Cancer Center, in the field of Breast-cancer'. In practice this approach can therefore be seen as a mix of a primary decomposition of cancer institutes into detailed designation in specific cancer areas, followed by a synthesis of the cancer institutes with their specific features into more general levels again.

In this way a right balance can be found in designating cancer institutes on a general level, but with still having the possibility to recognize specific features of cancer institutes. This acknowledgement is important since one of the system's main purposes is to create a beneficial overview of cancer institutes as well which are appropriate for research, diagnosis and treatment in specific cancer areas.

#### **Accent on stimulation**

A designation system not only contributes to the overall progress in European cancer care and research, but provides also great opportunities for individual cancer institutes to improve themselves by reflecting and comparing each others outcomes. In order to gain their acceptance, the system must possess a continuous stimulation for cancer institutes to improve. The nature of defined categories, criteria and review methods should therefore provide incentives for all cancer institutes, also for institutes which are already performing on the level of excellence, to work on their infrastructure and performance and to reach a higher level of quality.

#### **5.3.2 STRICT AND FLEXIBLE CATEGORIES**

Concerning the previous described challenges in the categorization of cancer institutions, the categories for designating cancer institutes need to be formulated very deliberate; they have to make sense for all parties, rest on consensus and cover all major types of cancer institutes in Europe. This leads to a contradictory conclusion that the categories need to be defined strict and flexible.

#### **'Prototype' approach**

A first suitable step in achieving this is by formulating categories on Rosch's (1978) concept of a prototype: the exemplary model of required features for a cancer institute in a particular category. Since literature shows that categories don't have strict defined boundaries, categories in this designation system should be defined flexible by illustrating the critical 'familiar' characteristics of that particular category rather than on strict detailed features and requirements. Cancer institutes, which not fulfill every strict required feature but still are capable of delivering substantial comprehensive cancer services or perform at levels of excellence, are in that way not underestimated and -valued. Moreover, a struggle on specific details and characteristics can be avoided and can there be coped with contextual (cross-national) differences.

### 5.3.3 SUITABLE SET OF CRITERIA

Second important item in the system-technical features for the designation system is a suitable set of criteria: they have to be appropriately and well designed in order to produce the desired outcome that is needed for an effective review. In that respect several features are necessary in order to overcome the previous mentioned challenges of comparability, complexity, subjectivity and feasibility.

#### **Mix of ‘closed’, ‘output’ and ‘open’ criteria**

In order to avoid complexity and multi-interpretable or even false results, the system primarily needs a clearly defined and simplified set of criteria. Some of these ‘closed criteria’ can be characterized as in a set specific minimum amount of capacity in a particular area, for instance the amount of operation rooms a particular cancer institute should have in order to reach the status of ‘Cancer Clinic’. Others are broader defined ‘cutting edge’ indications for infrastructural capacity. Criteria are then based on a cumulative required rate of different infrastructural capacities. For instance, cancer institutes should have a substantial infrastructural capacity in order to perform basic and/or translational and clinical research activities and to be able to reach the status of ‘Comprehensive Cancer Center’. On the other hand ‘output’, and ‘open’ criteria are needed as well to avoid too much rigidity in the measurements and to provide the ability to review the more complicated requirements. In order to measure performance and particular the levels of excellence by cancer institutes it is necessary to have a set of output parameters. Moreover, aspects involving institutional commitment to cancer research/ care, a sufficient institutional entity as well as more process-related requirements such as multidisciplinary collaboration and cooperation cannot only be assessed on quantitative numbers but they need qualitative assessment.

A right balance therefore has to be found between absolute/ cumulative (closed) and output criteria to increase transparency and benchmark possibilities, and open criteria to complete an extensive assessment of the requirements.

#### **Reasonable**

The criteria must be realistic for cancer institutes to meet. Otherwise it will lose its functionality in the end. A first step in achieving that is to avoid very detailed criteria as much as possible. One of the respondents made this point in the following words:

*“If you go for a minimum common set of standards (...) criteria that are not too detailed (...) you would find yourself that more institutes are able to comply to the criteria and fit such a system”.*

The reasonability of the criteria can be increased as well if they are deducted from existing and proper accreditation criteria. Optional therefore is to define the designation criteria in correspondence with the OECI accreditation and other professional organizations such as the NOCI and ESMO criteria. An additional idea is to develop criteria that are assessed by experts in the field which those particular criteria relate to, such as basic research or clinical research or radiotherapy and surgery.

#### **Stimulating**

Furthermore, the designation criteria must have an ‘inviting’ rather than an excluding character and offer a challenge for cancer institutes to improve themselves. The requirements must therefore be in a proper range for cancer institutes to reach if significant efforts will be done. Criteria must also

provide a constant motivation for them to improve their specific capabilities; the use of out-put parameters will therefore be most appropriate. Last but not least, the avoidance of very detailed and irrelevant criteria once again would contribute to the stimulating character of criteria as well.

#### **5.3.4 ROBUST REVIEW SYSTEM**

The last important feature for an appropriate designation system is related to the review system. It is said before that a proper review strategy would exist out of a general questionnaire along with an essential role for the review procedure on site. Unmentioned so far is the composition of the review system. General focus in this respect is its robustness: it must be able to endure the challenges on the authority, objectivity and ambiguity in the review process.

##### **Standards of conduct**

To avoid suspicion of conflict of interests or other aspects that contribute to an incorrect review and subsequent designation decision it is important to consider various standards of conduct. Those would then be formally agreed by institutes that apply for designation.

First of all the procedures related to the review and designation need to be consequent and uniform as much as possible. For instance, site-visits need to be performed according to a common applicable time and task-schedule and cancer institutes need to reapply for an official status after a certain time-period that is set equally for each cancer institute. Differences in procedures, that might leave space open for cancer institutes to question the objectivity, are thereby reduced.

If a conflict of interest is suspected, procedures must exist to address this and handle this in a proper manner. Potential subjectivity can thereby be discovered, taken serious and acted upon. The use of formal complaint procedures can be seen in this perspective as a perfect form to create 'checks and balances' in the review system.

Review members must also apply to a certain standard of conduct that stresses the importance of confidentiality. Any breach in confidentiality, for instance in admitting individuals who aren't involved in the review process to review results, is an unethical conduct that might have adverse effects on a reviewer's reputation or the reputation of their institution. Consequently it might damage the integrity of the peer review process. Confidentiality in the review process is therefore important in order to preserve the integrity, and thereby the reliability of the (peer) review system.

Additionally, in order to avoid rigidity and to keep the review system open to improvement there must be a periodical re-evaluation of the system.

##### **Formal and informal acceptance of review members**

For obtaining sufficient authority for review and designation decisions, review members must be accepted formally and informally. First of all, the execution of review and designation decisions must be formally supervised and on the responsibility of a cross-national institute. This institution will then be responsible for a correct and objective review of a cancer institute and will also grant the official status. As the 'umbrella organization' for European cancer institutes, the OECI would be an appropriate institute in undertaking this task. It is ultimately preferable that the legal supervision and responsibility for reviewing and granting an official status to cancer institutes will be formally attributed by the European Commission. Informal legitimacy can be created by the appointment of well-respected and highly qualified review members. Secondly, it will also be increased if the composition of review members is based on a well balanced mix of members from the different areas that preserve the objectivity, expertise and relevant review perspectives. This means that



patient representatives and governmental administrators are required to be in the review group as well as scientific and clinical members.

**Stability and flexibility of review groups**

Finally, the composition of review groups must be partly stable and partly flexible. Review members must be appointed for a certain duration in order to preserve the robustness of the review group. On the other hand correct evaluations of particular areas in cancer research and care require special attention of reviewers that won't be necessary in review processes in general. OECI accreditation experiences learn for instance that it would be a very good option to integrate national representatives on occasion as well, in order to synchronize European and national accreditation initiatives in a better way. Review members must then be appointed on a temporary basis, but with the same rights and obligations as the 'permanent' ones.

**5.4 CONCEPTUAL DESIGN DESIGNATION SYSTEM**

Based on the previous described (practical) hazards and challenges, and after suggesting the most important features, a first draft of the designation system has been developed (see appendix). The purpose of this draft is to facilitate the discussion on how European cancer institutes can be designated in a correct way. The draft is therefore open for feedback and forms the basis for a first set of pilots in the near future.

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*Part II:*  
*Social-political context and influences*

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## 5.5 INTRODUCTION

Designating European cancer institutes by a proper system-technical design is not enough to get the job done; there are other, social-political aspects that determine the success of the designation project. Central in this second part are therefore the answers to the last three sub-questions:

- F. Which are the relevant stakeholders and how are they configured?*
- G. What are the dynamics within the social-political context of the designation system and what are the consequences, in terms of limitations and preconditions?*
- H. What managerial recommendations can be offered?*

The results present first of all a description and analysis of the social-political context involving the most important stakeholders, their positions and managerial relevance in paragraph 5.6. This provides the basis for analyzing the dynamics and its consequences on the development and implementation of the designation system in paragraph 5.7. Based on the findings in these both paragraphs, the second part of the results chapter will finally end with the formulation of managerial recommendations in paragraph 5.8.

## 5.6 THE 'DESIGNATION COMMUNITY'

Field research showed a variety of reactions on the intention to designate European cancer institutes. The effect that these have on the advancements in the designation project is thereby expected to be different. By identifying who is really involved, and who they are positioned to the designation system and to each other, it might be possible to say something from a social-political point of view on expected reactions and the subsequent influence of these. The elaboration of this 'Designation community' has been done by analyzing data from the field research according to the theoretical concept of stakeholders (see chapter 3); what are the claims or stakes of certain entities, and what is their position and salience based on the degree of legitimacy, urgency and their (actual or potential) ability to influence the system. It has to be said that some are defined individually, but some also as a selection of individuals or organizations with the same sort of features. The list of stakeholders would otherwise be too extensive and unclear.

### 5.6.1 INDIVIDUAL CANCER INSTITUTES

The first important type of stakeholder in the designation community is the individual cancer institute situated all over Europe. The focus particularly lies on OECI members, as they are the first institutes that can apply for designation.

#### **Stake**

It seems obvious to consider cancer institutes as stakeholders: the designation system affects their reputation and might have consequences on their financial, social and political position on a national and European level. For that reason their claim in the designation project primarily seems to be the concern that the system meets the institutions interests. It might for instance lead to

unexpected, negative outcomes but, on the other hand, allows them to reflect on their current position in terms of their level of comprehensiveness and also their quality of performance.

#### **Position and salience**

Because the individual European cancer institutes are the ones to be designated, the designation system heavily depends on the access to their data. They have, in that respect, a huge potential to influence to system's success: it stands or falls with their participation. The experiences with the OEI accreditation project confirm this as well. The very cooperative and resistant performance by several institutes during the accreditation pilot for instance had a huge impact on the further advancements in the accreditation process.

Contrary to what is regulated by most health systems nationally, cancer institutes lack a concrete legal status in Europe. Formal legitimacy at this supranational level is therefore currently insufficient for cancer institutes to rely on. In fact, the legitimate status is mainly determined informally by their level of performance or specialism. A designated status derived from the European designation system might therefore increase their legitimate standing in both ways. As the development and implementation of the designation system become more concrete, it will become more urgent for cancer institutes as well. Future consequences of the system will increase the level of importance whereas the actuality will rise in case it directly starts to concern their own status.

This expected grow of urgency will increase the value of power and legitimacy for cancer institutes to preserve their stake. The effort to legitimize and force their preferences into the designation project will therefore take place more deliberately. For instance, in the use of their own data – by being cooperative or resistant-, but also by relying on resources -such as a professional, national and financial status- in which they are dependant of others. Therefore they are considered as strategic stakeholder with an important salient position.

#### **5.6.2 OEI**

As the initiator of the designation project it seems logic to appoint the OEI as a second important stakeholder as well.

#### **Stake**

The OEI's overall claim is to improve the quality and competitiveness of cancer care and research all over Europe, for instance by means of designating cancer institutes. The thing at stake in this respect appears for them to be the successful development and implementation of the designation system. To achieve that it is not only required to consider the system-technical challenges but also those in gaining acceptance and commitment of other stakeholders.

#### **Position and salience**

Currently the OEI has a relatively little amount of power to enforce European cancer institutes towards more harmonization of activities in one way or the other. The power that they have is largely based on symbolical and normative influences since many European cancer institutes are a member of this organization. The introduction of a designation system probably changes this situation significantly when the authority to designate becomes more formalized. On the other hand regarding their legal status of 'European Economic Interest Grouping' (EEIG) the OEI enjoys substantial formal legitimacy at the European level. The legitimate position of the OEI will in fact increase when they are legally appointed by the EU as the organization that safeguards and

controls the system. Most parties see this as a logical step in the near future. The OEI finally has a high level of urgency that can be explained in two ways. First of all it argues the importance of quality improvement in European cancer care and research that is quickly required to cope with the growing cancer burden. Secondly, in line with the OEI accreditation project, a designation methodology seems to be an indispensable development. The introduction of a designation system for European cancer institutes seems therefore to be an important and actual theme for the OEI.

Field research has shown that power and legitimacy are, and will be important attributes for the OEI in order to get acceptance and commitment amongst other parties involved. As the designation project can be considered as a follow up of the current process of accreditation, it has an urgent status for the OEI. This makes them to perform strategically. Approaching other stakeholders, that possess scarce resources and might reinforce their position are exemplary for such behavior. As second strategic stakeholder, the OEI has an important salient position as well.

### **5.6.3 GOVERNMENTAL AGENCIES**

Another type of stakeholder are the 'governmental agencies', on a supranational level like the European commission, and those on a national and regional level.

#### **Stake**

Their general claim is to guarantee good quality of cancer care and research, preserved by policies on respectively a national and European level. With respect to the development and implementation of a European designation system their most important concern is its societal, financial and legislative contribution. For example, the European Commission has huge interest in a well-functioning designation system that stimulates collaboration initiatives and allows efficient funding possibilities. However, in the end these designation activities must have an indirect contribution to the quality of life and survival of cancer patients in Europe. For national governments this is also the most important concern as long it doesn't conflict or damage their national policy; in fact it must contribute to the national situation.

#### **Position and salience**

National and European governmental agencies possess scarce resources to influence other relevant stakeholders. First of all their legislation for instance offers the OEI the possibility to strengthen its legitimate position via the attribution or delegation of authority to designate cancer institutes. Secondly, their provision of funds increases the budgets and therefore the capabilities of others, for example the OEI to realize its goals (of creating a financially strong supported designation system). In this respect stakeholders, especially the OEI, largely depend on these governmental agencies. As far as the legitimate standings of governmental and legal bodies in the designation project is concerned, one can be very short about that. They have a preserved legitimate status based on European and national legislation. This will still be the case when the EU would hand over formal authority for safeguarding and controlling the designation system. Field research furthermore show that governmental agencies acknowledge the importance of new policies for quality-improvement of cancer care and research in Europe. The position of national and regional governing agencies on the introduction of this European system depends however to a large extent on their own local circumstances; for instance in the presence or lack of such a system on a national level. At the moment the actuality of the designation project seems to be moderate: up to now it is

perceived as an interesting, but still very unknown field of activity which has to be further 'rooted' and considered.

Their strong legislative and financial capacity and legitimate standing make organizations like the EU and national governments important stakeholders. However, in contrast with the previous ones this is not because of their strategic behavior -regarding the little sense of urgency to defend their stake- but due to their facilitating role. Financial and legislative resources are difficult to obtain but for a strategic stakeholder like the OEI essential to have. This explains their salient position in the stakeholder-field.

#### **5.6.4 PROFESSIONAL ORGANIZATIONS**

The fourth type of stakeholder is formed by the 'European professional organizations'. This group consists of non-profit organizations, with or without governmental supervision, and with an organization-form that varies from formalized institutions and collaborative networks to temporary projects in cancer care and/ or research. Amongst others the most important examples related to the development and implementation of the designation system are the EORTC, ESSO, ESMO, 'International Association of Cancer Registries' (IACR), the Eurocan+plus project and the Stockholm-group.

##### **Stake**

Field research shows the representation of their professional domains and specific competences in the development and implementation of the designation system as the main concern for professional European organizations. Since the system will assess and label the appearances of European cancer institutes all over Europe, it will automatically involve the assessing and labelling of those specific domains. For the professional organizations in that particular domain it is important that it takes place according to what that they think is appropriate.

##### **Position and salience**

The power of professional organizations is quite big since they occupy a scarce resource with their specific knowledge in particular areas of cancer care and research. This power will become even bigger when their input in the development of appropriate criteria, such defining norms and standards, is significantly going to contribute to the legitimacy and reliability of the system.

European professional organizations put great effort in the coordination, stimulation and improvement of the quality of cancer care or research in specific domains by education, registration and audits. Their expert knowledge in these activities gives them, next to their specific professional knowledge, huge informal legitimate standing. With respect to the level of urgency, field research illustrated that activities for quality-improvement are a very important and current (actual) theme for European professional organizations in their own specific domain. However, this is less present in the purpose to designate the total sum of cancer care and research activities that European cancer institutes cover. The main argument is because it is not their primary concern or mission. This actuality probably increases when the system uses information that might be relevant for quality-improvement in own particular and professional domains.

European professional organizations are important stakeholders because of their power and (informal) legitimate standing. This is mainly derived from their specific professional knowledge and

expertise in quality improvement activities. Just like the governmental agencies, the lacking sense of urgency makes that most professional organizations aren't using these attributes strategically. Nevertheless, their specific knowledge is pretty unique as well, which is crucial for the development of a proper designation system. Considering this facilitating role they require sufficient managerial attention.

#### **5.6.5 PATIENTS AND RELATED ORGANIZATIONS**

Patients must be recognized as stakeholders as well since they are the consumers of cancer care and research activities. Their position is mainly represented by European patient organizations such as 'Europa Uomo' (patient-organization for prostate cancer) and 'Europa Donna' (patient-organization for breast cancer).

##### **Stake**

The claim of patients and patient organizations is to assure their interests in the best possible way. The growing mobility and empowerment of patients in the European Community have made those interests become more significant. The demand for having an overview of quality outcomes in research and treatment and where to get the best, adequate treatment are fine examples of this. Therefore their major concern in the development and implementation of the designation system is the integration of patient-interests. A risk might for instance be that the assessment and designation of the individual cancer institutes don't meet with the view of patients on essential standards and requirements.

##### **Position and salience**

Patient organizations seem to have little power in the representation and protection of these interests, except for a certain moral appeal. Nevertheless, with the increasing focus on patient-centeredness the patient's perspective is becoming more and more a valuable resource in the organization of cancer care and research. Consequently, it gives patient organizations the ability to influence policy-making processes such as in the development and implementation of a designation system. In order to assess and label the quality, the designation system nowadays is dependant on experiences and preferences from the patient as well. Nevertheless, their ability to influence the designation system is relatively modest as patient-centeredness so far turns out to be a limited concern in discussions on the system's development.

Patient organizations obtain legitimacy on moral and ethical grounds, but mostly formally through the patient's rights. According to national and European legislation every individual has the right to get good quality of care (e.g. Article 35 of the Charter of Fundamental Rights of the European Union, 2000). On top of that field research illustrated that patient organizations are constantly busy with the actuality by verifying what patients find important. However, since patients don't encounter the effects of a European designation system directly at the moment, the actuality seems to be on other issues on the agenda. The urgency of patient organizations to interfere in the development and implementation of a designation system is therefore quite modest currently.

Patients and related European organizations are relevant stakeholder due to a legitimate status, but more important, because they can provide input to the system from a patient-perspective point of view. They are therefore considered to be facilitating and not strategic stakeholders, as at the moment a real sense of urgency to defend their stake in the designation project is lacking. Although

field research has shown a relative modest concern for 'patient-centered input' at the moment, it will become increasingly important in the near future. Patients and related organizations therefore need modest managerial attention, but are nevertheless expected to be vital for the designation of cancer institutes in the near future.

#### **5.6.6 PROFIT ORGANIZATIONS**

The sixth type of stakeholder is considered to be the group of profit organizations. Main examples are pharmaceutical companies, insurance companies, and other organizations that deliver cancer care and research technological equipment.

##### **Stake**

Profit organizations are concerned with purchasing better possibilities in resource allocation, cost-containment and efficiency. In that respect a designation system forms the opportunity to reach these goals as it will create an overview of the capabilities and performances of European cancer institutes. Profit organizations become actual stakeholders from the moment they decide to support the designation project financially. Their stake is then based on the extent they think they benefit from the system in view of their financial input.

##### **Position and salience**

Field research makes clear that funding is a scarce resource in the development and implementation of a designation system. Therefore the financial capacity of profit organizations offers these organizations the possibility to participate in the decision-making. Only if they decide to invest money in the designation project, profit organizations have a significant social reference that gives them some sort of legitimacy.

Although field research didn't make it very clear, the possibility to assess potential investments more cost-efficiently and effectively assumingly urges profit organizations to acknowledge the importance of a designation system. The actuality of the designation system is as yet considered to be limited among profit organizations: while it has to be said that the designation project is in its first stage, field research has shown no significant rush to invest in the designation system so far.

Profit organizations, thus, seem to lack a sense of urgency and a concrete legitimate standing. Only their financial capacity offers them a potential ability to influence the designation project, since money is essential to set up a successful designation system. Profit organizations are therefore considered to be relevant, facilitating stakeholders that require salience, but only as long as financial input for the designation project is necessary.

#### **5.6.7 SOCIETAL ORGANIZATIONS**

The last type of stakeholder consists of the (non-governmental) societal organizations. The most striking example of such an organization is the 'International Union against Cancer' (UICC).

##### **Stake**

Societal organizations are stakeholders because they are concerned with the preservation and improvement of public health in Europe, in this case specifically in cancer. Since they are globally active in many fields related to cancer it is hard to define their exact stake in the development and implementation of a European designation system. Most probably it can be defined pretty similar to

the stake of patient organizations; that the designation system must contribute for the cancer population all over Europe without significant and unfair variations.

#### **Position and salience**

Normally societal organizations won't have the authority to enforce decisions in the development and implementation of the designation system on legal grounds. Still, they might affect the process through normative and ethical arguments, financial support or through sharing knowledge. The UICC for instance appears to have a well respected consultative status. Moreover, their independent perspective and societal affiliation to improve cancer global provides them a certain, but very small informal legitimate standing. Although field research hasn't shown significant indications, the level of urgency for societal organizations to interfere in the designation project is thought to be very limited. An argument for this is the relative modest experience with designation initiatives. A second argument is the limited attention for designation on a global, societal level. Designation of cancer institutes doesn't directly seem to affect health issues that play an important role in the daily lives of people. The actuality of societal organizations therefore concentrates on other activities that have or are expected to have more direct and visible effects for the European health.

Apart from having a globally defined stake in the designation project, societal organizations don't seem to feel the urge to invest in the project. Neither do they have a significant scarce resource that might provide them with some sort of influence. Societal organizations are therefore considered to be latent stakeholders that practically require no managerial salience.

#### **5.6.8 THE STAKEHOLDER CONFIGURATION**

The description of stakeholders in the 'designation community' along with their position and managerial salience is visualized in figure 6. This leads to the following conclusions.

##### **Strategic and facilitating stakeholders**

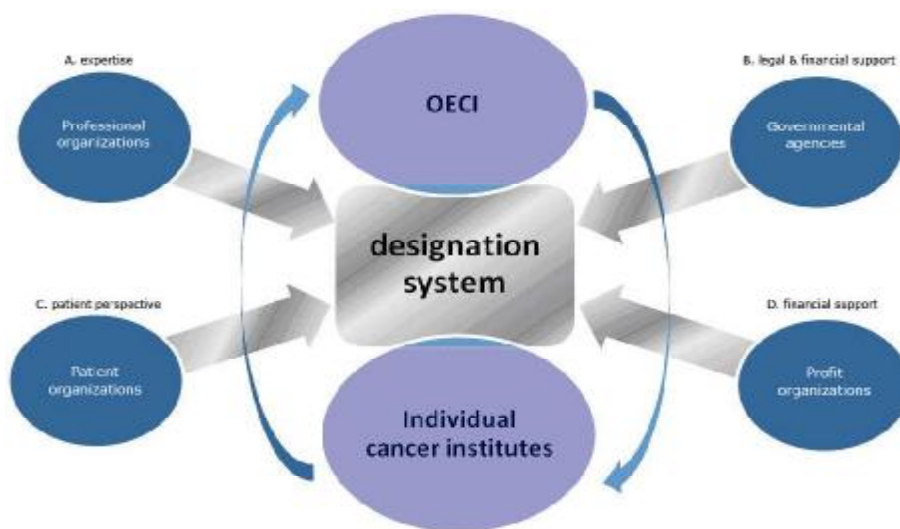
Individual cancer institutes and the OEI are playing a central role in the designation project as they seem to have the most urgent claims and, with their powerful or legitimate status, the direct ability to affect the system's development and implementation. They are thereby considered strategic stakeholders: with the focus first and foremost on maximizing own interest and preserving own stakes, partly on their own but also by forming allegiances with other stakeholders in the community they try to strengthen and use their attributes deliberately (indicated in the figure with the arrows). The OEI is mostly concerned with a designation system that corresponds with the interest of European cancer care and research on a supranational level. The individual cancer institutes are primarily more focused on how this system corresponds with their interest in own local contexts.

Governmental-, professional-, patient-, and profit organizations are important stakeholders as well, but more from a facilitating point. With limited or no sense of urgency to preserve their stake, they still have scarce resources to deliver input which is vital for the OEI and individual cancer institutes to reinforce their positions (see A, B, C, D). So, with regard to the development and implementation of the designation system the facilitating position of these stakeholders could oppose the OEI and the cancer institutes further from each other, but bring them closer as well (one could think of financial or professional input that leads to presumptions of a bias view or at the other hand increases of the system's legitimacy).



Looking at Mitchell's way of configuring stakeholders, those mentioned here as strategic or facilitating stakeholders are all considered to be expectant stakeholders as none of them fully possess all three attributes. Nevertheless, in view of their central position and relative high degree in two of the attributes, they can be seen as definitive stakeholders in the 'designation community'. Societal organizations, like the UICC, are the last stakeholders in the designation community. Despite having a significant stake they are considered to be latent stakeholders, since they don't have a serious urgency to preserve this stake. Moreover, they don't have a significant scare resource that might increase their salience as well. Based on their latent position they are considered to be irrelevant stakeholders in the designation community and therefore not illustrated in the figure.

Figure 6. Stakeholder configuration in designation of European cancer institutes



### Community rather basis for conflict than harmony

Designating European cancer institutes requires a harmonious setting on supranational level of those stakeholders who are able to influence the development and implementation of the system. Given the current fragmented configuration this seems to have some limitations. Although stakeholders are aware of the dependency on another to serve the common overarching goal of designation, that is to get European cancer care and research to another level, the will and ability of preserving own stakes is currently prevailing in the first place. The role of stakeholders on a supranational level furthermore varies due their local (e.g. national and regional) situation. The way for cancer institutes to preserve their stake in a European designation system is for example diverse, due to different social-political factors on a local level. Furthermore many stakeholders represent different not only the cancer institute, but also the stakes of other professional, non-governmental organizations since they are an active member of it. Consequently there are many parties with different perceptions (also within a particular stakeholder group) towards the designation project, which are difficult to clarify and bring together. When it comes to the concrete development and implementation of the system at a supranational level, these factors make it very complex.

Corresponding to what Noordegraaf (2004) stated this complexity leads to an uncertain, reserved pose among stakeholders on how to deal properly with this designation initiative. Most important consequence is that it leaves little space over for reaching a ‘negotiated information order’ since the first concern is to avoid jeopardizing own stakes. The designation community tends therefore to be rather a ‘parties-community’, fit for conflicts and competition (see paragraph 5.7), than a ‘system-community’ where stakeholders work on the development and implementation of a designation system as a socially coherent entity sharing a common motive. The following paragraph will elaborate the consequences of these conclusions further.

## 5.7 DYNAMICS AND SOCIAL-POLITICAL EFFECTS

Consensus amongst the mentioned stakeholders and commitment to the designation of European cancer institutes are essential for achieving the system’s actual purposes. The many positive reactions on the conceptual design of the system are very promising and valuable in that respect. Field research however illustrates two major social-political dynamics that might threaten the required consensus and commitment.

### 5.7.1 CONFLICTS ON THE SYSTEM’S DESIGN

One of these dynamics is expressed in the discussion on the design of the designation system. At this moment there is no consensus on the information and resources that are used for defining categories, criteria, review methods. Hence, there is a tension between the system’s design and two different logics which often leads to conflicts.

#### Ratio versus system’s design

First of all, professional and institutional interests appear to be in constant tension with the design of the system. Stakeholders seem to appreciate proposed suggestions positively or negatively depending on how the expected outcome of designation rationally will affect their interest, for instance in terms of social and financial status.

For example numerous cancer institutes appreciate the categories, criteria and review methods proposed by the OEI from a very calculative point of view, in terms of: ‘Does it reflect our institution’s capabilities and will it serve our interests?’. Many are, in that respect, afraid for a system that distinguishes a smaller group from the rest and will thereby harm the interests of most institutions:

*“With this designation system we may go to a situation of making some cancer institutes more important than others. (...) It will increase the feeling of ‘you are the best...and you are less...’ (...) We have to be careful for this kind of negative discrimination”.*

In line with this, the designation of cancer institutes might have consequences for the national and international ‘status quo’. To be more specific, it may affect the general perceptions of which one(s) is (or are) considered to be the leading national institute(s). Those that aren’t designated as comprehensive or that on other grounds are ‘submitted’ to other national and regional institutes consequently seem to fear negative consequences. For instance in terms of recognition, such as one of the respondents exemplifies:

*'This concept [of the designation system] has the tendency to suggest that a comprehensive cancer center is the only institution that leads to something. Of course that isn't the case (...) this should be formulated differently.'*

Although it hasn't been mentioned explicitly, possible negative consequences in patient distribution and funding seem to be feared as well. These rational feared consequences make designation issues of -who is a 'Cancer Unit', Cancer Center, a 'CCC', who is not, and on which grounds this is decided- very delicate. This specific tension is illustrated well in the following quotes:

*"I think that we have to be very careful in saying who is what?"*

*"I understand why some institutes are very fond in preferring the infrastructural requirements...that's because they don't have to show their actual quality of performance in that way".*

*"I can imagine how these criteria are being developed. (...) If we look at the closed criteria for a CCC we see that paediatric oncology is an optional requirement; that is because the larger centers don't have that. (...) The larger centers are doing that in their favour". (...) This is a situation of discrimination beforehand, were the ones that are defining the criteria are the same who have to apply to those criteria, and that is wrong".*

### **Appropriateness versus system's design**

The system's design does not only create tension with the rational thought of stakeholders, but also with their 'logic of appropriateness'. Various, opposing perceptions exist in the designation community of what are considered to be 'appropriate' categories, criteria or review methods. In that respect field research demonstrates many concerns and conflicts on the system's design.

This initially came to light in the disputes on the chosen standards for including and excluding cancer institutes. To regard 'community outreach activities' or 'a sufficient physical identifiable entity' as inherent requirements for being a CCC were for instance differently perceived and discussed. According to representatives of a few cancer institutes, some criteria and categories also wouldn't reflect their own position and identity, or those of others correct. The following citations are examples of this:

*"It is difficult for me to say that you are a 'Comprehensive Cancer Center' if you only deal with breast cancer for example. I don't think that it is right to speak of a 'Cancer Center', although others think differently on that (...)".*

*"A 'Comprehensive Breast Unit' or a 'Breast Cancer Center'? Well, you may say it like that, but then I don't think that you are really covering the comprehensiveness that we are dealing with".*

*"In the formulation of categories and criteria so far there is insufficient attention for proper designation of institutes with more focus only on fundamental research. These institutes just important as the other organization forms focusing on cancer".*

The logic of appropriateness versus the system's design has also been recognized in the different expectations of this designation initiative, especially considering the thoughts on the purpose of the system: whereas some primarily argued for the creation of a core network of comprehensive cancer centers and centers of excellence, others thought of creating a quality-improvement tool for all different types of cancer institutes. These different expectations fed the impression that large cancer institutes generally were more concerned with setting standards high enough, most probably enforced by the view to create a platform for centers of excellence. In contrary, the 'smaller' cancer institutes seemed to be more concerned with the feasibility of criteria. This by arguing that the criteria wouldn't make sense to them if only a few of these standards will be achievable in practice.

This impression became stronger by the critical comments of some cancer institutes, saying that the designation system must be wary of striving for perfection too much:

*"In case of designating European cancer institutes I believe we can say that the perfect will be the enemy of the good".*

Last major example of the discussion on the appropriateness of the system's design involves a more administrative concern. At the moment many regard the proposed designation categories, criteria and review methods as a good first direction. However, it is considered not to be fully appropriate yet for managing the numerous contextual differences:

*"[...] the effectiveness of designation on a European level might not be the best if criteria are used that conflict with similar initiatives in various countries".*

*"Cancer problems have to be placed much more in the local reality. [...] Designation by the mentioned criteria so far will only make sense and work if you integrate national and regional systems in a better way".*

This concern has led to various thoughts on how the development and implementation of a supranational designation system should comply with similar activities on the national or even regional level: whereas some plead for designation of cancer institutes as a full responsibility for the national governments, others argue that a European body should be primarily accountable for this.

While the previous discussions were so far fed by different frames of sense-making concerning identities, expectations and administrative concerns, the appropriateness of the system seems to be discussed on historical grounds as well. Different experiences with similar activities like designation have led to positive but also negative, or at least reserved, attitudes towards this designation system. The following comment by a respondent exemplifies the effect of such experiences perfectly, by illustrating a certain optimism and a sincere concern at the same time:

*"Although the accreditation activities are very interesting so far, it takes a lot of time and effort while the supportive preconditions to realize concrete results are often lacking (...) My enthusiasm for this project mostly depends on this".*

### **Maximizing and defensive behavior**

Both tensions -ratio and logic of appropriateness versus the proposed system's design- are frustrating the discussion on which information and resources cancer institutes should be designated. Up till now this process generally involves those cancer institutes which have taken part in the discussions on the designation project so far, and the OECI as it introduced this initiative and proposed a first concept of the system.

In the discussions so far they mostly intend to maximize their own interests or preferences. Yet, a designation system is simply unable to totally fulfill all these interests and preferences. The system's design has therefore become a platform where maximizing behaviors seem to reinforce each other: the more the OECI is striving proactively for a fast introduction a perfect designation system, cancer institutes become even more opposing and preserved. Consequently, a lot of cancer institutes primarily seem to act defensively against the proposed designation categories and criteria. Examples of this defensive behavior were: an excessive attention on the system's incompetency by

the focus on little detailed errors, questioning the objectivity of the system’s design by assuming conflicts of interests in its development, and referrals to the system’s design which shouldn’t be evidence-based enough. The following quotes are example of such defensive behavior:

*“The developers of these criteria and categories are also the ones to be designated”.*

*“ (...) who says that the cancer institutes, which actually think that they are comprehensive cancer centers, are indeed comprehensive based on a set of developed criteria (...) In fact, we don’t know this due to the many demographical differences (...) Let’s first of all start with proven the fact that comprehensive is the best”.*

This defensive behavior makes it difficult to negotiate effectively towards a common agreed designation system.

### 5.7.2 CONTESTED SIGNIFICANCE OF SYSTEM

Another theme that explains the current dynamic processes in the development of a designation system can be found in the discussion on the significance of the designation system. An important issue right now is why stakeholders should commit, or have to put effort into this particular system. In other words, the designation system needs an added value for stakeholders in order to have a right of existence and a reason for obliging to the system. Respondents of cancer institutes illustrate this well:

*“If this [designation initiative] is a way to fund a network of comprehensive cancer centers on the basis of providing a capacity to improve quality, meaning a way to fund infrastructures, then it’s perfect. However, if it is only a nice picture of designated cancer centers (...) if the project of designation is a goal itself, it will fail as it has no real meaning”.*

*“Designation will only work if it brings resources to cancer institutes to develop capacity and improve quality”.*

In practice the discussion on the system’s added value seems to have major consequences on the acceptance and commitment to the system. Those who recognize a significant contribution in the system show a certain degree of compassion and willingness to invest in the system, for instance by stressing the importance of designation and by forming coalitions in order to reinforce commitment of others as well. A respondent of a cancer institute confirms this by saying:

*“True, there are some major pitfalls, but I am convinced of the system’s effectiveness (...) Only, the point is that we have to prove it!”*

In contrary, others with doubts or a negative perception of the significance of the system are acting more reservedly or are having preconceived opinions on the designation initiative. For instance:

*“The problem with designation is that it includes an additional administrative burden without real, significant resources to improve quality”.*

This so called ‘contested significance’ of the system can be explained by the tension that stakeholders feel autonomous or dependant towards this designation initiative. Field research shows that at the moment cancer institutes are primarily driven by the fact that they don’t want to be dependant on something that hasn’t fully convinced them and gained their trust:

*“(...) the foreseen duties for us that are attached to the designation process, don’t seem to outweigh the positive consequences of this moment”.*

*“Well, it may have an added value, but we need to know what we are dealing with (...) what are they doing with our data?”*

The fear for being dependant is thus related to a high degree of uncertainty about the system’s significance. Although field research made clear as well that the majority are in favor of such a system, this same majority are still very reserved at the same time due to lack of experiences and the many foreseen practical hazards on the road ahead:

*“I stand behind the concept because we must have European guidelines, but at the same time I have become very realistic over time and ask myself a lot of questions to manage this (...) in a Europe with differences in regulation, jurisdiction et cetera”.*

A second reason for fearing dependency to this designation initiative is that the system’s added value is still very abstract. The real added value still depends on how the system will be developed and implemented in the future:

*“The question still is what the precise consequences will be for my institution in terms of a real chance for increasing resources and quality of care versus the increase of duties and paperwork”.*

Last but not least, the term ‘designation’ often seems to cover the real purpose and added value of the system for stakeholders. On several occasions the designation initiative has been perceived at first notice as a way to separate the ‘good ones from the bad’.

According to these types of reactions of stakeholders, it becomes clear that first of all the system has to realize its intentions and expectations at a more concrete level in order to be convincing enough. Until that moment, most stakeholders still seem to put the emphasis on preserving a certain autonomy towards designation.

#### **Limited feeling of commitment**

The discussion on the significance of the designation system causes a serious struggle and requires great managerial effort in getting stakeholders committed to the designation system. The added value, which at this moment is very uncertain, abstract or even misperceived, has made stakeholders feel less dependant and made them appreciate their autonomous position towards this designation initiative much more. Acceptance and commitment towards the system have thereby become reserved, limited, less urgent and therefore unstable at the moment. Especially the reserved behavior of cancer institutes is a critical consideration as they are essential stakeholders in the designation project.

The development and implementation of the designation system will be threatened if the participation of cancer institutes, due to this kind of strategic behavior, turns out to be marginal. Acceptance and commitment of cancer institutions all over Europe is especially vital in order to achieve an effective designation system.

## 5.8 SOCIAL-POLITICAL RECOMMENDATIONS

The development and implementation of the designation system stands or falls with a sufficient level of consensus and commitment among stakeholders, especially of the individual cancer institutes. Important hereby is to acknowledge that 80% of the cancer institutes with an average status are forming the critical mass. However, the most important findings in the previous chapter previous two paragraphs show: a fragmented designation community that seems to invoke conflicts in the development and implementation of a designation system rather than harmony, and two major social-political dynamics which threaten the consensus and commitment among stakeholders. Therefore, the following recommendations should be taken into consideration.

### 5.8.1 TOWARDS A 'SATISFYING' NEGOTIATED INFORMATION ORDER

Although the results make it seem to be an impossible task, it is definitely possible to develop a system where defined categories, criteria and review methods are accepted by all important stakeholders. For achieving this 'negotiated information order' it is, given the findings essential to invest in the development of a more harmonized climate in which stakeholders can agree with each other on sufficient satisfying grounds. A 'negotiated information order' that fully covers the interests of all parties is impossible. Nevertheless certain investments will make it possible to force a breakthrough in the current ineffective discussions/ negotiations that seem to be dominated by maximizing and defending behavior.

An important focus is to reduce complexity in the organization of the designation policy and the subsequent uncertainty for stakeholders in terms of what consequences the developments in the designation project *might* have for their stakes. A better understanding of each others position and motive as well as a better synchronization of the European designation project with national and regional contexts will provide more clarity and possibilities to bring different perceptions together.

An other important point of attention is to use of all available information resources. Research has shown if less information is available or known and if certainties are bounded, it will lead to more rational and psychological tensions on the system's design with maximizing, defending behavior in the end. The use of professional, legislative, financial and other resources conversely contributes to assess the system -at its reliability, legitimacy and objectivity- in the best possible way. In addition, the individual cancer institutes, which affect the system most directly, must be involved and given the chance to participate in the development and implementation of the system. By sharing responsibilities and considering each others resources and proposals seriously, a constructive development of the system will be stimulated and possible conflicts can be brought to a minimum.

This leads to the following concrete recommendations:

Make use of relevant aspects and experiences of other projects and systems in cancer care and research similar or linked to that of designation (e.g. OECl accreditation, EUSOMA certification). It could provide specific examples and learning points for the European designation system along the way.

Make use of the resources of professional organizations, such as 'the Stockholm Group' and the NCI, and legislative organizations, such as the European Commission and national governments. The designation methodology could be enriched with their scientific, clinical and legislative knowledge as well as their financial capacity.

Synchronize the European system to the regulations and network activities concerning accreditation and certification on a national and regional level as much as possible. Potential conflicts in the working- and designation methodologies may be avoided that way.

Lobby at governmental and profit organizations for gaining resources that reinforce authority.

Arrange invited conferences for the different types of cancer institutes in Europe. A periodic evaluation of the advancements in designation allows them to give recommendations, or at least creates space for them to share their perceptions, interests and knowledge.

### 5.8.2 CLARIFICATION AND PROMOTION OF SYSTEMS’ ADDED VALUE

Commitment to the system is very important at this stage, in terms of a certain devotion to invest time and effort in the development of the system or by participating in pilots. However, if a real added value of the designation system is lacking or if it isn’t convincing enough, it will put pressure on the dependency of stakeholders and subsequently on their commitment to the system.

Results have shown a certain reserved, unstable form of acceptance and even a resistant behavior amongst many stakeholders towards the initiative of designating European cancer institutes. An explanation for this can be found in the lack of confidence in the significance of the system. The system’s added value must therefore be further clarified and promoted. To be more specific, it has to separate itself in a positive way from other alternatives for stakeholders to improve their stakes concerning designation. With a special focus on the cancer institutes this means the possibility for them to improve performance, infrastructural capacity and transparency (and thereby gain financial incentives, network opportunities, and other sorts of benefits). Designation is therefore not so much the objective itself, but must be seen far beyond that; as a mean to reach these goals. A respondent illustrated this well by saying:

*“ (...) the label should not be the thing per sé to get. It is more important to know how to measure the current quality status correctly and how it provides possibilities for a particular cancer institute to improve”.*

It is therefore important to make cancer institutes aware of the fact that designation stands for entering a process that in the end involves getting a certain label, but initially focuses on quality improvement. The term ‘designation’ maybe doesn’t seem to cover the real purpose and added value of the system in that respect. It has not the aim to pinpoint who does well and who not, but rather in providing the abilities for cancer institutes to improve and thereby making advancements in cancer care and research in the larger supranational picture. This by: establishing comprehensiveness, benchmark possibilities, bridging the gap between cancer research and treatment and by stimulating various collaborations (in research funding, between researchers and clinicians, and between institutes). The more people recognize this as the added value of the system and accept it as the best alternative, the more legitimate it will be and less space will be available for resistance. This leads to the following concrete recommendations:

Promote the designation system to cancer institutes as a professional resource for reflection and improvement of their current status, rather than ‘naming and blaming’ their weak spots or shortcomings.

Integrate incentives in the system (e.g. self-reflection, grants, recommendations).

Start with pilots on a short-term basis. The effects and added value for cancer institutes will then be visualized in the best way.



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**Overview results and recommendations**


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To provide a global overview of the major findings and recommendations in the system-technical part and social-political part, they are put together in the figure 7.

**Figure 7. Overview main results**

System-technical findings	System-technical recommendations
<b><u>General hazards</u></b> <ul style="list-style-type: none"> <li>- Daily complexity of cancer care and research</li> <li>- Contextual differences at international level</li> </ul>	<b><u>General recommended strategy</u></b> <ul style="list-style-type: none"> <li>- Comprehensiveness as frame of reference</li> <li>- Important role for on-site review procedure</li> <li>- Mix of 'top-down' &amp; 'bottom up' approach</li> <li>- Accent on stimulation</li> </ul>
<b><u>Specific challenges</u></b> <ol style="list-style-type: none"> <li>1. Defining appropriate categories <ul style="list-style-type: none"> <li>- Diffuse and contested definitions</li> <li>- Ambiguous categorical boundaries</li> </ul> </li> <li>2. Formulating corresponding criteria <ul style="list-style-type: none"> <li>- Comparative measurement</li> <li>- Complex requirements</li> <li>- Feasibility</li> </ul> </li> <li>3. Creating a reliable &amp; legitimate review system <ul style="list-style-type: none"> <li>- 'Conflict of interest'</li> <li>- Ambiguity and diffusion in review procedure</li> <li>- Authority in review process &amp; designation decisions</li> </ul> </li> </ol>	<b><u>Specific features</u></b> <ol style="list-style-type: none"> <li>1. Strict and flexible categories <ul style="list-style-type: none"> <li>- 'Prototype' approach</li> </ul> </li> <li>2. Suitable set of criteria <ul style="list-style-type: none"> <li>- Simplified &amp; clear defined ('closed', 'output' &amp; 'open')</li> <li>- Reasonable</li> <li>- Stimulating</li> </ul> </li> <li>3. Robust review system <ul style="list-style-type: none"> <li>- Stability and flexibility of review groups</li> <li>- Standards of conduct</li> <li>- Formal &amp; informal acceptance of review members</li> </ul> </li> </ol>
Social-political findings	Social-political recommendations
<b><u>Stakeholder configuration</u></b> <ul style="list-style-type: none"> <li>- Strategic (European cancer institutes, OECD) Facilitating (Governmental, Professional, Patient &amp; Profit organizations) Latent (Societal organizations)</li> <li>- 'Parties-community' (fragmented community that invokes complexity and conflicts in organizing policy at a supranational level)</li> </ul>	<ol style="list-style-type: none"> <li>1. Towards satisfying negotiated information order <ul style="list-style-type: none"> <li>- Use classification experiences in cancer care and research</li> <li>- Use of knowledge of professional, legislative organizations</li> <li>- Synchronize system to national and regional initiatives</li> <li>- Involve all types of European cancer institutes</li> </ul> </li> <li>2. Clarification and promotion of system's added value <ul style="list-style-type: none"> <li>- Promote system as a professional resource for reflection and improvement</li> <li>- Integrate incentives in the system (e.g. self-reflection, grants, recommendations)</li> <li>- Start with pilots on a short-term basis</li> </ul> </li> </ol>
<b><u>Dynamics</u></b> <ol style="list-style-type: none"> <li>1. Conflicts on the system's design (rational &amp; social-psychological logics vs. proposed design)</li> <li>2. Contested significance of system (autonomy vs. dependency)</li> </ol>	
<b><u>Consequences</u></b> <ol style="list-style-type: none"> <li>1. Maximizing &amp; defensive behavior (ineffective discussions/ negotiations &amp; process of muddling through)</li> <li>2. Limited feeling of commitment (resistance, preserved pose)</li> </ol>	

## **6 CONCLUSION**

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The findings in the theoretical and field research make clear that the designation of European cancer institutes involves more than an abstract classification itself: the translation from theory into practice bears several system-technical and social-political hazards and challenges. From a system-technical point of view it mainly concerns the practical applicability of the system, while social-politically the difficulty is to get sufficient acceptance and commitment among stakeholders to the system, with in particular the cancer institutes as most important ones. These are mainly caused by the complex supranational context in which the designation system has to be developed and implemented.

As literature and other examples of classification already indicate, field research indicates that it is almost impossible to designate cancer institutes in a European on an overarching set of absolute categories, criteria and review methods. Designations have to respond to the daily complexity of cancer care and research, that at a European level is influenced by different, local environments. Measurement and designation therefore becomes less tangible, comparative standards will be more difficult to reach and the system's objectivity, legitimacy and reliability will be much more to question. A system in which all European cancer institutes can be designated is for that reason difficult to develop and implement.

The analysis of the social-political context resulted in important findings for the development and implementation of a designation system as well. The designation system is introduced in a complex and highly professional setting where the role of stakeholders due to local and professional background varies and is interrelated. However, a main distinction can be made in: strategic, facilitating and latent stakeholders. The individual cancer institutes and the OECl require most managerial salience since they seem to be involved and able to affect the development and implementation of the designation system most directly. By acting very deliberate, they try to preserve their stakes most significantly, in the best possible way. A sufficient degree of managerial salience is also required for governmental, professional, patient and profit organizations as they all occupy a scarce resource for the OECl and the individual cancer institutes. Considering that the 'designation community' exists of individual parties which primarily are striving for their own, differing stakes, it wasn't a big surprise to notice conflicts in the negotiation on the system's design. Concrete explanations for this are the different ways in how the system is perceived from a rational and emotional point of view. The development and implementation, secondly, has to deal with questions on its significance since not everybody is convinced yet on its added value. Acceptance and commitment towards the system is therefore currently unstable since an autonomous position, especially for cancer institutes, towards designation is still prevailing above a feeling of dependency.

In the context of these conflicts and discussions on the system's design and significance many of the individual cancer institutes and the OECl manifest strategic behavior, since this designation initiative seems to affect their stakes most directly. Both are thereby more focused on maximizing than satisfying their claims. Whereas the OECl is very proactive in striving for scarce resources to introduce a perfect designation system as quick as possible, individual cancer institutes are acting more defensively and reserved towards designation. Both behaviors seem thereby to reinforce each other. With regard to the

near future these dynamics can form a serious threat for the development and implementation of a designation system because it frustrates in reaching necessary consensus and commitment.

Looking ahead to the further development and implementation of a European designation system these system-technical and social-political challenges have to be overcome in order to take advantage of the system's actual purposes. An unmanaged divergence between the symbolical purpose of designation and the practical situation in which a designation system has to be developed and implemented (meaning a lack of global applicability as well as the required consensus and commitment to the designation system), will eventually harm to success of this designation initiative. For example, the designation of 'Comprehensive Cancer Centers' won't make sense or have no functional effect when categories, criteria or review methods don't anticipate to the contextual differences, when they aren't globally agreed or interpreted the same, or if only a few cancer institutes are participating in the designation project.

The big managerial challenge for that reason, from a system-technical and social-political point of view, is to find a balance between the overarching purpose and value of the system versus a 'satisfying' basis to all parties that is applicable to work with and worthy enough to be loyal to. For developing and implementing a successful European designation system in the near future, the following points are considered to be essential.

In the categories, criteria as well as the review methods of the designation system a balance has to be found between the level of abstraction and rigidity -for reaching a sufficient symbolical, effective purpose of designation on a supranational scale- and the level of specificity and flexibility -for anticipating to the material side of designating European cancer institutes in daily practice. The suggested features in paragraph 5.3, which are further outlined in a first draft of the designation system (see appendix), are in that respect concrete recommendations for managing this balance and to take maximum advantage of the benefits that designation has to offer.

Invest in the development of a more harmonized climate where stakeholders can agree with each other on sufficient satisfying grounds. By sharing resources, experiences, responsibilities and putting effort in understanding each others positions and motives towards designation, a constructive development of the system will be stimulated and possible conflicts can be brought to a minimum.

Work on commitment among stakeholders, with in particular the cancer institutes, via the clarification and promotion of the system's significance. First by disseminating and maintaining the profound purpose of this designation initiative in a broader context of ideas; namely that it must be a tool 'by professionals, for professionals' to benefit from and thereby helps to improve the quality of cancer care and research on a European scale. Secondly with the integration of incentives, especially for cancer institutes, to improve themselves. Third, by concretizing the added value for stakeholders as quick as possible. The initiation of pilots on a short-term notice and presenting its beneficial outcomes such as benchmark possibilities and network opportunities are hereby essential.

The last but not least important aspect, that mostly lies beyond managerial control but makes it nonetheless important to stress, is that the development and implementation of a successful designation system require a lot of patience, commitment, and the respect of all relevant stakeholders. Also the OECI must realize that it is impossible to introduce a completely perfect and

ultimate designation system. Working towards a designation system that serves its purpose sufficiently is an even big, but realistic challenge for all stakeholders involved. This can be achieved if everyone handles constructively and stands open for a pragmatic approach. Or, to use the words of Bowker and Star:

*'The only good classification is a living classification'.*

Concluding finally, this study has shown that designation of European cancer institutes ultimately comes down to the quote this thesis started with: designation -as being a form of classification- will only make sense and thus be successful if it is practically applicable, accepted and committed by those involved in it.

## 7 REFLECTION

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Looking back on the last five months of conducting this study, I have to say: ‘so far, so good’. Theoretical and field research offered important findings and suggestions to take the development and implementation of a European designation system to a next, more active phase. However, at the same time those findings have made it very clear that the success of this initiative depends on an extensive amount of factors varying from legislative, professional and demographical differences to the consequences of social-political contexts on a local or even regional level. Hence, a profound research where all those factors can be taken into account requires simply much more time than what stands for a master study.

A qualitative case-study has been chosen assuming to be the best method for performing an in-depth analysis on a relative new form of designation. The data that have been gathered from the literature review, interviews and observations corresponded most of the time with each other and allowed to draw valid and plausible conclusions. However, the huge amount of cancer institutes and other parties involved in designation plus practical limitations (such as time and the international setting in which research has been done), made it impossible to talk with all relevant stakeholders. Results are therefore mainly based on a relative small but important selection of stakeholders. With regard to the accuracy of this research one could say that this small research population harms the objectivity: results might tend to generalizations or subjective findings. To avoid this an option would have been to gather data by using questionnaires. They probably would have brought the earlier mentioned practical limitations to a minimum and made the research population more extensive. Then again, it would have been far more difficult to identify social-political patterns, discussions and relationships. Moreover, the interview plan has been sent to stakeholders on several occasions using it as a sort of questionnaire, but most of the time without any reply. Given the range of possibilities to gather data I therefore believe that my data collection was the maximum within reach.

There is one other important aspect that probably influenced the accuracy of the study as well. Given circumstances much time has been invested in the development of two documents which were closely connected to this study: (1) the conceptual draft of the OEI designation system and (2) the policy proposal ‘*designation of excellence in European cancer care and research*’. On the one hand I consider the documents as inherent activities in the development and implementation of a designation system and a perfect format for discussing the system-technical and social-political aspects of designation. Then again, the work on these documents took a lot of time and effort. Looking back it probably might have been better to invest more time in the collection of data (to increase the validity of the results) rather than keep fine-tuning the two conceptual documents as such.

Reflecting finally on my personal experiences, I must say that initial expectations came through in the end: it was a very interesting and most of all learnfull study. Most of all, it gave me more insight in many aspects that are involved when it comes to the organization of such health-policies on an international scale. At the same time, it made me realize as well that it is hard to stick to main findings and translating them into concrete recommendations. This I will take with me in future research activities.

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<http://www.ecco-org.eu/>

<http://estro.be/estro/>

<http://www.jointcommissioninternational.com/>

## APPENDIXES

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### A. INTERVIEWED PERSONS

U. Ringborg *(Karolinska Institutet, Stockholm)*

W. Van Harten *(Nederlands Kanker Instituut - Antoni van Leeuwenhoek Ziekenhuis, Amsterdam)*

D. de Valeriola *(Institut Jules Bordet, Brussels)*

M. Saghatchian *(Institut Gustave Roussy, Paris)*

H. Bartelink *(Nederlands Kanker Instituut - Antoni van Leeuwenhoek Ziekenhuis, Amsterdam)*

H. Hummel *(Integraal Kankercentrum Noord, Groningen)*

R. Otter *(Integraal Kankercentrum Noord, Groningen)*

G. Vassal *(Institut Gustave Roussy, Paris)*

T. Berns *(Nederlands Kanker Instituut - Antoni van Leeuwenhoek Ziekenhuis, Amsterdam)*

G. Storme *(Universitair Ziekenhuis, Brussels)*

I. Kössler *(Europa Donna)*

M. Vidal-Raggout *(Medical & Public Research Unit European Commission)*

M. Pierotti *(National Cancer Institute, Milan)*

C. Harrison *(Christie Hospital, Manchester)*

- L. Weiss *(National Cancer Institute, United States)*

## B. GENERAL USED INTERVIEW PLAN

### Interview plan

*'Developing and implementing a designation system for cancer institutes in Europe'*

#### SETTING

Place:

Interviewer(s):

Respondent(s):

#### PURPOSE INTERVIEW

To obtain insight in the perceptions of main stakeholders on the designation of European cancer institutes, in order to gain relevant information for the development of a draft designation system for European cancer institutes.

#### QUESTIONS

##### Social-political aspects system

- What is your opinion on the intention to designate European cancer institutes?
- Is designation of European cancer institutes an important and actual theme for you and your organization at the moment, and why is or isn't that?
- What do you see as the positive and negative aspects of such a system (added value, pitfalls, pre-conditions et cetera)?
- What kind of dynamics could occur when the consequences of the system are conflicting with the self-presumed status/identity or the interest of institutes?
- Do institutes have alternatives than conforming to this proposed designation system?
- Do you agree on the use of comprehensiveness as a frame for designation?
- What would you advise to increase the chance of acceptance of a designation system by cancer institutes or other relevant stakeholders?

**Please see the attached document 'A system for designation of institutes in European cancer care and research'.**

Categorisation of cancer institutes

- Should the categories be stricter or relatively open defined ?
- Should the focus be mostly on infrastructural (input) requirements, on performance (output) ?
- Are there contextual differences that have to be taken into account in the European categorisation of cancer institutes, and how can be dealt with that?

Criteria

- Is it a proper strategy (from closed, open and output criteria)? Other suggestions?
- How can we avoid bureaucracy and complexity?
- How can we improve benchmark possibilities?
- What do you think of the combination of accreditation criteria with the designation criteria?

Review system

- What do you think of the selection of review board members? Other suggestions?
- How can possible conflict of interests being dealt with in the review system?
- How can legitimacy in review and designation decisions be assured?
- What are the experiences of the cancer institute with reviewing/ accreditation/ designation/ certification so far?

Overall

- Are there other aspects that could contribute to the robustness, transparency and legitimacy of the designation system?
- What are your expectations on European designation of cancer in the future; what might be relevant points of attention (challenges) in the development and implementation of the system that were unspoken so far?
- Do you have interesting references (literature, persons) ?

## **C. CONCEPTUAL DESIGN DESIGNATION SYSTEM**

### **A system for designation of institutes in European cancer care and research**

By: W.H. van Harten, G. Hesselink, 2008

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## 1. INTRODUCTION

Although substantial progress has been made, European cancer research- and care institutions are facing an increasing number of cancer cases due to an increasing incidence as a result of an aging population and a higher prevalence due to longer survival (OEI, 2008). The increasing cancer burden and the growing complexity in cancer treatment and research, make it necessary to take extra measures in order to guarantee optimal cooperation between cancer treatment specialists and the cancer researchers. The OEI appear a suitable forum to take here the lead.

In comparison with the United States and some countries in Asia, the European expenses on cancer research are considered to be relatively modest (Sullivan, 2005). Although the current quality of cancer research and care in Europe is adequate, considerable improvements are possible and it is thus a collective challenge to bring both research and care to a higher level. This is needed, both from a public health as an economic point of view and will require initiatives at a supranational, European level.

In view of the need to bring European cancer research and cancer care as a whole to a higher and internationally more competitive level, the quality of and collaboration between oncologic institutes has to be improved. For the necessary benchmarking in order to monitor performance and progress, guidelines and criteria for reviewing these institutes need to be developed, in particular focusing on the level of comprehensiveness. The OEI has taken the initiative to define these guidelines and criteria by the development and implementation of a designation system for European cancer institutes

This document results from (and partly parallels with) a study on 'the challenges and critical features for developing and implementing a designation system for European cancer institutes', that will take place in the first half of 2008. It aims to contribute to the development of widely agreed categories, criteria and a review methodology for the designation of cancer institutes, especially on the (relative) level of comprehensiveness and excellence.

As the accreditation system is entering its pilot phase and is foreseen to be officially launched in the fall of 2008, the next phase of designation has been given a high priority by the OEI board and the steering group on accreditation. This document parallels the interests of the Eurocan+Plus group as well since it describes a proposal for the development of a system to Designate CCC's and CRC's of Excellence.

## 2. CATEGORIZATION OF CANCER INSTITUTES

In various European countries a range of definitions on comprehensive cancer care and -research already exist. However, since these definitions were primarily utilized to differentiate between institutions at the national level, they often differ from each other or can be differently interpreted; on European level the challenge is to describe and agree on definitions of a set of categories that can be used for all cancer institutions at the European scale.

In the OEI designation system 'Cancer Units', 'Cancer Centers', 'Cancer Research Centers', 'Comprehensive Cancer Centers' and 'Centers of excellence' will be the general categories on which cancer institutes will be designated (see appendix: 'working definitions').

### 2.1 Cancer Unit

The first category is the 'Cancer Unit'. Cancer Units are defined as clinical facility or hospital departments covering at least radiotherapy and medical or surgical oncology. Additionally they have a formalized collaboration with other hospital specialties.

### 2.2 Cancer Center

The category of 'Cancer Centers' can be divided into 2 different specific types. Initially all 'Cancer Centers' share the feature that the infrastructure and activities of the institution are organized in a sufficiently identifiable entity. The difference lays in the provision of care or research.

#### 2.2.1 Clinical Cancer Center

The 'Clinical Cancer Center' is characterized by the clinical capacity covering a sufficient degree of all medical, surgical and radiotherapeutical services and occasionally a limited degree of clinical research.

Optional here would be specifying 'Clinical Cancer Centers' on the variety and competence of their clinical capacity by adding the subcategory of '*Cancer Center of reference*'. Such a center where the infrastructure for a total provision of cancer care is integrated allows a recognition of centers who are most appropriate as a first referral for new patients diagnosed with cancer as they are covering all clinical oncologic services. At the moment a clear definition for a 'Cancer Center of reference' doesn't exist; once it is well-defined it will be tried to integrate it into the system.

#### 2.2.2 Cancer Research Center

The second type of cancer center, the 'Cancer Research Center', is characterized by the capacity in cancer research focusing on one or more areas in the field of fundamental and translational oncology.

## 2.3 Comprehensive Cancer Center (CCC)

The category of the 'Comprehensive Cancer Center' (CCC) is probably the hardest category to define as many different interpretations on a CCC already exist. Based on available information and many definitions on the concept of a CCC, the following features are considered to be essential for this particular category:

- a highly innovative character and multidisciplinary approach using the potential of basic, translational and clinical research and clinical facilities and activities, organized in a sufficiently identifiable entity
- a direct provision of an extensive variety of cancer care tailored to the individual patient's needs and directed towards learning and improving the professional, organizational and relational quality of care
- broad activities in the area of prevention, education, and external dissemination of knowledge and innovation.

In order to accentuate the differences with other cancer institutes, a CCC separates itself in the following points:

- the high level of infrastructure, expertise and innovation in the field of oncologic research
- maintenance of an extensive network including all aspects of oncologic treatment and research.

As for cancer institutes it is nearly impossible to be fully comprehensive in all cancer areas, it would be optional to categorize CCC's additionally more specific on the cancer areas in which they perform comprehensive (e.g. breast, prostate, lung etc.)

## 2.4 Centers of excellence

"Centers of excellence" finally are identifiable as the institutions with a proven performance at a high level in particular fields of either: cancer research (CRC ex), cancer care (Clinical CC ex) or an integrated combination of both (CCC ex).

### 3. CRITERIA FORMAT

The major aim for designating European care and research is to develop a robust system of sustainable criteria that will make designation of European cancer institutes possible and will stimulate cancer institutes to improve their performance in order to reach a higher qualification.

In that respect, cancer centers should both be designated on the level of (relative) comprehensiveness and the quality of performance in cancer research and clinical treatment. As excellence is a designation that primarily will be determined by performance, it seems logical to use the OEI accreditation system as a basis to identify the degree of comprehensiveness.

The criteria format is therefore a combined set of closed criteria for both care and research, output-, and open criteria.

#### 3.1 Closed criteria

First of all, the purpose of the closed criteria is to determine whether the cancer centre is indeed comprehensive. They act as minimum (infra)structural requirements on the relative level of the different defined categories.

Based on absolute norms or by a cumulative required rate these criteria have to be met in order to obtain the qualification of a particular category.

CLOSED/INPUT CRITERIA	NORM Comprehensive Cancer Center	NORM Cancer Center	NORM Cancer Unit
<i>Substantial infrastructure focused on cancer research</i>	Minimum scores or present (v)		
<ul style="list-style-type: none"> <li>▪ Infrastructures for basic research:               <ul style="list-style-type: none"> <li>- Cell biology, differentiation, cell cycle</li> <li>- Molecular biology, signal transduction, cell death, apoptosis</li> <li>- Biochemistry</li> <li>- Immunology</li> <li>- Imaging</li> <li>- Molecular pathology</li> <li>- Molecular cytology</li> <li>- Genetics</li> <li>- Tumour macro environment and metastases, angiogenesis</li> <li>- Genetics</li> </ul> </li> </ul>	- Minimum of 2	- Minimum of ...	- not applicable

<ul style="list-style-type: none"> <li>- <i>Epigenetics</i></li> <li>- <i>Structure biology</i></li> <li>- <i>Stem cell biology</i></li> <li>- <i>Other suggestions...</i></li> </ul>			
<ul style="list-style-type: none"> <li>• Infrastructures for other (translational) research: <ul style="list-style-type: none"> <li>- <i>Pharmacology, metabolism</i></li> <li>- <i>Diagnostic research</i></li> <li>- <i>Epidemiology</i></li> <li>- <i>Biostatistics</i></li> <li>- <i>Screening for new anticancer agents</i></li> <li>- <i>Animal facilities/ animal models</i></li> <li>- <i>Bionics (DNA, RNA, proteins)</i></li> <li>- <i>Bioinformatics</i></li> <li>- <i>Clinical trials, early clinical trials including biological questions</i></li> <li>- <i>Biobanks for tumour, normal tissues &amp; biofluids</i></li> <li>- <i>Validation of biomarkers</i></li> <li>- <i>Antibody production</i></li> <li>- <i>Patient data registries</i></li> <li>- <i>Quality of life assessment</i></li> <li>- <i>Other suggestions...</i></li> </ul> </li> </ul>	- Minimum of 7	- Minimum of ...	- not applicable
<b>Substantial infrastructure focused on cancer care</b>	Minimum scores or present (v)		
<ul style="list-style-type: none"> <li>▪ Oncology specialties: <ul style="list-style-type: none"> <li>- <i>Surgical</i></li> <li>- <i>Medical</i></li> <li>- <i>Radiotherapeutical</i></li> <li>- <i>Pediatric</i></li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>- Obligatory</li> <li>- Obligatory</li> <li>- Obligatory</li> <li>- Optional</li> </ul>	<ul style="list-style-type: none"> <li>- Obligatory</li> <li>- Obligatory</li> <li>- Obligatory</li> <li>- Optional</li> </ul>	<ul style="list-style-type: none"> <li>- Obligatory without Medical oncology</li> <li>- Obligatory without Surgical oncology</li> <li>- Obligatory</li> <li>- Optional</li> </ul>
<ul style="list-style-type: none"> <li>• Multidisciplinary coordination &amp; collaboration by multidisciplinary oncology teams</li> </ul>	- obligatory cf. criteria established by OEI	- obligatory cf. criteria established by OEI	- not applicable
<ul style="list-style-type: none"> <li>▪ Sufficient amount of clinical facilities focused on cancer care: <ul style="list-style-type: none"> <li>- <i>Preventive service</i></li> <li>- <i>Screening high risk patients/genetic advice</i></li> <li>- <i>Operating rooms (specific to oncology)</i></li> <li>- <i>I.C. beds</i></li> </ul> </li> </ul>	- Minimum of 4		

<ul style="list-style-type: none"> <li>- Radiotherapy units (including accelerators &amp; cobalt unit)</li> <li>- Radiology unit (including CT-scanners, mammography &amp; facilities for MRI)</li> <li>- Nuclear medicine unit (including Pet-scan, CT-Pet &amp; Radionuclide facilities)</li> <li>- Pathology (cytology &amp; histopathology)</li> <li>- Haematology unit</li> <li>- Pharmacy-chemotherapy unit</li> <li>- Paramedical unit</li> <li>- Psycho-social unit</li> <li>- Palliative care team</li> <li>- Supportive care</li> </ul>	<ul style="list-style-type: none"> <li>- Minimum of 4</li> <li>- Full range of diagnostics</li> </ul>	<ul style="list-style-type: none"> <li>- Minimum of ...</li> </ul>	<ul style="list-style-type: none"> <li>- Minimum of ...</li> </ul>
<b>Substantial human resource capacity</b>	Minimum scores or present (v)		
<ul style="list-style-type: none"> <li>▪ Total number of employees dedicated to cancer care/year</li> <li>▪ Total number of employees fully dedicated to cancer research/year</li> </ul>	<ul style="list-style-type: none"> <li>- 100 fte's specialists</li> <li>- 200 fte's nursing</li> <li>- ... research groups</li> <li>- ... fte's basic</li> <li>- ... fte's translational</li> <li>- ... fte's clinical</li> </ul>	<ul style="list-style-type: none"> <li>- ... fte's specialists</li> <li>- ... fte's nursing</li> <li>- ... fte's clinical</li> </ul>	<ul style="list-style-type: none"> <li>- not applicable</li> <li>- not applicable</li> </ul>
<b>Substantial financial capacity</b>	Minimum scores or present (v)		
<ul style="list-style-type: none"> <li>• Annual income/ expenditure for cancer care</li> <li>▪ Annual income/ expenditure for cancer research</li> </ul>	<ul style="list-style-type: none"> <li>- 60 mio • '9/year</li> <li>- 30 mio • '9/year</li> </ul>	<ul style="list-style-type: none"> <li>- ... mio • '9/year</li> <li>- ... mio • '9/year</li> </ul>	<ul style="list-style-type: none"> <li>- ... mio • '9/year</li> <li>- ... mio • '9/year</li> </ul>
<b>Substantial amount of activities focused on education</b>	Minimum scores or present (v)		
<ul style="list-style-type: none"> <li>• Basic education programs (to be defined)</li> <li>• Specialist education programs (idem)</li> <li>▪ Research education programs (idem)</li> <li>▪ Scientific meetings/ Seminar program (idem)</li> <li>• Other suggestions...</li> </ul>	<ul style="list-style-type: none"> <li>- Minimum of ...</li> </ul>	<ul style="list-style-type: none"> <li>- Minimum of ...</li> </ul>	<ul style="list-style-type: none"> <li>- Minimum of ... /- not applicable</li> </ul>
<b>Referral to other criteria</b>	<b>3</b> Open & Output Criteria	<b>2</b> Open Criteria	<b>1</b> Open criteria

### **3.2 Open criteria**

Additionally to the set of closed criteria, open input will be available for the institutions to emphasize activities, facilities or information that might be relevant for gaining a certain qualification.

Open criteria make it possible to assess the more complex organizational and administrative requirements, that are hard to measure by a normative approach. Central elements of this organizational and administrative requirements are adequate interdisciplinary and multidisciplinary collaboration and coordination of cancer treatment and -research processes as well as the extend to which cancer institutes recognize and meet prior commitments to the focus on cancer, provide sufficient resources to the assurance of organizational stability and reach full potential and commitment for gaining a certain qualification.

## 1. Cancer Unit

- Clarify the collaboration with other hospital specialties in a maximum of two pages.
- Place here comments to emphasize activities, facilities or other information that might be relevant for gaining the qualification of a Cancer Unit.

## 2. Cancer Center

- Demonstrate in a maximum of three pages the following organizational and administrative requirements in order to gain the qualification of a Cancer Center:

### Interdisciplinary and transdisciplinary collaboration & coordination:

- Level of effective transdisciplinary collaborations among the multiple disciplines in cancer care and clinical research.
- Extend to which activities among clinical research and treatment programs have added value to cancer related scientific activities.

### Institutional entity

- Dedicated budget on cancer care and sufficient autonomy
- Research and hospital staff under one administrative / institutional entity

- Place here comments to emphasize activities, facilities or other information that might be relevant for gaining the qualification of a cancer center.

## 3. Comprehensive Cancer Center

- Demonstrate in a maximum of five pages the following organizational and administrative requirements in order to gain the qualification of a Comprehensive Cancer Center:

### Interdisciplinary and transdisciplinary collaboration & coordination:

- Level of effective transdisciplinary and translational collaborations among laboratory, clinical and population cancer center members.
- Extend to which activities between and among research and treatment programs have added value to cancer related scientific activities.
- Actively taking part in international research cooperation.

### Institutional commitment:

- Formal codification of organizational status of a CCC in institutional policy and structure (authorities of the director over centres resources, control of space and permanent access of facilities, assurance of occupation positions, budget and funds, reporting structures, distribution of responsibilities)
- Clear defined scientific focus on cancer care in the organizations' vision and mission

### Qualified board members:

- High scientific and administrative qualifications
- Experience related to centers' objectives and activities
- Formal and informal authority

### Institutional entity

- Dedicated budget and sufficient autonomy
- Research and hospital staff under one administrative / institutional entity

- Place here comments to emphasize activities, facilities or other information that might be relevant for gaining the qualification of a comprehensive cancer center.



### 3.3 Output criteria

Secondly, a set of output criteria will be used to measure the quality of clinical and scientific performance. This will be measure according to a set of norms that act as standards for excellence. Applying output criteria will allow cancer institutes to focus on the improvement of policy and activities.

OUTPUT CRITERIA	PARAMETERS	PERFORMANCE STANDARD
<i>Quantitative performance</i>		Minimum scores
<ul style="list-style-type: none"> <li>Clinical production (medical, surgical &amp; radiotherapeutical)</li> </ul>	<ul style="list-style-type: none"> <li>Overall number of new cancer registered patients/year</li> <li>pm Further specification of patient numbers and treatments needed?</li> </ul>	<ul style="list-style-type: none"> <li>- 1000 medical</li> <li>- 1000 surgical</li> <li>- 1500 radiotherapeutical</li> </ul>
<ul style="list-style-type: none"> <li>Scientific production (fundamental, translational &amp; clinical research)</li> </ul>	<ul style="list-style-type: none"> <li>- Number of active clinical trials (phase I, II, III &amp; IV) (proportion)</li> <li>- Number of scientific Publications/ year</li> <li>- Number of publications in high impact journals</li> <li>- Volume of research project?</li> </ul>	<ul style="list-style-type: none"> <li>- 30 fundamental</li> <li>- 15 translational</li> <li>- 300 fundamental</li> <li>- 300 translational</li> <li>- 200 clinical</li> <li>- 10 or more</li> </ul>
<i>Qualitative performance</i>		
<ul style="list-style-type: none"> <li>Scientific performance (fundamental, translational &amp; clinical research)</li> </ul>	<ul style="list-style-type: none"> <li>- Impact factor (cumulative &amp; high score) of peer reviewed articles</li> <li>- Citation index</li> <li>- Membership of a number of formal international research cooperation networks/ framework program EU</li> </ul>	<ul style="list-style-type: none"> <li>- ... fundamental</li> <li>- ... translational</li> <li>- ... clinical</li> <li>- ...</li> <li>- ...</li> </ul>

<ul style="list-style-type: none"> <li>• Clinical performance</li> </ul> <p>Should be a criteria, but is difficult to indicate at the moment, and therefore to be developed...</p>	<ul style="list-style-type: none"> <li>- Percentage of patients included in trials (phase I, II, III &amp; IV)</li> <li>- Process or outcome related criteria ???</li> </ul>	<ul style="list-style-type: none"> <li>- ... surgical oncology</li> <li>- ... medical oncology</li> <li>- ... radiotherapeutical oncology</li> </ul>
<ul style="list-style-type: none"> <li>• Educational performance</li> </ul>	<ul style="list-style-type: none"> <li>- Invited lectures (scientific &amp; other) of senior staff/year</li> <li>- Number of educational courses</li> <li>- Number of PhD students/year</li> <li>- Number of PhD theses/year</li> <li>- Number of University? professors</li> </ul>	<ul style="list-style-type: none"> <li>-...?</li> <li>-...</li> <li>- 50</li> <li>- 15</li> <li>- 10</li> </ul>

## 4. REVIEW SYSTEM

This section will introduce the review methodology and helps to understand the rationale of the review process for designating European cancer institutes. It will respectively provide an overview of the components of the review system, defines the composition review teams and the roles of various review team members, describes standards of conduct to be followed and outlines details of the review and designation process.

Aspects of the here presented review material were originally adapted from the U.S. Army Breast Cancer Research Program (1997), the NC consumers’ guide to peer review (2006) and the Eusoma breast cancer certification program (2008).

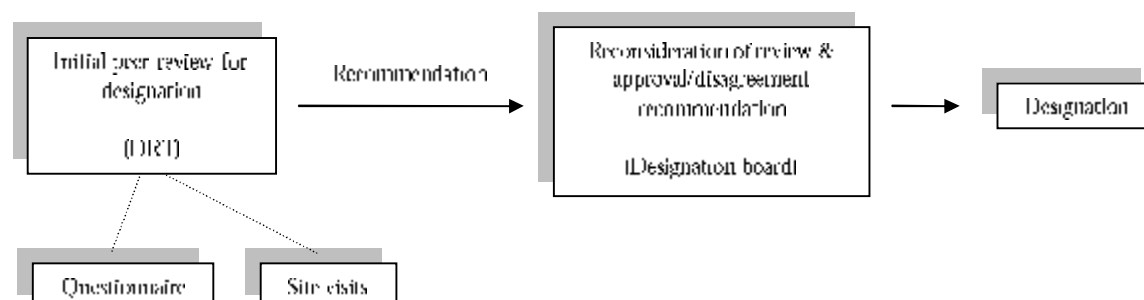
### 4.1 Overview of peer review

The review system exists out of a peer review consisting two sequential levels of review mandated by statute.

The first (initial) level of review, will be performed by an ‘Designation Review Team’ (DRT) whose primary function is to review and evaluate the application results and scores of cancer institutes on the designation criteria. The main responsibilities of the DRT are: serving as the corporate memory for reviews, ensuring uniform treatment across review cycles, assigning the priority score for the application and formulating a recommendation for designation to the ‘Designation board’.

The second level of review is performed by the formal appointed ‘Designation board’. With their final reconsideration on the review results it is the responsibility of this board to decide on the designation status of each applicant cancer institute.

**Figure 1. Review system overview**



## 4.2 Composition of review groups

The composition of the DRT and the designation board, on both review levels, is based on the purpose of having an objective, precise and acknowledged review system. The following will describe the type review members of both groups and their responsibilities in the review process.

### 4.2.1 Designation Review Team (DRT)

Members of a DRT are selected to review applications by matching expertise with the given topic areas of the application under review. Because of the complex, diverse and multidisciplinary nature of cancer care and research, the selection of members in a DRT is partly fluid. Members may be appointed as standing committee members with overlapping terms of up to 4 years, or as 'temporary' members with all the rights and obligations of committee membership. Consultants in specific relevant domains may also be invited to serve as special experts or ad hoc members to provide information or advice. Furthermore members must be from countries outside of the applicant cancer institute.

The team can be divided into voting and nonvoting members. Voting members of the team include:

- Chairperson/ visit coordinator
- Scientists
- Consumers
- Consultants (optional)

In order to fulfill the administrative and programmatic responsibilities, the following members are considered for completing the review team as nonvoting members:

- Scientific Review Administrator
- Governmental observers

Qualifications and responsibilities of the various review members are described in detail below.

#### *Scientific Review Administrator (SRA)*

The SRA is a scientist whose function, as a government employee, is to serve as the overall or site visit administrator. The SRA selects the Chairperson and the members, administers the meeting, records application scores and oversees the summary statement of the DRT to the designation board.

#### *Chairman/ visit coordinator*

The chairperson of a DRT is a highly qualified senior scientist and successful reviewer who offer extensive scientific leadership and cancer research/treatment evaluation experience as peer review panellists. The chairperson has broad expertise in relevant scientific or clinical area depending on the type of application, and is responsible for the formal meeting proceedings. During the review meeting, the chairman may also serve as a reviewer, coordinates and leads the team process and is responsible for ensuring that the application receives a fair and competent review.

*Scientists/ Clinicians*

Scientific/ clinical members are selected on the basis of their expertise and achievement in relevant scientific or clinical areas. The DRT contains a mix of junior, mid-level, and senior scientists to provide a balance of established and emerging scientific and clinical perspectives.

*Consumers*

Consumer stand in this respect for either cancer survivors, relatives of cancer patients, or the ones that are active in cancer advocacy organizations. They are selected on the basis of involvement in cancer (advocacy) experience; the ability to communicate and advocate well and their ability to think 'globally' beyond one's personal experience. As they have first-hand experience consumers contribute significantly in the review process by representing the patient and public perspective in addition to the evaluations of scientists and clinicians.

*Governmental observers*

As national systems of oncologic care provision can differ considerably it can be considered to add a representative of the relevant national governing body as an observer to the DRT.

**4.2.2 Designation board/ commission**

The designation board is selected on a mix of experts in the field of cancer research and care, mostly outside of Europe, and well-respected directors of well-known cancer institutes in the US. This to ensure a review and actual designation that is unbiased and based on high expertise. The appointment of the board members must take place in consultation with relevant stakeholders in European oncology.

**4.3 Standards of conduct**

The primary goal of the peer review process is to provide an unbiased, independent expert review on the set requirements for cancer institutions in order to consider and facilitate the designation decision by the designation board in the best way.

All participants in the review process must therefore adhere to several standards of conduct to ensure that the credibility of the review process and its review members is not compromised. The following discussion points are intended to outline each participant's responsibility in preserving the integrity of the peer review process.

**4.3.1 Conflict of interest in peer review**

An indisputable requirement of all members in the review process is the avoidance of conflicts of interest and/ or the appearance of conflict. Conflicts of interest exist when a review member or close associate can be viewed as being in a position to gain or lose personally, professionally, or financially from an application under consideration.

If a concern arises within the review team, the member must notify the Scientific review administrator (SRA). If it is determined by the SRA that a conflict of interest indeed exists, the member must excuse himself/ herself from the duration of proceedings for the given application

and refrain from voting on that application. It cannot be overemphasized that reviewers themselves bear the responsibility to be vigilant in avoiding actual or apparent conflicts of interest.

As for concerns of conflict of interest by the applicant cancer institutes a formal complaint procedure should be developed in the near future where they can address their concern.

#### **4.3.2 Confidentiality in peer review**

To provide the assurance to applicant cancer institutes that their identity, their applications, and the associated reviews are held in confidence, the applications, review materials and meeting proceedings are for the use of reviewers and the designation board only. All review members have to sign a confidentiality agreement. Any breach of confidentiality is considered as unethical. Such unethical conduct has adverse effects on a reviewer’s reputation or the reputation of their institution and undermines the integrity of the peer review process.

#### **4.3.3 Peer review procedure**

A first indication of the procedural steps of the peer review is the following.

##### *Pre-review activities*

The designation process is activated on request from the cancer institute; the information on the procedure and the application form will be available on a website yet to be determined.

##### *Questionnaire*

In response to the application of the cancer institute, the first step in the review process starts with a standard questionnaire that consists a set of criteria based on the general considerations for comprehensiveness. Throughout the questionnaire the requirements for designation of cancer institutes will primary be assessed by the cancer institutes themselves.

##### *Site visits*

After the questionnaire is self-assessed by applicant cancer institutes and once the results are known by the DRT, a side visit will be held by the DRT on location. The purpose of these site visits is to meet members of the cancer institute in all relevant specialties, talking through the replies given on the questionnaires, clarify unclear issues and gather additional information for use by the DRT in their final evaluations. The information may relate to the suitability of infrastructures for the required work proposed or other aspects that due to complexity, depth or nature of activities require more concrete evaluation.

Depending on the size and scope of the application and the information to be gathered, the side visit review team can consist of varying from 5 to 15 scientific/ clinical experts, including a few permanent DRT members and one consumer. These meetings range from 1 to 3 days. Although the details for these visits and including meetings may vary somewhat for each per review member and each application may differ a bit, the general procedure has to be consequent and uniform. Each visit is therefore carried out according to this general procedure. The concrete indication of the procedures, planning, et cetera should be developed in the near future.

### *Final evaluation*

Once the results of the questionnaire are known and the site visits are being held, the DRT members will finish their individual reports and draw them up in a 'preliminary review report' format. This preliminary report will be sent to all DRT members for their approval and the applicant cancer institute, which may be asked to answer additional questions or to give further clarifications.

The final evaluation of the DRT will take place during a special review meeting. In this meeting, that must be physically taking place, the final evaluation will get shape in the form of a 'summary statement', and can be seen as an official record of the review. This summary statement subsequently involves a designation recommendation to the designation board. The recommendation of the DRT has to be unanimously agreed upon. During this final evaluation the DRT has to take the following responsibilities into account:

- ensuring equitable and uniform used review standards and treatment for all applications
- ensuring compliance with the review criteria
- ensuring that the site visit team appropriately dealt with the review criteria
- looking and taking the overall application merit in perspective
- correcting any deviation by site visit teams from review criteria or uniform treatment.

Based on the summary statement and the subsequent designation recommendation from the DRT the designation board will overlook and reconsider the results of the review cycle in order to come to an appropriate designation status for the applicant cancer institute.

### **4.3.4 Designation procedure**

The members of the designation board have to approve or disagree with the DRT recommendation within 28 days. If the designation board fails to reach unanimity then the decision has to be taken by a majority vote: if more than 25% of the board are against the decision then it will be denied.

Once the designation board has reached the agreement on the designation status of the applicant cancer institute the final designation report will be prepared and sent to the cancer institute and the members of the DRT informing on the designation status and the results of the review process.

If a cancer institute wishes to appeal against an adverse decision then a formal complaint procedure should exist where they can address their concern to.

## **5. POSSIBLE MODIFICATIONS IN REVIEW & DESIGNATION**

There must always be room for changes in the review and designation process when arguments significantly show the benefits of it. However, as a safeguard for the robustness of the system, changes must be reduced to a minimum. Nevertheless, since this is a first concept of the review system, it will especially be open for modification during its introduction period. The most important issues at this moment are the following.

### **5.1 Initial and conditional designation**

Considering the huge and rapid changes in cancer care and research it might be preferable to make use of a prospective view on designating cancer institutes. This can be done by introducing a preliminary (initial) status for cancer institutes, if necessary, before granting a conditional designation status.

### **5.2 Validity of designated status**

At the moment the validity of the designated status for cancer institutes is another point of discussion. The question is when re-evaluation is appropriate with regard to the stimulation of continuous improvement and the legitimacy of the designated status since a lot can change in a few years.

### **5.3 Review of Cancer Research Centers**

It is a question whether the designation of Cancer Research Centers on excellence should be performed by the same organization. As an accreditation and designation infrastructure will be developed by OEI anyway, it seems logical to include the CRC's in this system; however for CRC's review and site visit teams will have to be selected on appropriate knowledge and authority.



## 6. FUTURE STEPS

On the long term the plan is to fully integrate designation as a quality-improvement tool for European cancer institutes. This implies a pragmatic introduction of designation activities in the near future.

The OEI proposes to perform a first designation exercise by initiating a first round of pilots that is based on the already performed self-assessments and accreditation pilots. A further proposal for the development and implementation of the designation system will be made based on the results of these pilots.

With respect to the designation of 'excellence' the OEI considers the professional expertise of the Stockholm Group as a fundamental resource that should be used extensively. The OEI requests therefore the Stockholm Group to further elaborate this domain of designation.

The future developments in designation by the OEI and the Stockholm Group, that will be running parallel to each other, allows a beneficial situation on both sides.

## 7. APPENDIX

### Working definitions categories of cancer institutes

#### Cancer Unit

"A clinical facility or hospital department covering at least radiotherapy and medical or surgical oncology, and that has a formalized collaboration with other hospital specialties".

#### Clinical Cancer Center\*

"A clinical facility or hospital covering a sufficient degree of all medical, surgical and radiotherapy services and clinical research to a limited extend together organized in a sufficiently identifiable entity".

#### Cancer Research Center

"A research organization focusing on one or more areas in the field of fundamental and translational oncology – related research".

#### Comprehensive Cancer Center (CCC)\*\*

"A combination of a cancer hospital facility covering and integrating the full range of cancer prevention/screening, medical-, surgical- and radiotherapeutical oncology and (fundamental), translational, (and clinical) cancer research activities as well as substantial activities in the field of innovation and education, organized in a sufficiently identifiable entity".

#### Comprehensive Cancer Center (CCC) of Excellence

"A Comprehensive Cancer Center that has proven to perform on levels of excellence on the full range of medical, surgical and radiotherapeutical oncology and of (fundamental) translational (and clinical) cancer research and of innovation and education".

#### Cancer Research Center (CRC) of Excellence

"A Cancer Research Center that has proven to perform on levels of excellence in most of its research fields".

\* *Optional: Cancer Center of Reference*

\*\* *Optional: CCC in a specific cancer area (e.g. breast, prostate, lung etc.)*

## **Working definitions 'comprehensive cancer research areas'**

### *Fundamental (basic) cancer research*

"Laboratory research activities that lays the foundation of other types of cancer research by the basic study on how cancer cells work".

### *Translational cancer research*

"Research activities that translate scientific discoveries from basic cancer research into potential practical applications for clinical cancer research and therefore bridges the gap between fundamental research and research with patients".

### *Clinical cancer research*

"Research activities that involve cancer patients by the appliance of clinical trials in which medical, surgical or radiotherapeutical procedures are being tested, aiming to develop more effective treatments for cancer".