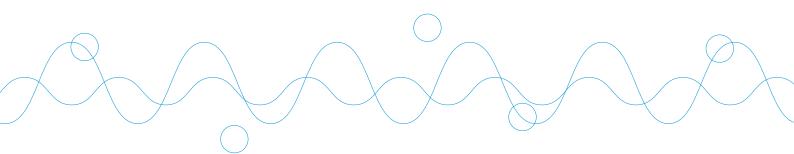
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# Innovation through knowledge transfer in Germany, United States, United Kingdom and France





Center for Research and Development Strategy Japan Science and Technology Agency

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## Introduction

The Center for Research and Development Strategy (CRDS), Japan Science and Technology Agency (JST), routinely conducts survey analyses of science and technology (S&T) trends in major countries of the world and publishes the results for the purpose of contributing to future planning and formulation of Japan's S&T policy. This report compiles the results of surveys on S&T expertise and innovation translation-related policies in major countries, conducted by CRDS.

Against the backdrop of the recent Lehman Brothers' bankruptcy-sparked economic crisis in developed countries and economic growth in China and the other BRICs countries, there is now shared a international understanding that S&T and innovation are important drivers of economic expansion and international competitiveness. Innovation is a particularly important keyword here, as the question of how to generate economic and social wealth by applying S&T expertise that was obtained from R&D to industry and society poses a challenge shared by all nations. It is thought that an important factor here is the fact that although vast amounts of public funds are invested in S&T, such investment produces few results that are readily visible to the general public. Although more R&D is taking place at universities and public research institutes and more and more papers and patents are produced as a result, the public is not getting a real sense that those activities are bringing greater prosperity. Given this, various efforts are made in the United States and major European countries to tie scientific knowledge to innovation. This report calls this linkage of scientific knowledge and innovation "translation" and compiles the results of survey analyses that focused on it.

Looking at all of the research translation measures mentioned in this report, the one thought to be the most internationally well known and most effective as a measure that bridges scientific knowledge and innovation is Fraunhofer of Germany. Fraunhofer began as an organization that distributed industrial technology funds related to the Marshall Plan, a post-World War II economic assistance program by the United States for European reconstruction. Fraunhofer subsequently became an organ that redistributed work among S&T-related organizations in Germany and then one that contributed to corporate innovation through research on pre-competitive fields. Fraunhofer is known for the "Fraunhofer method," which adjusts operating subsidies in accordance with the values of contracts with private enterprises. However, this method is simply one form of the "research translation" that is discussed in this report. In fact, Fraunhofer should in itself be considered a system for bridging scientific knowledge and innovation in Germany.

At the present time, the United States appears to be the best in the world at innovation. Certainly, a look at the success of Microsoft, Apple, and other companies from Silicon Valley provides a true sense of the United States' innovative prowess. However, there is very little evident in the way of federal government policies, measures, or involvement that directly target Silicon Valley, and therefore it is thought that Silicon Valley's success is largely attributable to the drive of highly motivated people in the private sector. Thus, it appears that the kind of comprehensive research translation policies that exist in major European governments are weak in the United States. Nonetheless, this report examines the Clinical and Translational Science Award (CTSA) program of the National Institutes of Health (NIH) and the Engineering Research Center (ERC) program of the National Science and pharmaceuticals by building teamwork between clinical researchers (physicians) and basic researchers and fundamentally reinforcing data-driven medical research, an area whose importance has grown exponentially in recent years. The latter creates new engineering

systems and develops human resources to lead those systems.

The United Kingdom was a key player in the birth of modern science and the home of the First Industrial Revolution. Today the S&T potential of its universities and public research institutions ranks among the best in the world. In particular, such famous universities as Oxford and Cambridge stand shoulder-to-shoulder with American universities. However, when it comes to the industries that support the economy, it is thought that the UK's manufacturing industries fall behind when compared to those of the US, Germany, and others. Understanding the need to address this situation, the British government has formulated a policy—called the "Catapult Programme"—to link the superior potential produced in the UK with industrial innovation. A "catapult" is a device used to "propel things forward with great force," and thus it was deemed to be the optimum name for the concept of bridging the "valley of death."

Like the UK, France has a history of producing remarkable innovative achievements in S&T. However, it currently does not lead the world with innovation in the way that the United States does. To tackle this problem, the French government introduced the Carnot Institutes program to strengthen the ties between public research and corporate research and to reinforce the R&D capability of private enterprises, including SMEs. This is the last of the "research translation" measures to be examined in this report.

It should be noted that efforts to tie scientific knowledge to industrial innovation are taking place in other countries as well. Representative of those efforts not discussed in this report are work by the Finnish Funding Agency for Innovation (TEKES) and European Institute of Innovation & Technology (EIT) as well as an academy-community cooperation program of the Chinese Academy of Sciences.

Within the discussion of each measure is an examination of points from the report's surveys that may be applicable to Japan. However, in general, such points are very elementary in nature. The reason for this is that, with the exception of Germany's Fraunhofer, all have been in use for no more than a comparatively short period of time. Accordingly, the report's content should be viewed as being preliminary in nature. Rather that studying it in terms of immediate application in Japan, it is advisable to make judgments on its applicability only after the measures mentioned in it are observed in their respective countries for a little longer.

The original is written in Japanese and published in March 2016. This English translation version is tentative, made by CRDS.

September 2016

Yukihide Hayashi Principal fellow (Overseas Research Unit) Center for Research and Development Strategy Japan Science and Technology Agency

## Chapter 1: Fraunhofer Gesellschaft e.V., Germany

Fraunhofer Gesellschaft e.V. (hereafter "Fraunhofer") serves as a bridge between industry and academia in Germany. Fraunhofer has been in existence for more than 60 years, it has attracted international attention for its effective implementation of industry-academia collaboration. For this reason, we conducted the following analysis of Fraunhofer's role in Germany's innovation systems.

## 1.1 Background

## 1.1.1 History

Fraunhofer was established in Munich in 1949 by the state of Bavaria for the purpose of handling post-World War II industrial reconstruction. It was concerned with the distribution of funds under the Marshall Plan, the United States' program for rebuilding Europe. It had provided funding for applied research that helped in the reconstruction of industries that were destroyed in the war, and particularly of the machine industry sector. Its name comes from Josef von Fraunhofer, a successful inventor in Munich during the 19th century. At the outset it was looked to as a third "pillar" supporting Germany's scientific circles, following the German Research Foundation (DFG), which is a funding institution, and the Max Planck Society (MPG), which engages in basic research. It later established an independent research institute<sup>1</sup> in Mannheim in 1954 that was separate from its work distributing funds under the Marshall Plan.

Despite the fact that it began receiving operating subsidies from the federal government in 1969, Fraunhofer's research institute continued to operate under tough financial circumstances. At the same time, it was unable to demonstrate a strong presence, failing to become something of a second Max Planck. Against this backdrop, it became increasingly apparent that structural reform was needed in Fraunhofer, and its operating structure underwent a fundamental reorganization in 1973. Based on a cabinet decision of the federal government, the institute was given a financial framework modeled after the Battelle Memorial Institute<sup>2</sup> of the United States, which is operated entirely with contract research from industry. This resulted in one-third of its budget coming from contract research and the remaining two-thirds coming from government operating subsidies and competitive funding. This framework continues to be the operating foundation for Fraunhofer's research institutes.

## 1.1.2 Main operations

Fraunhofer contributes to corporate innovation through research on pre-competitive fields. Specific operations are classified into the following five categories:

- Contract research from industry
- Licensing of patents acquired as research output
- Return of new inventions and services to society through business startups
- Supply of researchers to industry
- Provision of cutting-edge facilities to private enterprises

<sup>&</sup>lt;sup>1</sup> Institute for Applied Microscopy, Photography and Cinematography (IMPK)

<sup>&</sup>lt;sup>2</sup> A research institute based on Ohio, the United States. It established a branch in Frankfurt, Germany, in 1953 that was operated entirely with contract research from industry.

## 1.2 Organization

#### 1.2.1 Overview

Fraunhofer's headquarters is located in Munich in the southern German state of Bavaria. Only this headquarters has legal personality.

The federal government ministry having jurisdiction over Fraunhofer is the Federal Ministry of Education and Research (BMBF). At the state government level, the department in charge of education and culture of each state has jurisdiction. Additionally, Article 91b of the Basic Law for the Federal Republic of Germany (Constitution of Germany) establishes that the federal government and state governments will support research jointly. The body in charge of coordinating such support is the Joint Science Conference (GWK), which is a conference of ministers and senators in charge of S&T at the federal and state, *Länder* levels. Fraunhofer's operation is promoted based on an agreement with GWK.

#### 1.2.2 Headquarters organization and affiliated research institutes

As is shown in the organizational chart below, Fraunhofer has an Executive Board comprised of a President and two Executive Vice Presidents,<sup>3</sup> one each in charge of financial affairs/IT and personnel/legal affairs, as well as the leaders of six Groups (excluding Defense and Security). Its General Assembly is comprised of 1,145 members that include members of federal and state assemblies, under-secretaries of departments in charge of education and research at the federal and state levels, university professors, and directors of Fraunhofer's research institutes. The General Assembly's responsibilities include approval of annual reports submitted by the Executive Board, approval of the resignation of Senate and Executive Board members, and approval of by-laws. The Senate is comprised of corporate representatives, the previous Fraunhofer President, politicians, and others. The Senate's responsibilities include the elimination and consolidation of research fields and institutes, formulation of medium- and long-term financial plans, and approval of General Assembly members. The Scientific and Technical Advisory Board is comprised of 145 members, 80 of whom are directors of Fraunhofer's research institutes and the remaining 65 of whom are technical staff members. The board's chairperson is Prof. Dr. Dieter Prätzel-Wolters (Fraunhofer Institute for Industrial Mathematics [ITWM]). The Scientific and Technical Advisory Board is also the organization that provides advice on S&T-related projects.

Fraunhofer's Munich headquarters has the authority to make personnel decisions concerning the appointment of research institute directors and financial management as well as the authority to formulate organization-wide strategy. Additionally, Fraunhofer recently switched to a system through which patents and utility models that were previously managed by individual research institutes are now managed by the headquarters in a concentrated manner. This trend has gained momentum under the leadership of Fraunhofer's current President, Prof. Dr. Reimund Neugebauer,<sup>4</sup> who assumed the post in 2012.

<sup>&</sup>lt;sup>3</sup> As of January 2016

<sup>&</sup>lt;sup>4</sup> Prof. Dr. Reimund Neugebauer, professor at the Chemnitz University of Technology and former head of the Fraunhofer Institute for Machine Tools and Forming Technology (IWU)

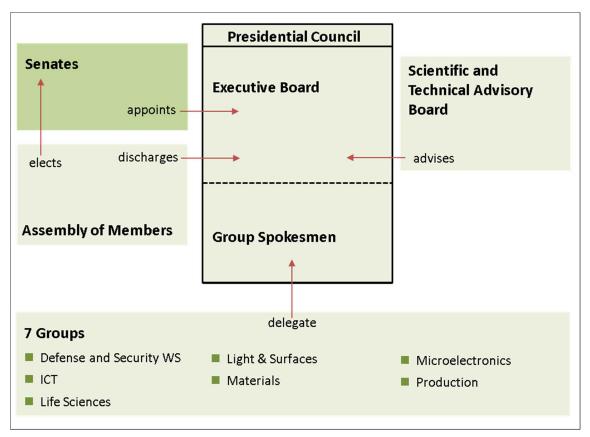


Figure 1-1: Organizational chart

Source: Prepared by CRDS based on Fraunhofer Jahresbericht 2014

All of the 67 research institutes existing under the Fraunhofer umbrella are equal in terms of rank and status. A list of institutes is provided in Reference 1. Fraunhofer employs a dispersed control-type style in all aspects of institute management, as management of each institute is entrusted entirely to that institute's director. Headquarters plays no direct role. Each director has unlimited authority over his or her institute and autonomously manages all matters concerning the institute's operations, including the selection of research themes, applications for competitive funding, and personnel affairs.

Research is largely classified into seven groups. The Production Group, which is the oldest of the groups, has existed since Fraunhofer's establishment. The other groups cover Macroelectronics, Light & Surfaces, Life Sciences, Information and Communication Technology (ICT), Materials and Components, and Defense and Security. The research institutes are grouped according to their field, and their directors meet regularly within their respective groups. The main activities at regular meetings are information exchange and dialogue to identify those research topics that are receiving overly redundant attention and determine how market trends are being grasped among other matters. A certain amount of competition among institutes is welcome.

Almost all of the research institutes are located on or adjacent to a university's grounds. In general, the institute directors simultaneously serve as university professors; indeed, of the 79

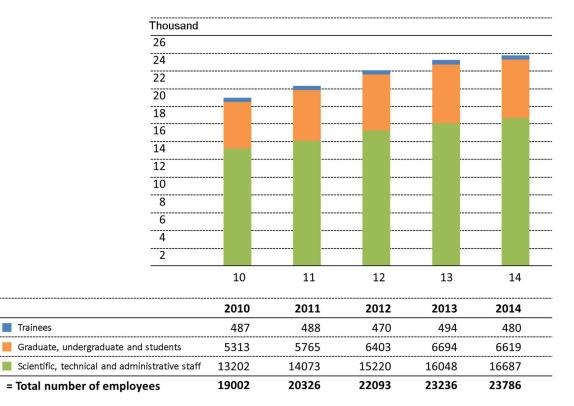
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directors (as of 2014),<sup>5</sup> 74 are professors. The way in which this occurs can take various forms. In some cases the director's work hours are set in advance by the university and Fraunhofer, while in others the director has already retired and serves as a professor emeritus or has been granted a research sabbatical from his or her university. More than simply ensuring physical proximity between universities and Fraunhofer, such arrangements expand opportunities for the master's and doctoral students who study under an institute director/professor to gain employment as fixed-term employees of Fraunhofer and thereby become actual assets for Fraunhofer. Only the directors serve dual roles; department heads and other employees do not have to work at universities.

Fraunhofer is currently an extremely popular employer. According to a ranking of popular employers that is prepared each year by the Swedish survey company UNIVERSUM,<sup>6</sup> a 2015 questionnaire survey of 34,000 graduates of natural science undergraduate programs (Germany) revealed that Fraunhofer ranked third behind Max Planck and Bayer (a German chemical and pharmaceuticals company). Fraunhofer also ranked fourth in questions to 7,800 researchers.

Figure 1-2: Change in number of employees

Grouwth in the Fraunhofer-Gesellschaft's workforce 2010-2014



Source: Prepared by CRDS based on Fraunhofer Jahresbericht 2014

 <sup>&</sup>lt;sup>5</sup> The total number of institute heads exceeds the number of research institutes, as some institutes have two heads.
 <sup>6</sup> http://universumglobal.com

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#### 1.3 Budget

## 1.3.1 Overview

Fraunhofer's research undertaken is comprised of contract research from industry; research that is based on competitive project funding from states, the federal government or EU; and voluntary research. The breakdown of research expenditures (actual values for 2014) reveals hat contract research accounted for 36%, competitive funds for 38%, and institutional funding for 26%. The allocation of personnel and effort is mainly entrusted to research institute directors and research department heads. As for why Fraunhofer conducts voluntary research, such research is in line with its mission of always returning and transferring cutting-edge technologies to society. Thus, in addition to its contract research, Fraunhofer proactively studies pre-competitive fields prior to industrial application and cultivates technical capability at levels that can be immediately provided as demanded by industry.

Fraunhofer's total 2014 budget was 2.006 billion euros, of which total R&D expenditure exceeded 1.7 billion euros. Although defense-related research was begun in the 1950s, the expenditure for such research is budgeted separately from other research. Today the federal government continues to provide 100% of the funds for such research. Defense-related expenditure was 118 million euros in 2014, or about 5% of the total budget.

The three main sources of Fraunhofer's total R&D expenditure are operational expenditure grants (440 million euros), research contract fees (620 million euros), and project funding and other forms of revenue (650 million euros). The contribution ratios for the operational expenditure grants, which cover some 30% of total R&D expenditure, are 90% from the federal government (90%) and 10% from state governments. Operational expenditure grants have been increasing during the past ten years by annual rates of 3% (2006 to 2010) and 5% (2011 to 2015) in accordance with policy based on the federal government's Pact for Research and Innovation that was initiated in 2006. The number of employees has roughly doubled since 2002 as a result.

In Germany, the *Länder* governments have jurisdiction over education, including universities. They provide operational expenditure grants to universities. However, in the case of Fraunhofer, the federal government contributes 90% of such grants. This arrangement allows Fraunhofer, which is a body of the central government that operates around "cross point" university professors, and local government universities to engage in collaboration in the truest sense of the word at the same or adjacent locations.

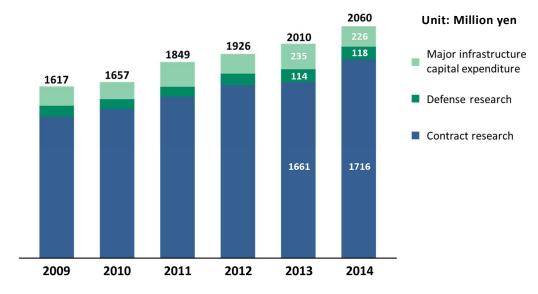
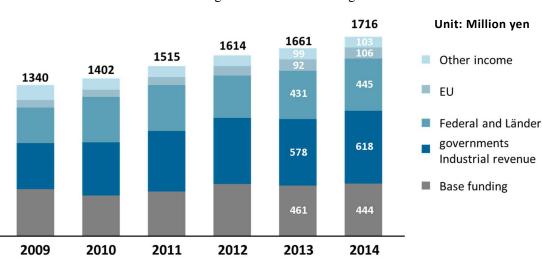


Figure 1-3: Overall budget<sup>7</sup>

Source: Prepared by CRDS based on Fraunhofer Jahresbericht 2014

## 1.3.2 Contract research

Fraunhofer handles some 9,000 cases of contract research (2012) annually. Two-thirds come from SMEs. And forty percent of Fraunhofer's contract research fees come from SMEs. Neither Fraunhofer's headquarters nor its research institutes have departments or personnel that handle sales to private enterprises. Much of Fraunhofer's contract research from enterprises comes in through personal connections.





Source: Prepared by CRDS based on Fraunhofer Jahresbericht 2014

<sup>&</sup>lt;sup>7</sup> Prepared based on Fraunhofer's presentation material "THE FRAUNHOFER MODEL: Business Development Manager Asia" (Munich, Feb. 16, 2015) and Annual Report.

<sup>&</sup>lt;sup>8</sup> Prepared based on Fraunhofer's presentation material "THE FRAUNHOFER MODEL: Business Development Manager Asia" (Munich, Feb. 16, 2015) and Annual Report.

## 1.3.3 Clusters

Outside of its contract research and independent research activities, Fraunhofer uses a mechanism in which multiple research institutes located in close proximity to each other form regional clusters with local universities and private enterprises in the state for joint research. This mechanism—called "innovation clusters"—was started in 2005. At the present time, twenty-five clusters are operating throughout Germany. The first innovation cluster was established on the theme of "mechatronics." It was built around the Fraunhofer Institute for Machine Tools and Forming Technology (IWU), located in Chemnitz in the state former East German state of Saxony, and included Chemnitz University of Technology and eight private enterprises. A factor behind the success of this cluster was that it achieved stable operation by applying the expanded operational expenditure grants through the aforementioned The Pact for Research and Innovation. In 2014, two national performance centers (nationale Leistungszentren) that grew out of this cluster were established in Freiburg im Breisgau, Baden-Württemberg, and Erlangen, Bavaria. It is anticipated that these centers will be more than venues for joint research by universities, research institutions, and private enterprises. By sharing the same roadmap, they are also expected to promote research, education, and human resources development; the construction of infrastructure; and the building of bases for innovation and technical transfer.

#### 1.3.4 Fraunhofer Alliances

Fraunhofer Alliances are cross-field groupings of research institutes that differ from the field-specific groups. They are organized for the purposes of identifying social issues and conducting research that contributes to their solution. They engage in joint research and joint application for competitive funds within Fraunhofer. Depending on the theme, one institute can participate in multiple alliances. In many cases, institutes come together to execute joint projects implemented at the sectoral level.

An example is the AdvanCer alliance. Formed some twenty years ago, this alliance is comprised of four Fraunhofer research institutes (Ceramic Technologies and Systems (IKTS), Production Systems and Design Technology (IPK), Silicate Research (ISC), and Mechanics of Materials (IWM). IKTS is entrusted with all contact functions and receives inquiries throughout Germany. Making use of the technical potential possessed by the four institutes in the areas of materials, ceramics technology, production technology, material mechanics, and fatigue strength, the alliance executes joint research as well as services involving the development and supply of customized system solutions for private enterprises. It also provides consulting and organizes seminars for SMEs, and creates opportunities for members of the general public to come into contact with new technologies and materials by establishing material and technology demonstration centers within the institutes.

The alliances existing within Fraunhofer as of the end of 2015 are listed in Reference 3.

## 1.4 Research management

#### 1.4.1 **Project management: From the IPA survey**

The individual research institutes are permitted to manage their own affairs to a large extent. Besides their management of contract R&D from the private sector, applications for project funding based on competitive funds, progress of own independent research, annual number of projects, personnel allocation, and other matters varies from institute to institute and department to department.

The following presents a discussion based on an interview that was conducted at Fraunhofer Institute for Manufacturing Engineering and Automation (IPA).<sup>9</sup> IPA is located in Stuttgart in southwest Germany. It has a total staff of some 1,000 people, 490 of whom are researchers. It is comprised of fourteen departments. With an annual budget of 60 million euros, it is the third largest institute under the Fraunhofer umbrella. One of the fourteen departments focuses on functional materials. Its four teams handle some sixty projects a year.

The department head monitors all activities in the department and engages in detailed progress management, delivery schedule management, and budget management (controlling). Each team leader is expected to achieve a good balance in terms of project content and use rate (contracts from industry). He or she establishes medium-sized projects of six months and then procures research fees from the private sector. If, for example, a team delivers the results of its research to the private sector in just two months and has no funds remaining to finance an additional project for the remaining four months, the leader instructs his or her team to make greater efforts to approach industry for new projects. On the other hand, if the team consistently procures at least 45% of its six-month research expenditure from the private sector, the leader instructs his or her team to engage in more scientific research. The leaders of projects established within a team must possess the qualities needed to formulate detailed project plans, set milestones and prepare concrete outcome targets, and manage and execute those activities. Many researchers have fixed-term contracts, and few are given firm promises that they will have a post in the future. Thus, IPA uses an employment model that is based on having individuals secure their own contracts and maintain their own posts.

IPA ascertains research level of a project's content using the Technical Readiness Levels (TRL).<sup>10</sup> It classifies planned projects between TRL 4 and 8 and achieves balance from more basic research to research at the patent acquisition level.

Additionally, IPA brings the fourteen department heads together to hold working meetings once a year. It applies the basic strategies that are prepared here into implementation plans. Quarterly discussions are held among department heads to determine whether or not the plans are being properly executed or require modification. Team leaders' meetings are held once monthly for the formulation of projects based on the implementation plans. Team leaders hold weekly meetings with team members to manage project progress. Budgetary meetings are also held on a monthly basis.

 <sup>&</sup>lt;sup>9</sup> Interview: Conducted in June 2015 with Ivica Kolaric, Dipl.-Ing. (FH), MBA (functional materials department).
 <sup>10</sup> According to the Technology Readiness Levels 1 to 9, Fraunhofer is positioned at the applied research levels, between levels 4 and 8. Universities are between levels 1 and 5 and industry is ranked between 7 and 9.

TRL is an indicator used to measure the readiness of new technologies. It is a nine-rank scale that is used to evaluate the level of development of new technologies based on systematic analysis. Level 1 is the closest to basic research, while level 9 is the closest to actual commercial application. TRL was developed by NASA in 1988 for the evaluation of space technologies. In Europe, it is applied to standards for evaluating research projects in Horizon 2020. A list of specific levels is provided below.

TRL indicator	Research stage	Level
TRL1	Basic research	Discovery of basic principles and phenomena
TRL2	Basic research	Formulation of principles and phenomena
TRL3		Experimental verification technical concepts
TRL4	Applied research	Technical verification at the laboratory level
TRL5	and development	Technical verification in assumed usage environments
TRL6	Verification	Verification and demonstration
TRL7	vermeation	Top user testing
TRL8	Drastical application	System completion and inspection
TRL9 Practical application		Mass production

#### 1.4.2 Researcher evaluation: From the IWS survey

The evaluation of researchers also varies from institute to institute. However, one point of general commonality among the institutes is that researchers are not evaluated based on the number of scientific papers they produce, as is the case in other research institutions and universities.

The following is a discussion of the methods used to evaluate researchers that is based on an interview that took place at the Fraunhofer Institute for Material and Beam Technology (IWS).<sup>11</sup> IWS is located in Dresden, Saxony. It was established in 1991 following the reunification of East and West Germany. It is a small research institute with a staff of some 500 employees, which includes research staff from the Dresden University of Technology. Roughly half are researchers.

IWS's researcher evaluations are based on the number of contract research projects that the researcher secures from private enterprises as well as the frequency and content of those projects. In other words, its evaluations focus on whether or not the researcher engages in intense communication with those in charge on the corporate side (i.e., IWS's clients) and client management. When a project ends, IWS conducts a questionnaire survey containing concrete questions that targets the contracting enterprise and gauges its level of satisfaction. It utilizes the results of this questionnaire in its researcher evaluations from the standpoint that client satisfaction with the delivered products and services and willingness to contract future research is the best indicator of client satisfaction.

Additionally, because the acquirement of patents has great significance in terms of Fraunhofer's future survival, IWS also includes efforts to patent research outcomes. Patents protect research outcomes that were achieved through contract research from enterprises. They are applied for and acquired with a long-term perspective to ensure the smooth application of those outcomes in future

<sup>&</sup>lt;sup>11</sup> Interview: Conducted in February 2014 with Prof. Dr. rer. nat. Andreas Leson (vice director).

production. Technical transfer takes place when many enterprises are allowed to use patents. IWS does not actively use revenue from license-related royalties as an indicator in researcher evaluation, as it does not anticipate that it will immediately receive license revenue from acquired patents.

IWS is continually studying the best possible evaluation indicators and regularly making improvements. It also views cases in which a fixed-term researcher advances his or her career by moving on to a better post in industry after serving in a research position at Fraunhofer as representing a good evaluation of that person.

## 1.5 The corporate partnership mechanism

Fraunhofer is well recognized as a model for partnerships with private enterprises in countries other than Germany. The following is a concrete presentation of the partnership mechanism.

#### 1.5.1 Technical transfer through circulation of human resources

Within Fraunhofer is a technical transfer system that is based on the circulation of human resources. Specifically, Fraunhofer hires talented young researchers on a fixed-term basis. After those researchers have gained experience and built personal connections, Fraunhofer sends them to industry. After they have moved on to industry, those same researchers commission R&D to Fraunhofer, thereby becoming Fraunhofer's clients. This circular model is the basic mechanism common in Fraunhofer's research institutes.

One factor that makes the mechanism possible is the system whereby 74 of the 79 institute directors simultaneously serve as university professors (as of the end of 2014). However, this does not represent a system that is unique to Fraunhofer, as similar measures are generally taken by other public research institutions in Germany. As a general rule, only institute directors serve dual roles; department heads and other employees need not take dual roles. There are exceptions after all, and in rare cases department heads are also university professors. In actuality, there are many cases in which master's and doctoral students who are affiliated with such professors' laboratories and who wish to engage in research at Fraunhofer for a salary sign employment contracts.

A second factor is young researchers' accumulation of research achievements at Fraunhofer. The researchers stay at Fraunhofer for between five and seven years on average. During their first and second years, they are entrusted with portions of projects or single issues of larger projects, and as a result gain experience as researchers with the achievement of each goal. Eventually they rise to positions that allow them to see projects in their entirety. In their third year, they are entrusted with small projects and expected to be able to manage delivery schedules, communicate with clients, and calculate profit and loss. Finally they are placed in supervisory positions as leaders of one or two major projects, where they experience a practical understanding of management. In this way, the researchers are required to improve not only knowledge but also experience as managers who can quickly grasp industrial trends. Additionally, the students who finish their doctoral thesis while also keeping a busy research schedule have value that is highly appreciated in the labor market when they seek employment.

In this way, the researchers who have accumulated experience at Fraunhofer move on by finding posts in companies in which they have built companionships through contracted projects or companies that have participated in clusters. This offers an advantage to industry as well, as the ability to hire researchers who have already acquired the required abilities and character through actual projects reduces risk during recruiting. Of Fraunhofer's 23,000 employees, some 7,800 are researchers, of which 5,800 are fixed-term employees. 830 researchers reached the end of their service at Fraunhofer. Many of them moved on to industry in 2014.

The young researchers and as well as the people at the department head and institute director level who move on to industry. Although some differences exist from state to state, nearly all universities in Germany make having a career of at least five years in industry a requirement when hiring engineering professors, and as a result many professors have employment experience in the private sector. In an environment in which human resources move about with great frequency, such career

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movement is seen in a positive light. Thomas Weber,<sup>12</sup> currently a member of the board of Daimler, was once simultaneously director of the previously mentioned Fraunhofer Institute for Manufacturing Engineering and Automation (IPA) and an engineering professor in the University of Stuttgart. Additionally, President Elmar Degenhart<sup>13</sup> of the automotive parts manufacturer Continental Corporation was head of IPA's robotics department in his previous post. Thus, a circular system exists in which researchers who leave Fraunhofer to join private enterprises become R&D supervisors who then place research orders with Fraunhofer. In Fraunhofer's words, this is "technical transfer achieved with the human brain."

Basically speaking, career paths at Fraunhofer come in the following three forms:

- (1) Internal promotion: Research employee  $\rightarrow$  group head  $\rightarrow$  department head
- (2) Research employee: An employee returns to university or transfers to the private sector after five to seven years of service. In many cases, this is because acquisition of a doctoral degree has become necessary.
- (3) Business startup

All Fraunhofer researchers have a specific field of technical expertise. Leaders must calculate profit and loss in terms of their own costs (personnel expenses) and sales of their research institute (team). In other words, if Researcher A has an annual salary of 100,000 euros, earning enough to cover this amount (i.e., his own personnel expense) is his most basic concern. To make that amount, Researcher A must actively engage in dialogue with industry and continually take on contract research from industry. A result of this pressure is the occurrence of technical transfer that links industry with Fraunhofer.

## 1.5.2 Research autonomy

Another characteristic aspect of Fraunhofer is the autonomy of its research institutes and strong authority possessed by institute directors. At least nominally, all 67 of its research institutes focus on different research themes. Of course peripheral overlap of fields creates some competition among institutes; however, such competition is actually welcomed rather than discouraged.

The directors of Fraunhofer's research institutes have great authority in such areas of institute operation, personnel affairs, and the selection of research themes. As was mentioned previously, the research institute directors also serve as university professors. They thus have heavy responsibilities and must possess capabilities as managers, for that reason have high social status Nonetheless, it is thought that it was this kind of dispersed and autonomous style of research institute operation that made Fraunhofer the success it is today. The headquarters never issues instructions on research themes in a top-down manner; instead, decisions concerning those themes are always made in a bottom-up manner by individual institutes. Fraunhofer's Munich headquarters' involvement in research activities is minimal. The research institute directors often communicate directly with policymakers of the federal and Länder governments, and they have a significant influence in the government's cluster program and industry-academia collaboration. Although this relationship sometimes creates a clash of interests between headquarters and individual institutes, like competition among institutes, such clashes are thought to create just the right amount of tension between the two sides. However, ultimate authority for the establishment of new research institutes and the abolition or merger of existing institutes rests with headquarters.

During the 1970s, the future of Fraunhofer became a subject of debate. Two issues that arose as a

<sup>&</sup>lt;sup>12</sup> Prof. Thomas Weber

<sup>&</sup>lt;sup>13</sup> Dr. Elmar Degenhart

result were that, as an applied research organization, Fraunhofer must always grasp market trends and respond to changes accordingly, and that it must proceed with research activities of the present by keeping an eye on future demand. It was concluded that, in order to achieve these aims, Fraunhofer must grasp market demands by listening directly to enterprises' opinions from a position of even greater proximity, and that creating a disperse organization rather than an intensive organization is the best way of achieving that. Such a dispersed control-oriented style is easily accepted in Germany, a country that has always used the federal system as its form of government. It is a methodology that has a culture of entrusting activities to individual components when those components can achieve established goals, and is likely a factor in the penetration of institute autonomy throughout the organization.

## 1.5.3 The contract-based Fraunhofer model

This final section will explain the "Fraunhofer model." It is a results-linked institutional funding framework whereby operational expenditure grants for the following year increase relative to contract research revenue from private enterprises. Generally speaking, this scheme—known as the Fraunhofer model—has been utilized without modification since it was approved by Germany's Cabinet in 1973. The key point is that, rather than being simply being based on proportion, whereby institutional funding increases in line with higher amounts of contract research, the scheme encourages institutes to actively accept contract research from private enterprises based on fulfillment of their missions as public research organizations, namely by implementing pre-competitive research and applying for project funding. Operational expenditure grants are comprised of four elements.

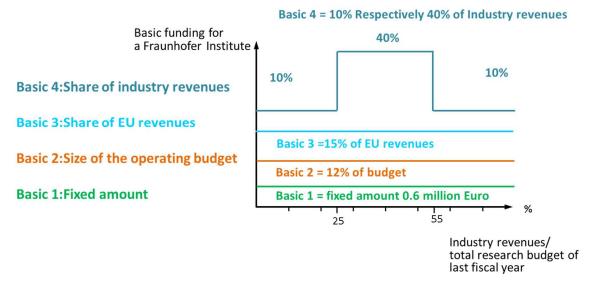
- Basic 1 Research funds of 600,000 euros that is distributed uniformly to all research institutes
- Basic 2 Research funds equivalent to 12% of the entire research budget of the previous year. The amount varies depending on the size of the research institute.
- Basic 3 The amount corresponding to contract research revenue from private enterprises is calculated as 10% when contract research revenue from the previous year falls below 25% of the research budget, 40% when it stands between 25% and 55%, and 10% again when it exceeds 55%.

Basic 4 15% of the amount of competitive funding accepted from the EU.

Of these, Basic 3 is a rule that is unique to Fraunhofer. The basis for this calculation is as follows: When contract research revenue falls below 25%, it is deemed that the research being undertaken by the institute does not have sufficient demand in the market. On the other hand, when this revenue exceeds 55%, it is deemed that the institute is overly partial to corporate R&D and is not sufficiently engaged in research that is consistent with its status as a public research institute.

Figure 1-5: Institutional funding to research institutes

## Allocation criteria for basic funding



Source: Prepared by CRDS based on Fraunhofer presentation materials

Within Fraunhofer, operational expenditure grants are used to in pre-competitive research to develop new strategic fields. Specifically, the grants are used in independent research by research institutes and to cover expenditure related to applications for competitive funds from the EU. As for the EU, the existing overhead rate for funding for applied research (25%) from Horizon 2020 was lowered, meaning that, for Fraunhofer, there is less incentive to acquire conventional EU project funding and increase operational expenditure grants. This is having an impact on fund procurement by many research institutes under the Fraunhofer umbrella.

In Germany, it has been decided to continue a policy of increasing operational expenditure grants to four public research institutions and the German Research Foundation from 2016 until 2020 based on the Pact for Research and Innovation that has been in effect since 2006 under the "High-Tech Strategy," a basic policy for S&T innovation. However, the rate of increase will be lowered from 5% to 3%. Accordingly, there is growing awareness within Fraunhofer that it must make greater efforts than universities and other research institutes to further improve its competitiveness and increase the amount it receives from outcome-linked operational expenditure grants.

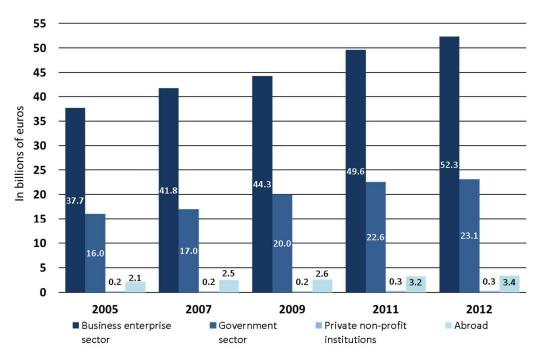
## 1.6 Outcomes

## **1.6.1** Fraunhofer, a trusted friend of German industry

R&D investment by German industry continues to be strong, even after the international economic slump that followed the 2008 bankruptcy of Lehman Brothers and the European currency crisis. In particular, there is growing demand for the Fraunhofer services that support R&D by SMEs, and as a result the number of contract research orders it receives from industry has continued to grow. Amid advancing globalization, individual SMEs have a difficult time catching up in terms of information and new technologies. It could be said that this has made Fraunhofer's role even more important. With the kind of corporate groupings that are characteristic of Japan's industrial structure nonexistent in Germany, SMEs account for more than 30%<sup>14</sup> of the country's exports. Accordingly, maintaining the international competitiveness of SMEs presents a major challenge for Germany.

Figure 1-6: Total R&D expenditure (changes by type of entity bearing cost)

Gross domestic expenditure on research and development (GERD), by funding sectors (implementation view) and GERD in % of the gross domestic product (2005-2013)



Source: Prepared by CRDS based on "Education and Research in Figures 2015"

Although Fraunhofer does not have the sales departments, this does not mean that it simply waits for contract research orders to come in from private enterprises. Fraunhofer always has its antenna on in search of industrial demand. For example, it establishes training courses on new technologies (at the "Fraunhofer Academy") for corporate engineers and managers and issues course certificates to those who attend. It also makes some of its facilities and equipment available to SMEs that have difficulty making frequent capital investment and enterprises that require inspection equipment for limited periods of time. Moreover, it provides services through which Fraunhofer's engineers provide support in inspections and processing. Through initiatives such as these, Fraunhofer gets a

<sup>&</sup>lt;sup>14</sup> METI, 2012 White Paper on International Economy and Trade

practical handle on corporate needs and makes steady efforts to link its understanding of those needs to future contract research.

For the private enterprises, Fraunhofer is not the only organization they can ask for technical development. However, with 67 research institutes located throughout Germany, it is extremely attractive for its ability to use this network to provide services in all technical fields. Additionally, for German SMEs that are active exporters, cooperation with Fraunhofer offers advantages. They acquire technologies and know-how, and also access information on joint businesses with overseas enterprises in which Fraunhofer has a stake as well as local information possessed by Fraunhofer's overseas offices.

#### 1.6.2 Human resources development

Germany sequentially executed a reform of its university system in line with its participation in the Bologna Process, a scheme to improve mobility by standardizing European university systems that was ratified in 1999. It abolished Germany's traditional degree (Magister) that required 11 semesters<sup>15</sup> until graduation (four and a half years) and replaced it with the bachelor degree that could be earned in between six and eight semesters and the master's degree requiring two to four terms. Moreover, in Germany, where university lessons are in effect tuition-free, it took a considerable amount of time for the average student to graduate. It was not uncommon for students to be in their thirties by the time they finished their magister program and earned their doctoral degrees. Consequently, industry strongly desired to have young, highly skilled human resources enter companies at an earlier stage.

At the present time, ten years since the Bologna Process was introduced, the mobility of students and instructors has improved greatly. However, many feel that, in terms of supplying highly skilled human resources to the labor market, the process's results has not lived up to expectations. In Germany, where people who have not only acquired knowledge but also mastered practical skills are valued, those who have the ability to step straight into business are in particularly high demand. Therefore, many private enterprises have the impression that graduates of the accelerated academic program lack the necessary skills.

Given this, the research experience available at Fraunhofer—a venue for vocational training for engineering-oriented master's degree students from around the country—is in the social spotlight. The fixed-term researchers stay in Fraunhofer for an average of five to seven years, and during that time they are engaged in practical R&D. In their third year, they manage projects as project leaders. An important duty at this time is communicating with the client companies. Additionally, because Fraunhofer's fixed-term researchers can participate in an in-house program to earn a doctoral degree, those researchers can become human resources with experience producing results as researchers and capable of fully grasping market needs by the time they "graduate" from the organization. Accordingly, those who leave Fraunhofer with the intention of gaining employment in industry enter an extremely favorable seller's market.

#### **1.6.3** Research papers and intellectual property

The research paper production is not used as an indicator when evaluating researchers at Fraunhofer. Moreover, researchers there have their hands full with daily research, which means that

<sup>&</sup>lt;sup>15</sup> A two-term (summer term and winter term) year is used. With the exception of some faculties, such as medical schools, students can enroll in either term.

those who seek an academic career do not have the time to carefully prepare research papers. However, Fraunhofer understands that doctoral theses are required by researchers who wish to capture better positions in R&D departments when they move to industry, and thus it has a mechanism in place to help students in their doctoral programs. A unique aspect of this is that researchers can select a theme based upon a concrete project and then write a doctoral thesis that adds scientific analysis to it. In 2014, 2,920 researchers were students in a doctoral program, and 620 doctoral theses were produced by them.

As for intellectual property, in principle, all patents generated from contract research belong to Fraunhofer. Exceptions—such as research results generated from feasibility studies on new materials or technologies that are far removed from practical application, even within contract research—are handled separately with contracts.

Of the 831 inventions that were produced in 2014, applications for new patents were made for 564, or 68%. Of the total of 6,618 inventions, 2,932 are registered as patents in Germany. A total of 3,526 of them are used in actually licensing. Fraunhofer was selected as one of the Thomson Reuters Top 100 Global Innovators as a result (2014). In 2014, the departments related to intellectual property evaluation and licensing were concentrated in the headquarters and placed under the board member in charge of technology management and business models. Until then, intellectual property that had been acquired by individual research institutes was managed in those institutes. However, Fraunhofer began efforts to translate patents into forms that are more easily useable in the market by integrating them into its headquarters and packaging them there. Annual licensing revenue grew 11% year-on-year to 129 million euros (2014), partially as a result of internal work to develop this system. Of this, revenue from licensing of MP3 patents exceeds 30 million euros on a single year basis. The revenue earned from licensing MP3-related intellectual property, which was a product of independent research, brings in enormous profits to Fraunhofer. However, all related intellectual property licenses will expire by 2017, and thus Fraunhofer is faced with the challenge of finding licensing revenue to cover this loss.

#### Column: Development of MP3

From the mid-1980s until the early 1990s, Fraunhofer Institute for Integrated Circuits (IIS) produced the MP3 audio file format, an advancement that made it possible to compress audio data into a file about one-tenth the conventional size while suppressing loss of quality. The idea for compressing audio files originated in research conducted at the University of Erlangen-Nuremberg. In 1987, IIS, which was adjacent to the university, launched a joint research team to conduct voluntary and independent research. This team eventually translated the idea into a commercial product. This episode is often mentioned as a successful case in which Fraunhofer reached beyond contract research from private enterprises to develop a university-produced seed into a technology that could be marketed and then incubate it into an international hit product. In actuality, Fraunhofer established the Fraunhofer Fund by investing one hundred million euros in patent licensing revenue that was generated by this invention as a portion of the principal (2007). Fraunhofer is implementing various initiatives to support the acquirement of patents throughout its organization and earn sustainable licensing revenue.

## 1.7 Future orientation

For more than 60 years that have passed since its founding, Fraunhofer has continually executed reforms both large and small and been reorganized as the times require. Moreover, its individual research institutes have adjusted their management policies and research fields as successive directors take control. It is therefore expected that Fraunhofer will continue to change flexibly going forward.

As Germany enters the 21st century, the roles that universities will play within its S&T circles is about to change. Amid decreasing operational expenditure grants from the states, a revision of the Basic Law for the Federal Republic of Germany at the end of 2014 made it possible for the federal government to contribute funds directly to universities if it receives state governments' consent. On the other hand, it appears that universities are steering toward directly accepting external funds, and particularly research funds from the private sector, to improve their fiscal health, and it is thought that they will take steps to further improve their research functions. In this sense, it is possible that Fraunhofer's position as an organization that bridges conventional basic research in universities and industry may change.

One possible direction that Fraunhofer may take is to further increase the contract research it receives from overseas enterprises and the overseas affiliates of German enterprises. At the present time, contract research fees from overseas account for about 25% of Fraunhofer's total research budget, and it is thought that a gradual increase in this percentage will be seen in the future. In its capacity as a public research institution of Germany, Fraunhofer should contribute to the creation of innovation by German enterprises. However, the opportunity for researchers to have their research achievements applied not only in Germany but also overseas enterprises should be welcomed. In reality, it was American and Japanese companies, not German that licensed MP3 technology and translated it into commercial products, and thus Fraunhofer's road to internationalization should not be a difficult one.

Another direction Fraunhofer may take is to promote venture startups using its research seeds. Fraunhofer started 16 businesses in 2014. Of these, it has made corporate investments and holds stock in four. There are concerns that businesses will compete with client SMEs, and there is debate about whether or not starting businesses from research that received public subsidies is fair. However, Fraunhofer's position is that transferring and returning technologies produced from business startups to society is proper. It is expected that the number of Fraunhofer-started ventures will increase with, for example, the preparation of a mechanism to support business startups using a portion of the above-mentioned MP3 licensing revenue.

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## 1.8 Implications to Japan

#### 1.8.1 A superior human resources development system

We examined Germany's Fraunhofer as an organization that embodies the kind of research translation functions that give form to basic research seeds and make them useable in the market as products and services. Through our examination, we discovered the core of this function is "people." Fraunhofer hires the master's and doctoral program students from universities and employs them as its main research personnel for five to seven years. During this time, they gain new knowledge and receive training for producing achievements against set deadlines in a high-pressure environment that constantly demands results. Moreover, they must acquire the ability to communicate with clients. For this, they learn practical knowledge of what industry demands, what solutions exist for addressing those demands, and what resources are available in giving clients the best possible results. Moreover, a cyclical process is in place whereby researchers who leave Fraunhofer to enter industry later ask Fraunhofer to conduct contract research on challenges that emerge in their employer's development of products and services. Researchers' post-Fraunhofer movement is not limited to major corporations, as many enter the R&D departments of the middle-sized enterprises ("Mittelstand"). This system produces advantages for SMEs, as it reduces recruitment risk because they can hire researchers who are already proven. And for students, as they can remain involved in R&D fields that interest them. It is thought that Fraunhofer-a human resources development organization that trains talented young personnel with the skills industry needs and then sends them into the workforce—represents a system that can provide useful hits to Japan, a country that is looking for ways of utilizing postdoc personnel in industry. In Fraunhofer's case, its system achieves human resource circulation, as its sending of researchers out to industry is not the end of the story. Those same researchers later ask Fraunhofer to take on research and, in some cases, return to its research as university instructors. According to a survey conducted in Germany, less than half of all students in doctoral programs are striving to earn their degree in order to build an academic career. The majority want their PhD to help them find employment in industry. Two-thirds of doctoral degree candidates in Germany pursue their research while also working as assistants in their university. As the remaining one-third conduct research in private enterprises or research institutes, the example of Fraunhofer is just one part of German society.

#### 1.8.2 Priority on regional needs

Additionally, Fraunhofer has a deep relationship with state universities and local industries. It has close physical proximity to universities, as its institutes are located on and near university grounds and university professors serve dual roles within the institutes. Moreover, whenever a new Fraunhofer research institute is established, the state government is required to pay operational expenditure grants on its own for the first five years. After that, the burden of payment becomes 90% for the federal government and 10% for the state if the institute's size is maintained, the institute can be expected to generate revenue, and an agreement between the state and federal government is reached. In other words, it is the state governments' responsibility to build infrastructure necessary to open institutes, and as a result they only invite those institutes that are truly needed by the state government and state industries. Thus, in this case, bridging of industry, academia, and governments only occurs when not only universities, research institutes, and industry but also state governments and even the federal government work together.

## 1.8.3 Shortening the time from applied research to market introduction

According to marketing theory, within the product life cycle, the time between invention to market introduction can take as many as seven years, and the time from applied research to market introduction takes about five years. Through our onsite interviews, we found that Fraunhofer sees the time between applied research and market introduction to be eighteen months. It undoubtedly takes time to link seeds generated from basic research to commercialization through the processes of pre-competitive research and applied research. If Fraunhofer can achieve this in just eighteen months, it is turning conventional thinking on its head. The only way it can do this is by constantly grasping where market needs exist and considering which seeds can be applied to meet them.

## **Reference 1**

List of research institutes

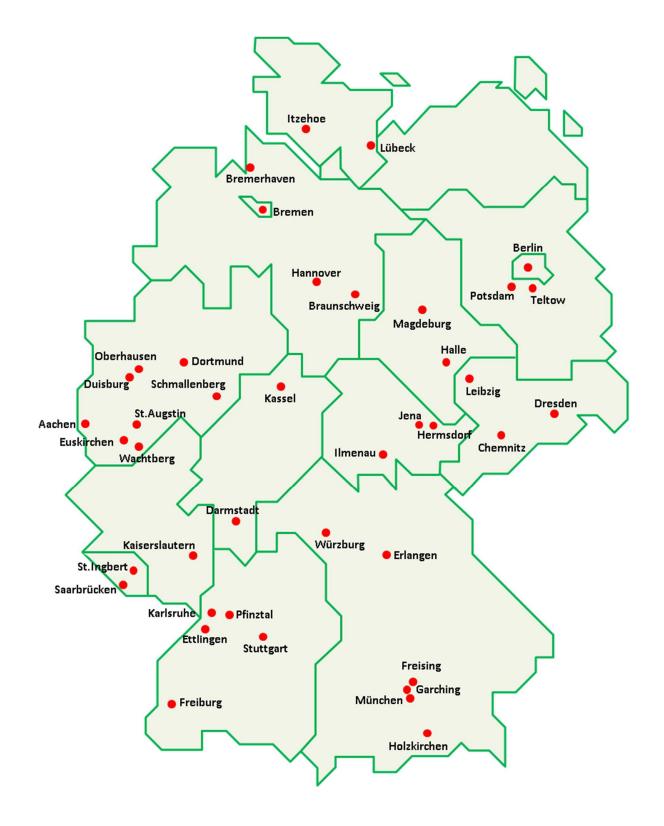
Research institute	Abbreviation	Location
Fraunhofer Institute for Applied and Integrated Security	AISEC	Munich
Fraunhofer Center for Maritime Logistics and Services	CML	Hamburg
Fraunhofer Research Institution for Marine Biotechnology	EMB	Lübeck
Fraunhofer Research Institution for Microsystems and Solid State Technologies	EMFT	Munich
Fraunhofer Institute for High-Speed Dynamics, Ernst-Mach-Institut	EMI	Freiburg im Breisgau, others
Fraunhofer Institute for Electronic Nano Systems	ENAS	Chemnitz
Fraunhofer Institute for Embedded Systems and Communication Technologies	ESK	Munich
Fraunhofer Institute for Organic Electronics, Electron Beam and Plasma Technology	FEP	Dresden
Fraunhofer Institute for High Frequency Physics and Radar Techniques	FHR	Wachtberg
Fraunhofer Institute for Applied Information Technology	FIT	Sankt Augustin
Fraunhofer Institute for Communication, Information Processing and Ergonomics	FKIE	Wachtberg
Fraunhofer Institute for Open Communication Systems	FOKUS	Berlin
Fraunhofer Heinrich Hertz Institute	HHI	Berlin
Fraunhofer Institute for Applied Solid State Physics	IAF	Freiburg im Breisgau
Fraunhofer Institute for Intelligent Analysis and Information Systems	IAIS	Sankt Augustin
Fraunhofer Institute for Industrial Engineering	IAO	Stuttgart
Fraunhofer Institute for Applied Polymer Research	IAP	Potsdam
Fraunhofer Institute for Biomedical Engineering	IBMT	Sankt Ingbert, others
Fraunhofer Institute for Building Physics	IBP	Stuttgart, Holzkirchen
Fraunhofer Institute for Chemical Technology	ICT	Pfinztal
Fraunhofer Institute for Digital Media Technology	IDMT	Ilmenau
Fraunhofer Institute for Experimental Software Engineering	IESE	Kaiserslautern

Fraunhofer Institute for Manufacturing Technology and Advanced Materials	IFAM	Bremen, Dresden
Fraunhofer Institute for Factory Operation and Automation	IFF	Magdeburg
Fraunhofer Institute for Interfacial Engineering and Biotechnology	IGB	Stuttgart
Fraunhofer Institute for Computer Graphics Research	IGD	Darmstadt, Rostock
Fraunhofer Institute for Integrated Circuits	IIS	Erlangen, Dresden
Fraunhofer Institute for Integrated Systems and Device Technology	IISB	Erlangen
Fraunhofer Institute for Ceramic Technologies and Systems	IKTS	Dresden
Fraunhofer Institute for Laser Technology	ILT	Aachen
Fraunhofer Institute for Molecular Biology and Applied Ecology	IME	Aschen, Schmallenberg
Fraunhofer Institute for Material Flow and Logistics	IML	Dortmund
Fraunhofer Institute for Microelectronic Circuits and Systems	IMS	Duisburg
Fraunhofer Institute for Technological Trend Analysis	INT	Euskirchen
Fraunhofer Institute for Applied Optics and Precision Engineering	IOF	Jena
Fraunhofer Institute for Optronics, System Technologies and Image Exploitation	IOSB	Karlsruhe, Ettlingen, others
Fraunhofer Institute for Manufacturing Engineering and Automation	IPA	Stuttgart
Fraunhofer Institute for Production Systems and Design Technology	IPK	Berlin
Fraunhofer Institute for Physical Measurement Techniques	IPM	Freiburg im Breisgau
Fraunhofer Institute for Photonic Microsystems	IPMS	Dresden
Fraunhofer Institute for Production Technology	IPT	Aachen
Fraunhofer Information Center for Planning and Building	IRB	Stuttgart
Fraunhofer Institute for Silicate Research	ISC	Würzburg
Fraunhofer Institute for Solar Energy Systems	ISE	Freiburg im Breisgau
Fraunhofer Institute for Systems and Innovation Research	ISI	Karlsruhe
Fraunhofer Institute for Silicon Technology	ISIT	Itzehoe

Fraunhofer Institute for Software and Systems Engineering	ISST	Dortmund
Fraunhofer Institute for Surface Engineering and Thin Films	IST	Braunschweig
Fraunhofer Institute for Toxicology and Experimental Medicine	ITEM	Hanover
Fraunhofer Institute for Industrial Mathematics	ITWM	Kaiserslautern
Fraunhofer Institute for Transportation and Infrastructure Systems	IVI	Dresden
Fraunhofer Institute for Process Engineering and Packaging	IVV	Freising
Fraunhofer Institute for Wind Energy and Energy System Technology	IWES	Bremerhaven, Kassel
Fraunhofer Institute for Mechanics of Materials	IWM	Halle
Fraunhofer Institute for Material and Beam Technology	IWS	Dresden
Fraunhofer Institute for Machine Tools and Forming Technology	IWU	Chemnitz, Dresden
Fraunhofer Institute for Nondestructive Testing	IZFP	Saarbrücken
Fraunhofer Institute for Cell Therapy and Immunology	IZI	Leipzig
Fraunhofer Institute for Reliability and Microintegration	IZM	Berlin
Fraunhofer Institute for Structural Durability and System Reliability	LBF	Darmstadt
Fraunhofer Institute for Medical Image Computing	MEVIS	Bremen
Fraunhofer Center Leipzig	MOEZ	Leipzig
Research Division Polymeric Materials and Composites	РҮСО	Teltow
Fraunhofer Institute for Algorithms and Scientific Computing	SCAI	Sankt Augustin
Fraunhofer Institute for Secure Information Technology	SIT	Darmstadt, Sankt Augustin
Fraunhofer Institute for Environmental, Safety, and Energy Technology	UMSICHT	Oberhausen, others
Fraunhofer Institute for Wood Research Wilhelm-Klauditz-Institut	WKI	Braunschweig

## **Reference 2**

Distribution of Fraunhofer research institutes (Small-scale facilities, such as research centers and units, are excluded.)



- 1. Itzehoe
- 2. Lübeck
- 3. Bremerhaven
- 4. Bremen
- 5. Hanover
- 6. Braunschweig
- 7. Oberhausen
- 8. Duisburg
- 9. Aachen
- 10. Euskirchen
- 11. Wachtberg
- 12. Dortmund
- 13. Schmallenberg
- 14. Sankt Augustin
- 15. Kassel
- 16. Berlin
- 17. Magdeburg
- 18. Potsdam
- 19. Teltow
- 20. Halle
- 21. Leipzig

- 22. Dresden
- 23. Jena
- 24. Ilmenau
- 25. Hermsdorf
- 26. Chemnitz
- 27. Erlangen
- 28. Würzburg
- 29. Darmstadt
- 30. Kaiserslautern
- 31. Sankt Ingbert
- 32. Saarbrücken
- 33. Karlsruhe
- 34. Ettlingen
- 35. Pfinztal
- 36. Stuttgart
- 37. Freiburg im Breisgau
- 38. Freising
- 39. Munich
- 40. Garching
- 41. Holzkirchen

## **Reference 3**

List of research alliances

Alliance name	Research focus	No. of research institutes
Adaptronics	Functions whereby physical properties (e.g., shape or rigidity) change automatically and "adapt" on their own to changes in environment or situation.	6
Additive Manufacturing	Processes for manufacturing designs, parts, and components	11
AdvanCer	High-performance ceramics research. Fields of application: antifriction bearings and medical implants	4
Ambient Assisted Living	System solutions for safe and secure living, energy conservation, labor, health, and social networks	11
Automobile Production	Energy conservation and cost reduction based on concepts oriented toward realizing a sustainable motorized society	18
Battery	R&D on storage batteries and super condensers	19
Building Innovation	Design of highly energy efficient buildings and energy savings-based urban planning	16
Big Data	Focus on not only manufacturing and transport fields but also application of R&D fields	26
Cloud Computing	Security and software services for use of out-of-company infrastructure services and cloud computing	6
Digital Cinema	System solutions in such areas as cameras, storage, audio, and post production for digital movies	4
Embedded Systems	Embedded systems for automobiles, machine tools, medical equipment, and audiovisual devices	12
Energy	Renewable energy, technology for energy efficiency, smart grid, storage batteries, etc.	19
Food Chain Management	Research on all aspects of the manufacture-sales-consumption cycle for preservation of safe and high-quality foods	12
Lightweight Design	Research on component structures that combine rigidity, dynamic stability, strength, and lightness	15
Nanotechnology	Crosscutting technologies for materials, components, systems, and functions that apply special properties (scale of <100 nm)	19
Numerical Simulation	Simulation of products and manufacturing processes	17
Photocatalytic coating systems having special characteristics, such as self-cleaning, antibacterial, and antifouling properties		6
Polymer Surfaces	Research on modification of polymer surfaces to develop new compounds	7
Cleaning Technology	Cleaning and cleansing technologies and processes for sectors ranging from historical structures to hygiene	8

Space	Space-related technologies with anticipated applications in weather forecasting, navigation systems, satellite television and global internet use	15
Water Systems	Sustainable waterworks and sewerage infrastructure and system solutions	11
Traffic and Transportation	Traffic sector systems for automobiles, railroads, aviation, shipping, etc., based on market needs	15
Vision (Image Processing)	Research in optical measurement and automatic inspection technologies, including the spectrum from infrared rays to x-rays and sensor applications	16

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- Fraunhofer Gesellschaft e.V. https://www.fraunhofer.de/
- Fraunhofer Representative Office Japan http://www.fraunhofer.jp/
- Website of the Federal Ministry of Education and Research (BMBF) https://www.bmbf.de/

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# Chapter 2: The Clinical and Translational Science Awards Program of the National Institutes of Health, USA

Although the importance of "translational research"<sup>16</sup> in achieving innovation in medicine has been underlined, the implementation of effective research assistance has proven to be a major challenge for public funding organizations in major countries. This chapter will give an overview of the current state of and challenges facing the Clinical and Translational Science Awards (CTSA) program under the National Institutes of Health (NIH). It will also present trends in the establishment of research and innovation hubs for medicine of the United States.

## 2.1 Background

## 2.1.1 Expansion of the NIH budget

With an annual budget of \$30 billion (more than roughly 3 trillion yen), NIH is the world's largest medical research and support organization. Approximately 80% of the NIH's budget goes to researchers at universities and research hospitals that are outside NIH through grants, research contracts, and educational programs. As for the purpose of spending, more than 50% of the NIH's research budget is allocated to support for basic research. The rest is used to support clinical research, including clinical trials.

It is worth noting that the NIH's budget has undergone a rapid expansion since the 1980s. In 1987, the budget was around \$6 billion, but by 2015 it had grown five-fold to roughly \$30 billion. Behind this expansion was that, from the mid-1980s into the 1990s, medical research with public funds lagged in comparison with investment in drug discovery research by industry and the effects that such research had on the American economy. The increase in the NIH's budget was made to rectify this situation with public funds.<sup>17</sup> It has also been asserted that rapid advancements in genetics, including molecular biology and decoding of the human genome, from the mid-1990s into the 2000s generated increasing public expectation for new medical research and the development of treatments, and that this was an additional factor behind the budget increase.<sup>18</sup>

#### 2.1.2 Lack of cooperation between basic researchers and physicians

A number of challenges have come to light with the growing NIH budget, and one of them is translational research. The NIH budget has mainly been allocated to basic research. However, the processes for translating much of the knowledge gained from basic to actual clinical activities are insufficient. In recent years, the fact that investments of national expenditure have not brought adequate advancements in the public's health has attracted Congressional attention.

Efforts to accelerate translational research absolutely require cooperation between basic researchers and physicians who work in actual medical settings. However, frameworks for cooperation between the two sides had been deficient in many American research institutes. One possible factor behind this was the rapid advancement in molecular biology that began in the 1970s. This development led many basic researchers in the field of molecular biology who were not

<sup>&</sup>lt;sup>16</sup> The term "translational research" as it is used here is broadly defined as extending from basic research and pre-clinical research to bridging to research (clinical research) on humans and bridging of clinical trial results and approved drugs to clinical practice. IOM (2013) *The CTSA Program at NIH: Opportunities for Advancing Clinical and Translational Research*. National Academy Press: Washington, D.C.

H.Con.Res. 284 (105th): Budget resolution FY1999 https://www.govtrack.us/congress/bills/105/hconres284/text
 Smith, P. (2006) "The National Institutes of Health (NIH): Organization, Funding, and Congressional Issues", CRS Report for Congress. The Library of Congress: Washington D, C. http://www.nih.gov/about/director/crsrept.pdf p.15

physicians to participate in medical research. A look at concrete data reveals that, in the 1970s, the ratio of successful researchers for NIH grants was 5:10:3 for physicians (MDs), basic researchers (PhDs), and persons classified as both, respectively; however, this ratio changed to 2:7:1 by 2005. This shows a rapid increase in the percentage of basic researchers engaged in medical research.<sup>19</sup> A framework for supporting clinical research had been promoted within NIH from the 1960s. However, in general, this framework was limited to clinical trials by physicians. It was not designed to encourage cooperation between basic researchers in microbiology and other fields, whose numbers increased from the 1970s, and clinical researchers.<sup>20</sup> The result is that research cooperation between physicians and basic researchers has ceased.<sup>21</sup>

## 2.1.3 Delayed response to data-driven medical research

Another problem is the slow response to data-driven medical research that makes great use of genetic sequence and information engineering. Since 2000, the costs of genetic sequence have fallen at a dramatic pace. In 2001, the per-person cost for human genome sequence was about \$100 million, however today the cost is falling rapidly to below \$1,000. The data obtained from such analyses has greatly expanded our understanding of the molecular pathogenesis of disease.<sup>22</sup> Additionally, advancements in imaging technology and application of informatics have spurred the use of big-data in medical research at an unprecedented pace. At the same time, much of the medical data utilized in clinical settings has been digitized, thus expanding the possibilities for their use in research. Against this backdrop, there has been growing need to train researchers in bioinformatics who can lead data-driven medical research as well as researchers in clinical statistics who can actually analyze patient data using statistical methods. Unfortunately, however, many research institutes have not been equipped to sufficiently support human resources development.

<sup>&</sup>lt;sup>19</sup> Butler, D. (2008) "Crossing the Valley of Death", *Nature*, 12(453), pp. 840-842.

<sup>&</sup>lt;sup>20</sup> Zerhouni, E. A. (2005) "Translational and Clinical Science – Time for a New Vision", *New England Journal of Medicine*, 353(15), pp. 1621-1623.

<sup>&</sup>lt;sup>21</sup> Ibid.

<sup>&</sup>lt;sup>22</sup> NIH. (2015) NIH Wide Strategic Plan: Fiscal Years 2016-2020. NIH.: Washington, D.C.

## 2.2 The CTSA program

Dr. Elias Zerhouni, who was named NIH Director in 2002, approved the establishment of the Clinical and Translational Science Awards (CTSA) program in 2006 to resolve the above-mentioned issues.<sup>23</sup>

## 2.2.1 Outline and objectives

The purpose of CTSA is to build a foundation for integrated translational research in academic institutions and hospitals. Specifically, it has the five objectives mentioned below. NIH uses three means to achieve these objectives within the CTSA program; namely, infrastructure development, postdoctoral support, and training of predoctoral researchers. Particularly important among these is infrastructure development. It specifically includes maintenance of governance, development of scientific infrastructure (i.e., development of research environments using informatics, support for interdisciplinary research, and strengthening of relationships with the patient community), and establishment of advisory programs (biostatistics, epidemiology, and regulatory science).<sup>24</sup>

## (1) Human resources development

This refers to the training of personnel for translational research. In addition to covering academic content concerning basic and clinical research, the program strives to develop human resources through instruction on preparation of research plans, grant application, regulatory science, and biomedical ethics among other topics.

(2) Cooperation with interested parties and cooperation among research hubs

Cooperation between research hubs and local/interested parties (e.g., universities, industry, patients' groups and citizens, and state governments) as well as cooperation among research hubs are essential for the linier implementation of translational research. Given this, when NIH establishes hubs within the CTSA program, it must gain as much participation as possible from patients and their families, industry, charitable organizations, disease-specific patients' organizations, local medical institutions, and non-medical organizations (e.g., race advocacy groups, human rights organizations, etc.). Specific approaches here include hiring external interested parties on a part-time basis to serve on an advisory council that gives advice to the hub or to serve as lecturers in the curriculum for hub researchers.

## (3) Development of an integrated research environment

In addition to cooperation between basic and clinical researchers, translational research particularly requires a crosscutting research structure that includes the participation of researchers with expertise in pharmacology, informatics, and statistics. Under the CTSA program, NIH promotes the participation of such experts with small-scale hub-specific competitive funds called "pilot grants" that can be managed (in terms of the size and purpose) at the discretion of individual hubs.

(4) Development of methodologies and research processes

One of the NIH's purposes for establishing the CTSA program is to develop methodologies and research processes for translational research. To achieve it, consultation desks are set up at hubs to

<sup>&</sup>lt;sup>23</sup> Zerhouni, E. A. (2005) Op., cit.

<sup>&</sup>lt;sup>24</sup> Department of Health and Human Services: Part 1 Overview Information, accessed 24 December 2015. http://grants.nih.gov/grants/guide/pa-files/PAR-15-304.html

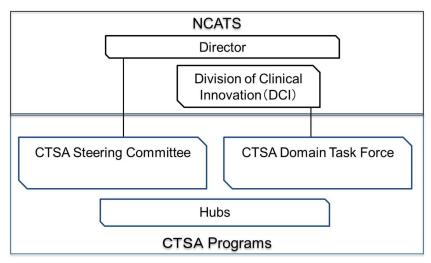
provide practical advice on such matters as biostatistics, epidemiology, and pharmaceutical regulations (regulatory science).

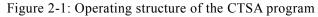
(5) Promotion of informatics that facilitates translational research

The development of informatics-based research infrastructure is a core objective of the CTSA program. This specifically requires the development of infrastructure for various forms of data (e.g., electronic medical information, such as diagnostic information, and data from genetic analyses made using biological samples) and of environments for the integrated use of research, as well as the building of data teams to maintain them at hubs. When creating databases of different types, it is important to build a system that will allow researchers to access information in as centralized a manner as possible. Thus, the handling of information statistics within medical research in the "big-data" era, which includes the development of statistical software that facilitates research by onsite clinical researchers, is one of the CTSA program's highest priorities.

## 2.2.2 NCATS and DCI

The organization within the NIH that oversees the CTSA program is the National Center for Advancing Translational Science (NCATS). The NCATS was established in 2012 to accelerate translational research following the enactment of the National Institutes of Health Reform Act (2006). The NCATS division having jurisdiction over the CTSA program is the Division of Clinical Innovation (DCI). (See Figure 2-1.)





NCATS supports both internal research and external research. Its budget request for FY2017 amounts to approximately \$690 million, of which approximately 80% will be allocated to the CTSA program.<sup>25</sup> NCATS's first director, Dr. Christopher Austin, was appointed to the position because he has succeeded in basic research, clinical research, and industry and is highly trusted by the NIH's director.<sup>26</sup> From this, it is apparent that the first person to take charge of the newly established NCATS needed to have broad experience handling the complex undertakings involved in translation research.

<sup>&</sup>lt;sup>25</sup> Department of Health and Human Services National Institutes of Health National Center for Advancing Translational Sciences (NCATS), Budget. http://www.ncats.nih.gov/about/center/budget.

<sup>&</sup>lt;sup>26</sup> Wadman, M. (2013)'Translational Research: Medicine Man', *Nature*. 494(7435). pp. 24-26.

The person in charge of DCI, which is the department that has direct jurisdiction over the CTSA program, is Dr. Petra Kaufmann. Dr. Kaufmann has simultaneously served as the director of the program and of the Office of Rare Diseases Research, another NCATS division, since 2015. Prior to taking the position, she headed the Office of Clinical Research at the National Institute of Neurological Disorders and Stroke (NINDS), where she was in charge of the planning and implementation of large-scale clinical trials for neurological disorders and rare diseases. After earning her doctor of medicine degree at the University of Bonn in Germany, she earned a master's of science degree in biostatistics from Columbia University's Mailman School of Public Health.<sup>27</sup> Dr. Kaufmann is one of a total of twelve people who currently comprise DCI.<sup>28</sup>

## 2.2.3 Advisory bodies of NCATS

#### (1) Steering Committee

A program Steering Committee is set up below the NCATS director (Figure 2-1). The committee meets three times a year. As of February 2015, it is comprised of 18 members. The members include 12 persons of responsibility (ordinarily Principal Investigators [PI]) who were selected from 62 research hubs adopted under the CTSA program in 31 US states. They also include one person each from four NIH research centers that are other than NCATS (National Cancer Institute, National Institute of Neurological Disorders and Stroke, National Institute of Arthritis and Musculoskeletal and Skin Diseases, and National Center for Complementary and Integrative Health); one person from the Food and Drug Administration (FDA), which is in charge of pharmaceutical affairs and approvals; and one person from a private-sector organization of Parkinson's disease patients.<sup>29</sup>

The Steering Committee's roles are to reinforce collaboration with the people in charge of hubs (hub head: PI), assist in strategic decision-making by NCATS, and provide advice to the CTSA Domain Task Forces to be described below.

#### (2) CTSA Domain Task Forces

The CTSA Domain Task Forces are organized into five fields: Workforce Development, Collaboration/Engagement, Methods/Processes, Integration across the Lifespan, and Informatics. Their duties are to share successful cases with hubs and promote joint research among hubs.

Each of the task-forces is managed by six leaders, five of whom come from hubs and the remaining one is a NCATS staff member. The rest of the membership is comprised of one representative who possesses expertise in a related field from each of the more than 60 hubs. Accordingly, each task-force is comprised of nearly 70 people in total. Responsibility for setting the operating policy of each task-force is entrusted to the six leaders. The task-forces are required to give a report on their activities at the CTSA annual meeting.<sup>30</sup>

## 2.2.4 Budget

(1) Overview

As is shown in Figure 2-2, the CTSA program's budget has amounted to between \$460 and \$470 million a year since FY2012. Twelve hubs were selected when the program was launched in FY2006.

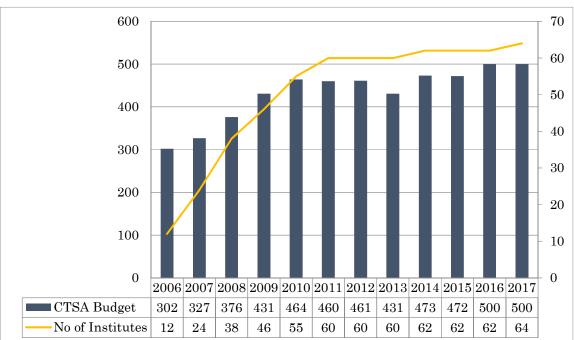
<sup>&</sup>lt;sup>27</sup> Staff Profile: Petra Kaufmann, accessed 24 December 2015. http://www.ncats.nih.gov/staff/kaufmanp2

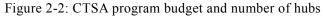
 <sup>&</sup>lt;sup>28</sup> Division of Clinical Innovation Staff, accessed 24 December 2015. http://www.ncats.nih.gov/about/center/org/dci
 <sup>29</sup> Six PIs are replaced each year. Austin, C., and Kaufmann, P. (2015) 'Clinical and Translational Science Award

Program in the Division of Clinical Innovation', Presentation at *CTSA Principal Investigator Meeting*. 3-4 February, NCATS, Washington, D.C.

<sup>&</sup>lt;sup>30</sup> CTSA Central. *Domain Task Force*, accessed 24 December 2015. https://ctsacentral.org/consortium/domain-task-forces/

Later, more CTSA hubs were certified as the program's budget grew. As of November 2015, the number of hubs operating under the CTSA program is 62. These hubs are located in 31 states.





<sup>31</sup>Unit: US dollars; data for 2006 to 2015 are actual performance, for 2016 are estimated, and for 2017 are from the budget draft

Source: Prepared by CRDS based on "Overview of FY2017 President Budget"

Each hub certified under the CTSA program ordinarily receives between roughly \$3 million and 7.5 million a year for five years to develop its translation infrastructure. In addition to this, it receives funds for postdoc support as well as support for training of predoctoral researchers that are matched to the size of the infrastructure development budget.<sup>32</sup> Figure 2-2 also shows that the number of hubs has not changed significantly in recent years. However, in FY2015, for example, eighteen organizations were newly certified as hubs. Thus, it can be seen that, among the hubs, there are those that continue to be selected for the program and those that are not following the end of the five-year support period.<sup>33</sup>

## (2) The case of the Duke University hub

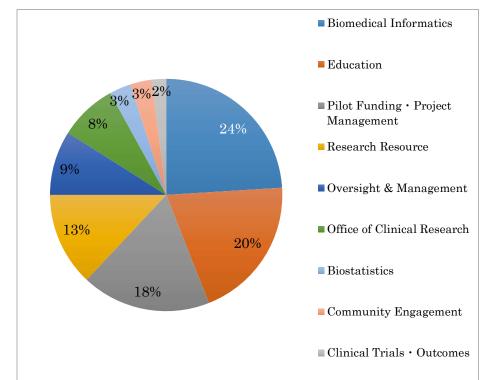
Figure 2-3 presents a budgetary breakdown for the CTSA hub in Duke University. Because the development of human resources, technical development, and establishment of data systems in the field of medical informatics are stressed here, investment into these fields has relatively high weight within the budget. Recruiting researchers who are proficient in informatics is important in the

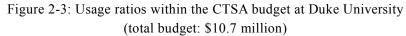
<sup>&</sup>lt;sup>31</sup> NIH Office of Budget. (2016) Overview of FY2017 President Budget. and Austin, C. (2015) 'National Center for Advancing Translational Sciences: Catalyzing Translational Innovation', Presentation at IOM CTSA Review Committee, 24 January 2013. NCATS: Washington. D.C.

<sup>&</sup>lt;sup>32</sup> Department of Health and Human Services: Part 1 Overview Information, accessed 24 December 2015. http://grants.nih.gov/grants/guide/pa-files/PAR-15-304.html

<sup>&</sup>lt;sup>33</sup> NCATS Announces CTSA Program Hub Awards to Help Transform How Clinical and Translational Science Is Conducted Nationwide, accessed 24 December 2015. http://www.ncats.nih.gov/news/releases/2015/ctsa-ul1-awards

development of hubs for CTSA selection, and thus efforts to acquire such researchers are becoming increasingly active among hubs.





Source: Prepared by CRDS based on Duke Translational Medicine Institute (2015), *Duke CTSA Accelerating* the Journey from Idea to Innovation. DTMI: NC.

## (3) Weight of the CTSA budget within hubs

The organizational operation of CTSA hubs is not supported solely by NCATS. In fact, CTSA funds account for only a portion of hub budgets. The breakdown of overall hub income varies from hub to hub. However, the following presents an example using a particular university. The FY2016 budget for the university's hub was approximately \$15 million (roughly 1.8 billion yen). Of this amount, approximately \$3 million, or 20%, was support provided by the CTSA program, approximately \$3 million was support provided from within the university (support by the university's health center), and approximately \$3 million came from another source of support from within the university (university research office). The rest came in the forms of approximately \$3 million in support from various and diverse faculties and local colleges, approximately \$2 million (13%) from fees for services provided by the hub, and approximately \$1 million (7%) as repayment of indirect expenditure from the university. In other words, although support from the CTSA program is important as initial investment for hub development, continually securing other income sources becomes essential for maintaining the hub's operation.

## 2.2.5 Target fields and development stages of targeted research

The CTSA program is not concerned with promoting R&D for specific diseases or technical fields. Rather, what is required is the building of infrastructure that can support the promotion of translational research for all diseases.<sup>34</sup> Because efforts to promote research in particular diseases are supported by disease-specific Institutes and Centers of NIH (such as the National Cancer Institute), universities and others are encouraged to promote the establishment of CTSA hubs in cooperation with those efforts.

On the other hand, there are R&D stages that particularly underlined under the CTSA program. Translational research covers an extremely broad scope that includes basic research, clinical research, drug approval, and post-marketing evaluation studies. However, the research stage that is particularly stressed in the CTSA program is first-in-man study, where the results of pre-clinical research that was conducted with animals and samples originating from humans, are applied to human. This first involves clinical trials that evaluate safety in humans (so called phase-I trial) and then trials that evaluate the drug's efficacy with patients (phase-II trial).<sup>35</sup> However, in the case of clinical trials conducted with pilot-grants (small-scale research grants for acquiring initial research data) that are managed within individual hubs, projects need to be limited to just the initial stage of phase-II trials.<sup>36</sup>

<sup>&</sup>lt;sup>34</sup> An exception is AIDS research. In this case, mentioning translational research initiatives that are specially focused on AIDS research when planning a hub undertaking is permitted.

<sup>&</sup>lt;sup>5</sup> IOM (2013) Op., Cit.

<sup>&</sup>lt;sup>36</sup> Because tertiary trials require large-scale budgets, as they necessitate the acquisition of data from numerous patients, such trials are normally conducted by pharmaceutical companies.

## 2.3 Program operation

#### 2.3.1 Application and selection

#### (1) Call for application

Prior to the application by research institutes for CTSA program, NCATS consultates with the institutes about a possible form of the cooperative structure between the NIH and institutes in terms of the program's objectives, method for establishing hubs, outcomes, and program implementation. Then individual institutes propose a detailed action plan for their establishment in a form that takes advantage of the special characteristics of their university or hospital and based on the general framework that NCATS presented in the application requirements.

#### (2) Selection

The selection of CTSA hubs takes place through a two-step review process.<sup>37</sup> The first-step involves a peer review by a scientific review group established in NCATS. This review is conducted based on specific criteria for the CTSA program. The CTSA program seeks to establish hubs at which research institutes execute initiatives in an organized manner, and thus not all application items are evaluated based on "scientific merit." Instead, they are evaluated from the strategic aims of CTSA program. For example, education-related initiatives are not always easily viewed in quantifiable terms, and thus they cannot be evaluated using such indicators as numbers of research papers or patents. The following takes a concrete view of the review.

- Significance: Does the project address an important problem or a critical barrier to progress in the field? If the aims of the project are achieved, how will scientific knowledge, technical capability, and/or clinical practice be improved? How will successful completion of the aims change the concepts, methods, technologies, treatments, services, or preventative interventions that drive this field?
- Investigator(s): Are the Program Director(s)/Principal Investigator(s) and other researchers well suited to the project? Do they have appropriate experience and training?
- Innovation: Does the application challenge and seek to shift current research or clinical practice paradigms by utilizing novel theoretical concepts, approaches or methodologies, instrumentation, or interventions? Are the concepts, approaches or methodologies, instrumentation, or interventions novel to one field of research or novel in a broad sense?
- Approach: Are the overall strategy, methodology, and analyses well-reasoned and appropriate to accomplish the specific aims of the project? Is the proposal feasible? Does it present a framework that can support research on the entire human lifespan (from the embryonic stage to the end of life)? Does it present a hub system that allows cooperation with interested parties in translational research (e.g., industry, regulatory authorities, patients' organizations, race advocacy groups, etc.)? To what degree are informatics-related initiatives planned? Is the application of informatics envisioned for all stages of translational research (from basic research to research uses of clinical data)? To what degree will cutting-edge informatics be used in hub establishment (e.g., in research methods, inter-hub cooperation, and patient participation in research)?
- Environment: Will the scientific environment in which the work will be done contribute to the probability of success? Are the institutional support, equipment and other physical resources

<sup>&</sup>lt;sup>37</sup> "JSPS Gurobaru Gakujutsu Joho Senta Beieidoku no Faundeingu Ejenshi no Shinsa Shisutemu (JSPS Center for Global Science Information, funding agency review systems in the United States, United Kingdom, and Germany) CGSI Report vol. 2, February 25, 2015.

available to the investigators adequate for the project proposed?

In addition to the above points concerning hub establishment, frameworks for postdoctoral support and support for training of predoctoral researchers are also reviewed. The main criteria here are expressed with the following indicators: Will the proposal hire promising young personnel and allow them to pursue careers as biomedical or clinical researchers? Will the hub's PIs and research administrators be capable of executing the proposal? Have the researchers who will instruct young personnel possess established educational experience and background? Have young researchers that have received instruction in the past succeeded in building careers in research fields?

Proposals that have passed this first review go on to the second step, which is conducted by an NCATS advisory council comprised of the NCATS Director and some 15 researchers from academia. The final decision on whether or not a proposal will be approved is made by the NCATS Director. With consideration for the results of the scientific review of the first step, the review in this second step focuses on the following points from a more policy-oriented standpoint: Does the proposal fit with the program's objectives? Is the proposal financially feasible? In terms of its relationship with other hubs, does the hub contribute to geographical dispersal throughout the country? Is the proposal designed to allow the participation of organizations for specific races or patients? Will the data and software to be developed and stored at the hub be useable at other hubs?

## 2.3.2 Cooperative agreements

Successful hubs sign a cooperative agreement with the NIH's NCATS.<sup>38</sup> Unlike investigator initiated grants for which individuals or groups are the main players, in case of CTSA program, research institutes sign the cooperative agreements with NIH as organizations. Each agreement is made based on substantive consultation and cooperation between the NIH and the research body. On the other hand, the cooperative agreements also differ from outsourcing contracts. The outsourcing contracts that the NIH enters are solely for the direct benefits of NIH (resources and services). Therefore, NIH designates the implementation method and outsources only operational aspects to the implementing party. Consequently, the implementing party has no freedom to shape the project. In this way, the cooperative agreements are positioned between investigator initiated grants and outsourcing contracts made with the federal government. When executing the program, the implementing party works to establish the hub in cooperation with the NIH. It strives to achieve objectives that were set by the NIH as it also maintains a certain degree of autonomy.

#### 2.3.3 Program management

The researcher in charge of each hub (Program Director or Principal Investigator) is required to attend CTSA meetings that are held once or twice annually and participate in monthly telephone conferences with NCATS personnel. He or she must also submit a research progress evaluation report (self-evaluation) on the hub's activities to hubs activities to NCATS each year.<sup>39</sup> This annual evaluation report is ordinarily a five-page document that covers the hub's development, postdoc support, and training of predoctoral researchers. Its primary purpose is progress management. Particular stress is placed on reports of problems the hub faces when it implements projects. If a problem is identified, a report must be submitted together with a plan for resolving it.

 <sup>&</sup>lt;sup>38</sup> Circular A-110 Revised 11/19/93 As Further Amended 9/30/99 To the Heads of Executive Departments and Establishments, accessed 24 December 2015. https://www.whitehouse.gov/omb/circulars\_a110 110 subpart B
 <sup>39</sup> NCATS. (2014) *Research Performance Progress Report (RPPR)*, accessed 24 December 2015.

https://ncats.nih.gov/files/CTSA-RPPR-instructions-2015.pdf

As for outcomes of research, an item for review that is in addition to research papers and intellectual property is the number of approved cases under the Investigational New Drug (IND) program, which is a scheme through which regulatory authorities give approval when clinical trials are conducted with an unapproved drug or an existing approved drug is being applied to a heretofore different disease.<sup>40</sup> In this case, the research plan that was submitted to the hub's clinical trial review board, names of researchers, number of clinical trials reviewed and approved, and other items must be reported. In addition, clinical trials that the hub plans to execute in the following year, status of research on pediatric diseases, and initiatives concerning AIDS research must be presented.<sup>41</sup>

An advisory committee of external experts is established in each hub. The committee meets once a year to review the hub's activities and give recommendations to the person in charge. The content of the committee's review must be provided in the annual evaluation report of the following year. Although the size of this advisory committee varies from hub to hub, in many cases, its membership includes some ten people who are heads of other CTSA hubs. A breakdown of the budget for the year of execution must also be provided in the report.

<sup>&</sup>lt;sup>40</sup> In the case of medical devices, the number of approved Investigational Device Exemptions (IDE) is reported.
<sup>41</sup> Although CTSA is not a program that seeks to promote research on specific diseases, it is noted that a certain percentage of hub activities should be allocated to AIDS research.

## 2.4 Program achievements

One overall result of the CTSA program is the progressing development of integrated translational research infrastructure. Prior to the program, the resources needed for translational research—such as basic research databases and research methods for genome data, databases of clinical departments for patient data, biological samples, and approval procedures for clinical trials—of each research institute were used in a limited manner within individual departments. In many cases, there was no system in place for executing integrated organization-wide research. The CTSA program has played a significant role as a catalyst for eliminating such barriers. Medium-sized universities, in particular, had few funds available to develop research infrastructure. By acquiring CTSA funds, those universities can now build such infrastructure.

Moreover, almost all of the top universities in the United States participate in the CTSA program. Thus, when a research institute is selected by the program, this certifies the institute's high quality to others and makes it easier for the institute to obtain other outside funding as well as support from affiliated universities and hospitals. This same is true for researchers with universities and hospitals that participate in the program, as they can more easily earn grants and engage in joint research within the CTSA network.

The following presents specific undertakings that are related to the CTSA program's objectives (1) to (5) that were mentioned above in the "Outline and objectives" section.

#### (1) Human resources development

Taking the CTSA hub at Harvard University as an example, this hub offers a broad range of over twenty educational programs for human resources development. They include a one- or two-hour biostatistics seminar that is open to all hub researchers, a six-week training course on grant application methods, and a two-year clinical and translational research training program for postdoc researchers.<sup>42</sup>

These programs are implemented in a number of ways. In some cases, the program was newly created using CTSA funds. And in others, a program that already existed in the medical faculty to which the hub is affiliated was used, and funds from the CTSA program were applied to help cover its expenditure. It should be noted that the budgets of these human resources development programs are calculated outside of the frameworks for postdoc salaries and research expenditure assistance.

(2) Cooperation with interested parties and cooperation among research hubs

Interested parties in the CTSA program include patients with rare diseases and special groups (such as for particular races, etc.). One of the objectives of the program is to build infrastructure for clinical research concerning these groups and bring together nurses, coordinators, and other necessary technicians at hubs.

Particularly in the cases of pediatric and rare diseases, few patients can participate in research. For this reason, experts in science communication are sent to local hospitals and patients' organizations to explain the importance of clinical research by CTSA hubs and conduct educational activities concerning patient participation in research. In 2014, a national conference on this topic was held at Duke University. The activities of the more than 60 hubs were presented there, and a proposal to create common indicators to evaluate cooperation between hubs and interested parties

<sup>&</sup>lt;sup>42</sup> Harvard Catalyst Education and Training Overview Matrix, accessed 24 December 2015. https://catalyst.harvard.edu/ed\_training\_overview\_matrix.html

41

was put forth.43

As for cooperation among hubs, the five task forces that were mentioned in the section on "CTSA Domain Task Forces" have been established and share information on successful undertakings. One part of this is the creation of a website for information sharing. Vanderbilt University is in charge of operating this website as well as overall administrative functions for inter-hub cooperation. In 2011 the university was awarded a five-year \$20 million grant totaling \$20 million.<sup>44</sup> One initiative here is an attempt to arrange in visual form information on the various kinds of research equipment possessed by the various hubs, the kinds of biological samples that can be provided (e.g., from biobanks), and the kinds of disease research being conducted using them.<sup>45</sup>

#### (3) Development of an integrated research environment

Pilot grants are offered as a way of promoting joint research by basic researchers and clinical researchers. Taking the pilot grant program of Columbia University as an example, that program provides grants of \$40,000 each for a research period of one year. It issues three grants per year.<sup>46</sup> Requiring the participation of one PI (associate professor level) each from faculties in the basic research and clinical research fields, the program encourages cooperation among researchers who have not traditionally engaged in joint research. Research fields include molecular biology, epidemiology, medical informatics, genetics, and neuroscience. Research is conducted at the pre-clinical stage.

The Columbia University program also offers separate pilot grants to support research by young researchers in bioinformatics, imaging technology, and precision medicine.<sup>47</sup> On the other hand, at Duke University, pilot grants designed to gain the participation of researchers from different CTSA hubs are also offered.

As for reviews, at some universities, first-stage peer reviews are conducted by researchers specializing in fields relating to the field of application, while second-stage peer reviews include researchers from different fields in the interest of gaining a cross-cutting viewpoint. At other universities, however, approximately ten peer reviewers from different fields complete reviews at one time. Review periods also vary. In small-scale cases of around \$2,000, the result may be issued in just a few days at the discretion of the hub's Program Director. However, in other cases a two-step peer review is required that can take several months to complete. When supporting clinical trials, judgments require a relatively long period of time. Such trials involve humans, and thus plans for involving patients in research and systems for managing and supervising research data must be comprehensively considered.

Pediatric diseases present a difficult research challenge in that research focuses on the entire human lifespan. Moreover, using fetuses and infants as subjects for research raises ethical concerns. Programs specialized in pediatric diseases are being advanced within the CTSA program, an example being the hub under development at the Children's National Medical Center in Washington D.C. Ninety percent of the researchers participating in this program are physicians who work at the center; the remaining 10% are basic researchers. The George Washington University participates in the

<sup>&</sup>lt;sup>43</sup> DTMI. (2014) 2014 National Conference on Engaging Patients, Families and Communities in all Phases of Translational Research to Improve Health, *Conference Summary*. DTMI. NC.

<sup>&</sup>lt;sup>44</sup> Snyder. B. (2011) *VUMC to Lead National CTSA Consortium*, accessed 24 December 2015.

http://www.mc.vanderbilt.edu:8080/reporter/index.html?ID=10883

<sup>&</sup>lt;sup>45</sup> Shirey-Rice, J. (2014) 'The CTSA Consortium's CATCHR (Catalog of Assets for Translational and Clinical Health Research)', *Clin Transl Sci.* 7(2) 100-107.

<sup>&</sup>lt;sup>46</sup> Pilot and Collaborative Translational and Clinical Studies Resource (PCSR), 24 December 2015.

http://irvinginstitute.columbia.edu/research\_ops/pcsr.html

<sup>&</sup>lt;sup>47</sup> Ibid

program as a joint operator of the hub and supplements its staff of basic researchers. Work is progressing at the hub to build infrastructure for using the vast amount of data obtained through hospital treatment-including genetic data and imaging data-in clinical research. In 2013 the hub began using electronic medical records and, together with a private company, began building the first database in the United States to be specifically focused on pediatric diseases.<sup>48</sup>

(4) Building of methodologies and research processes

At Harvard University, free consultation on the filling out of grant applications and ways of preparing materials for clinical trial review boards is available.<sup>49</sup>

At Vanderbilt University, advice on research design is available for those specialized fields that are thought to require counseling. Advice is offered in ninety-minute sessions following expert selection and schedule coordination. Some hubs include such consultation as part of the pilot grant review process. There are even hubs that engage in effective research design by modify application content with advice from experts at the time that pilot grant applications are made.<sup>50</sup>

(5) Promotion of informatics that facilitates translational research, human resources development, and sharing of successful cases

The CTSA program places the greatest stress on the development of informatics-related infrastructure. For this reason, the following identifies several points concerning this topic and discusses them using Vanderbilt University as an example.

• Creation of a website for researchers

A website called "StarBRITE" that is accessible by hub researchers has been created at Vanderbilt University.<sup>51</sup> One form of content that can be accessed through the website is a system that allows round-the-clock viewing of biological samples kept in the university's hospital as well as related patient and clinical data. Blood samples and other biological samples are maintained as a biobank. It is a genome information platform that includes approximately 195,000 people (170,000 adults and 25,000 children). Vanderbilt University ranks among the top twenty institutions in the United States in terms of the biological data it holds. Genome analyses have been completed for 10,000 of these people at the present time.<sup>52</sup> Hub researchers can also ask the university's genetic analysis center to conduct analyses, using a portion of the research expenditure they obtain from pilot grants. Patients' clinical data is kept anonymous in accordance with the federal government's Health Insurance Portability and Accountability Act. However, if, based on the clinical data, it becomes necessary to have an individual patient participate in research, it is possible to contact the patient following an examination by the clinical trial review board. This information can be accessed through the website. The information mentioned above is updated weekly by the university's research information office. The office also provides advice to researchers concerning the anonymity of clinical data and its use in

<sup>48</sup> Children's National and Cerner Collaborate in First Pediatric Health Information Technology Institute in the Country, 24 December 2015.

http://childrensnational.org/news-and-events/childrens-newsroom/2013/childrens-national-and-cerner-collaborate-in-firstpediatric-health-information-technology-institute-in-the-country <sup>49</sup> Harvard Catabast Provention

Harvard Catalyst Biostatistical Consulting, 24 December

<sup>2015.</sup>https://catalyst.harvard.edu/services/biostatsconsult/

Design, Biostatistics, and Research Ethics Program Description, 24 December 2015.

https://victr.vanderbilt.edu/pub/message.html?message\_id=152

Harris. P. et al. (2011) 'StarBRITE: the Vanderbilt University Biomedical Research Integration, Translation and Education portal', Journal of Biomedical Informatics. 44(4). pp. 655-62.

From information obtained through the survey interviews.

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#### research.53

#### $\circ$ Automatic calculation of research cost

Software has been installed that automatically calculates the amount of anticipated necessary expenditure when actually designing a clinical research project using the types of data mentioned above. This is achieved by entering the number of people thought to be necessary to conduct the research (e.g., research assistants, nurses, etc.), number of beds, amount of payments to statisticians, and other items into a website form. Once a research budget has been finalized, the same website handles application procedures for pilot grants. Thus it is possible to also make grant applications online by selecting application items from three classifications—\$2,000, \$10,000, and more than \$10,000—based on the calculated amount.<sup>54</sup>

#### o Patients' participation in research

The website makes it possible to browse anonymous information on patients of the university hospital (e.g., future appointments, etc.). This allows researchers to compare their research objectives against clinical data and to plan the participation of necessary patients in their research.<sup>55</sup> Additionally, a national online network to support patient participation is being constructed in Vanderbilt University with support from the CTSA program to handle cases in which participation from patients who are outside the local area is required. As of the present time, 86,256 patients and 3,417 researchers are registered in the network.<sup>56</sup> The online network was developed by Professor Paul Harris, who heads Vanderbilt's bioinformatics courses.

#### Clinical statistics software

A free web data collection system called Research Electronic Data Capture (abbreviated as REDCap) was developed in Vanderbilt University with assistance from the CTSA program. This system addresses the necessity for researchers to manage and statistically process trial data when conducting clinical research. REDCap was also developed by the above-mentioned Professor Harris for the purpose of creating software with simple yet comprehensive functions that is easy to use by working physicians who participate in clinical studies.<sup>57</sup> REDCap can be accessed by all employees and students of Vanderbilt University from the previously mentioned StarBRITE website. It is used in almost all clinical research undertaken at the university. The system leaves a complete audit trail<sup>58</sup> and can ensure the anonymity of data in accordance with the Health Insurance Portability and Accountability Act. For these reasons, its use is encouraged by the university hospital's clinical trial review board from the standpoint of maintaining research ethics. It should be noted that REDCap is currently used by 303,000 researchers with 1,718 research institutes in 96 countries.<sup>59</sup>

<sup>&</sup>lt;sup>53</sup> Danciu. I. *et al.* (2014) 'Secondary Use of Clinical Data: The Vanderbilt approach', *Journal of Biomedical Informatics*. 52. Pp28-35.

<sup>&</sup>lt;sup>54</sup> Harris. P. et al. (2011) Op., Cit.

<sup>&</sup>lt;sup>55</sup> Subject locator, accessed 24 December 2015. http://www.mc.vanderbilt.edu/crc/workshop\_files/2013-03-08.pptx

<sup>&</sup>lt;sup>56</sup> Research Match, accessed 24 December 2015. https://www.researchmatch.org/ (data are as of November 27, 2015). It is reported that although patients are registered from all 50 states, 75% of those patients are concentrated in ten states. Moreover, the number of registered patients falls below 100 in 25 states. A total of 478 research projects in 113 research institutes are supported through the network, and 135 research papers have been reported. Harris. P. *et al.* (2012) 'ResearchMatch: a national registry to recruit volunteers for clinical research', *Acad Med.* 87(1). pp. 66-73.

<sup>&</sup>lt;sup>57</sup> Harris, P. *et al.* (2009) 'Research Electronic Data Capture (REDCap) - A metadata-driven methodology and workflow process for providing translational research informatics support', *J Biomed Inform.* 42(2) pp. 377–381.

<sup>&</sup>lt;sup>58</sup> An "audit trail" refers to a record of the content and processes of data system processing that is stored in time sequence for tracing by a system auditor. It is used to prevent the alteration of data.

REDCap: Research Eelectronic Data Capture, accessed 6 December 2016. http://project-redcap.org/

#### • Master's program in clinical statistics

A master's program for clinical researchers is offered in Vanderbilt University in collaboration with the CTSA program. It is intended to help students master the software that clinical researchers use in actual research settings. Through the program, young physicians who are training in a medical specialty not only engage in comprehensive study of clinical research theory under medical statisticians, informatics specialists, ethical experts, and experts, they also receive opportunities to join in translational work with instructing researchers and work with experts within the university. The program is designed to so that young physicians can independently develop their career paths as clinical researchers. They acquire knowledge that is applicable in actual clinical statistical settings rather than theoretical, ways of using statistical tools such as REDCap, and methods for applying for research grants.<sup>60</sup> In other words, Vanderbilt University develops software and other tools that clinical researchers can use and couples them with an educational program that gives researchers the knowledge to use them. These initiatives support hub researchers and fit with the CTSA program's strategy founded on human resources development and tools development.

All of the Vanderbilt University services that were described in this section can be accessed from one website, StarBRITE. During the period between 2007 and 2015, the total number of research papers that received support from the university's hub reached 981.<sup>61</sup> Many of them were the result of joint research by researchers coming from disparate fields.<sup>62</sup>

## • Partnership with Japan

REDCap, the clinical statistics software that was mentioned above, has also been introduced into Japan. It is available on Osaka University's campus cloud server through Osaka University Hospital's Medical Center for Translational Research and Department of Clinical Epidemiology and Biostatistics.<sup>63</sup> Osaka University began providing the system to outside facilities in December of 2015. However, accessing REDCap with a server that is not a data server of Vanderbilt University is not ordinarily permitted internationally. A Japanese consortium established by Professor Harris and Professor Ayumi Shintani, who is in charge of the Department of Clinical Epidemiology and Biostatistics, received special permission for this. The Department of Clinical Epidemiology and Biostatistics is currently building a Japanese-language website, preparing a lecture video on its use, and arranging matters concerning the Japanese consortium. In addition, Professor Harris attends symposiums that are held twice annually, thereby providing opportunities for dialogue with participants from throughout Japan.<sup>64</sup>

## 2.4.1 Publication and patents

Of all published research papers between the CTSA program's establishment in 2006 and December 2015, selected papers that were presented as research outcomes on the NCATS website numbered some 900.<sup>65</sup> Additionally, a look at compiled trends in the number of research papers

<sup>&</sup>lt;sup>60</sup> Master of Science in Clinical Investigation Program, accessed 24 December 2015.

https://medschool.vanderbilt.edu/msci/

<sup>&</sup>lt;sup>61</sup> From information obtained through the survey interviews. <sup>62</sup> Dancin L at al. (2014) On Cit

<sup>&</sup>lt;sup>62</sup> Danciu. I. et al. (2014) Op., Cit.

<sup>&</sup>lt;sup>63</sup> Website of the Department of Clinical Epidemiology and Biostatistics, Osaka University Hospital (accessed on December 24, 2015): http://stat.academy.jp/

<sup>&</sup>lt;sup>64</sup> REDCap portal site of the Medical Center for Translational Research, Osaka University Hospital (accessed on December 24, 2015): http://www.dcc.med.osaka-u.ac.jp/redcap/

<sup>&</sup>lt;sup>65</sup> *Scientific Publications*, accessed 24 December 2015. http://www.ncats.nih.gov/research/pubs/sci-pubs-archive.html

published during the first five years following the CTSA program's establishment (2006 to 2011) reveals that the journal with the greatest number of papers published by CTSA researchers was *PLoS ONE*, the world's largest open access journal. Furthermore, papers have appeared in well-known and authoritative academic journals that include *Blood*, the journal of the American Society of Hematology, which handles research reports covering a broad range of fields, from basic to clinical research; the *Journal of Clinical Oncology* of the American Society of Clinical Oncology; *The New England Journal of Medicine*, which is one of the world's oldest journals on clinical research; and *The Journal of Clinical Investigation* published by the American Society for Clinical Investigation.<sup>66</sup>

The research papers presented here were not the result of research conducted solely with CTSA support; rather, they were the product of support provided by the CTSA program in parallel with other NIH grants (for example, major grants from disease-specific research institutes, such as the National Cancer Institute). Under the CTSA program, when a paper on research connected to a CTSA hub is published, the CTSA's grant number must be noted in the paper if it benefitted from the support or services of the hub, even if only minimally. This requirement helped produce the above-mentioned volume of papers during the short five-year period that began in 2006, when the program was established.

Through our interview survey concerning the writing of manuscripts, we learned that many of the researchers receive large-scale grants, and that some are opposed to having to note the CTSA grant number in their papers despite receiving only minimum benefit from the program's facilities and support. However, as will be discussed in more detail later, there are also researchers who believe that mentioning the program is reasonable, as the receipt of CTSA support can lead to the acquisition of large-scale grants at a later date.

Looking at patents and other forms of intellectual property, a private-sector survey company commissioned by NCATS published a report on outcomes of the CTSA program between 2006 and 2011. It reported that the most numerous of the program's non-research paper outcomes were those that had been selected for additional grants from the NIH. Thus, the program's production was limited in terms of intellectual property.<sup>67</sup>

Accordingly, it is thought that the CTSA program's outcomes have not been large in terms of research papers and intellectual property, and that the outcomes of its efforts to develop hubs come in the form of initiatives related to research environments and education. This structure remains unchanged at the present time.

<sup>&</sup>lt;sup>66</sup> Freching. J. et al. (2012) The CTSA National Evaluation Final Report. Westat. MD.

<sup>&</sup>lt;sup>67</sup> *Ibid*.

## 2.5 Program challenges

## 2.5.1 Evaluation at the end of the first period

At the end of the first five-year support period following the CTSA program's establishment in 2006, voices in Congress pointed out the need to evaluate the program. As a result, the Institute of Medicine (IOM; currently the National Academy of Medicine<sup>68</sup>), was ordered to conduct an evaluation and present proposals for improvement. On June 25, 2013, the IOM published the results of its study in an evaluation report titled "The CTSA Program at NIH: Opportunities for Advancing Clinical and Translational Research."<sup>69</sup>

## 2.5.2 Insufficient leadership by NCATS

Two major issues were identified in the IOM's report. The first was a lack of leadership in the program's operation by the National Center for Advancing Translational Sciences (NCATS), which is an organization of the NIH. By "leadership," the report was referring to command of the operation of all hubs by NCATS and its driving of their activities toward the achievement of the CTSA program's overall goals in cooperation with them. As was mentioned previously, the CTSA program is operated within the framework of "cooperative agreements."<sup>70</sup> Consequently, NCATS and the hubs must develop and operate the hubs through mutual cooperation. However, the report stated with regard to CTSA program's management between 2006 and 2011 that the degree to which NCATS displayed leadership and participated in the initiatives of each hub was unclear.<sup>71</sup>

Nevertheless, each hub effectively operated based on its own discretion with funds provided by NCATS. The reason for this was that the translational research environments that were established were strongly influenced by the character of the individual research institutes, and NCATS had difficulty providing uniform evaluation and management. In addition, although the CTSA program was established in 2006, NCATS was not established within the NIH until 2012. As a result, NCATS did not yet have the organizational structure needed to immediately display leadership.<sup>72</sup>

## 2.5.3 Limited inter-hub network

The second issue mentioned in the IOM report was the slowness with which a network was built between the hubs, which are scattered across the United States. Since 2006, the CTSA program has promoted the establishment of infrastructure for translational research at more than 60 hubs. Among them are those that operate their own large biobanks, those that possess their own equipment for genetic analysis, those that maintain data on patients with specific diseases, and those that have high expertise in informatics and clinical statistics. There are instances where the activities of some hubs appear to overlap those of others, and all of the hubs have been late in responding. Thus, the resources offered by the CTSA program are not always being optimally utilized. If the approval processes of clinical trial review boards that concern research planning can be unified, this can shorten the time researchers need to spend on procedures when they are conducting clinical research requiring the participation of researchers and patients from many university hospitals in different regions. Additionally, if electronic medical data from different regions can be used in a unified database, sharing information on which patients (i.e., in terms of age, race, and disease) are in which hospitals will become possible. The IOM report noted that although efforts toward networking within

<sup>&</sup>lt;sup>68</sup> Currently the National Academy of Medicine

<sup>&</sup>lt;sup>69</sup> IOM (2013) Op., Cit.

<sup>&</sup>lt;sup>70</sup> The method for operating projects differs from those under researcher-led grants and NIH's outsourcing contracts.

<sup>&</sup>lt;sup>71</sup> IOM (2013) *Op.*, *Cit.* 

<sup>&</sup>lt;sup>72</sup> *Ibid.* p.6 para2

regions and states were seen in some hubs, those efforts are limited. A nationwide push to optimize translational research resources is required, and for this reason, networking of information among hubs will be important.

## 2.5.4 NCATS's improvement strategy

Based on the above points raised by the IOM, NCATS established a working group to study responses in November 2013. The group issued its report in May of 2014.<sup>73</sup> This section will present policy responses that NCATS implemented to tackle the two issues of "insufficient leadership by NCATS" and "limited inter-hub network" from new concrete proposals that were made by the working group.

To begin, NCATS began studying metrics for "insufficient leadership" by establishing a working group in 2012, prior to the release of the IOM's report. In the wake of the IOM report's release, the working group checked the following fifteen metrics that many hub researchers found to be valid and reported them to the CTSA Steering Committee.<sup>74</sup>

- Time from institutional review board (IRB) submission to approval
- Studies meeting accrual goals
- Time from notice of grant award to study opening
- Career development (education and training)
- Career trajectory (post-education career)
- Volume of investigators who used services (various hub services including medical data, pilot grants, research planning consultation desks, etc.)
- Volume of types of services used
- Satisfaction/needs assessment
- Leveraging/return on investment (ROI) of pilot studies and KL2 scholars (post doc support)
- Researcher collaboration
- Institutional collaboration
- Number of technology transfer products
- Time to publication
- Influence of research publication
- Time from publication to research synthesis

These fifteen metrics were presented in 2012, after which they were introduced on a trial bases in seventeen hubs. The results were published in 2015.<sup>75</sup> From the trial introduction, it was found that more time and human resources than anticipated would be required to gather information for the metrics, and thus effective data gathering would be difficult. Given this result, it was proposed that building joint metrics for CTSA should require keeping cross-hub metrics at the minimum and making the objectives and definitions used when setting them as clear as possible. It was therefore suggested that the period for introducing metrics on a trial basis should be extended. NCATS will proceed with building a system that can use gathered information in cross-hub evaluations based on the above-mentioned metrics and the results of their trial introduction.

<sup>&</sup>lt;sup>73</sup> A Working Group of the NCATS Advisory Council to the Director. (2014) *NCATS Advisory Council Working Group* on the IOM Report: The CTSA Program at NIH. NCATS: Washington. D.C.

<sup>&</sup>lt;sup>74</sup> Rubio. DM. *et al.* (2013) 'Common metrics to assess the efficiency of clinical research', *Eval Health Prof.* 36(4). pp. 432–446.

<sup>&</sup>lt;sup>75</sup> Rubio. DM. *et al.* (2015) 'Developing common metrics for the clinical and translational science awards (CTSAs): Lessons Learned', *Clinical Translational Science*. 8(5). pp. 451-9.

As for the second point, "limited nationwide networking of translational hubs," the public invitation outline for the CTSA program that was newly revised in July 2015 mentions the necessity of networking by directly quoting from the IOM report. It requires sharing and cooperation vis-à-vis all translational research resources, including databases, educational methods, research methods, and patient information. It encourages hubs to prepare designs that are usable by other hubs when developing educational programs, for example, and requires hubs to keep universal use among hubs in mind when developing databases and clinical statistics software.<sup>76</sup> Because simply demanding that hubs abide by these requirements cannot be expected to produce real effects, NCATS incorporated a new framework that provides additional support for joint research by hubs in disparate fields (participation by at least hubs) in its budget beginning in 2015. At the same time, it has approved and begun public invitation for the addition of a new framework to support the building of methodologies that encourage the participation of patients from multiple facilities in research as well as a framework to support the building of methodologies oriented toward integrating the examination procedures of clinical trial review boards when clinical research is undertaken by multiple facilities.<sup>77</sup>

 <sup>&</sup>lt;sup>76</sup> Department of Health and Human Services National Institutes of Health National Center for Advancing
 Translational Sciences (NCATS), accessed 24 December.http://grants.nih.gov/grants/guide/pa-files/PAR-15-172.html
 <sup>77</sup> Department of Health and Human Services National Institutes of Health National Center for Advancing
 Translational Sciences (NCATS), accessed 24 December. http://grants.nih.gov/grants/guide/rfa-files/RFA-TR-15-002.html

## 2.6 Future orientation

Translational research is a complicated undertaking that requires cooperation among people in diverse fields, including basic research, clinical research, informatics, statistics, pharmaceutical regulations, ethics, and industry. Developing successful research hubs is not a simple task for this reason. As was described in this chapter, the CTSA program has been implementing support in five-year units since 2006, and some hubs will be recipients of this support for a total of fifteen years when the five-year period that started in 2015 is included. This kind of long-term support in hub development is extremely important in that it makes timely responses to medical research trends, which can change with lightning speed, possible.

Current medical research requires data-driven research that links both vast amounts of basic research data and clinical data. The CTSA program stresses infrastructure and human resources development in such fields as informatics and statistics, and thus it is worth watching in this respect. Basic information and statistical infrastructure is an essential element in the implementation of such undertakings as the Precision Medicine Initiative,<sup>78</sup> which was mentioned in the President's State of the Union Address in January 2015. Thus, building it into CTSA program's hubs suggests a posture oriented toward making maximum use of those hubs as a foundation for addressing this kind of national priority.

Accordingly, it is thought that there is more than a slim possibility that the current CTSA hubs will play an important role in future medical research in the United States. However, budgets that support cross-cutting research, like that of the CTSA program, remain extremely small within the overall NIH budget. In fact, such budgets amount to just 0.5% of the research expenditure of American pharmaceutical companies. This situation demands a level-headed evaluation of their actual impact on society.<sup>79</sup> Similarly, considering the size of the NIH's translational research budget, it is highly unlikely that industry harbors no concerns about whether NCATS's initiatives truly lead to innovation.<sup>80</sup> It is thought that NCATS's CTSA program will become an important trial case in efforts to promote medical research—and in particular translational research—in the United States of the future.

<sup>&</sup>lt;sup>78</sup> "Precision medicine" is sometimes translated into Japanese as *kobetsuka iryo* (individualized medicine). However, a definition of precision medicine that was issued by the National Research Council in 2011 states that, while precision medicine seeks to provide medical treatment tailored to individuals, it does not mean the development of drugs that are suited to each patient, but rather the classification of individuals into specific subpopulations with similar hereditary factors and clinical data, and then the advancement of common disease treatment for that subpopulation. In this way, it refers not to the conventional practice of applying treatment to a vast range of cases based on a single drug, but rather an effort to provide more precise treatment to more limited and specific groups. National Research Council. (2011) *Toward Precision Medicine: Building a Knowledge Network for Biomedical Research and a New Taxonomy of Disease*. NRC: Washington. D.C. Appendix E Glossary.

<sup>&</sup>lt;sup>79</sup> Shekhar, A. (2014) "Active skepticism beyond the IOM's CTSA Report", *Sci Transl Med.* 6(232). 232-233.

<sup>&</sup>lt;sup>80</sup> Wadman, M. (2012) "NIH Director Grilled Over Translational Center", *Nature News Blog*, 20 March.

## 2.7 Implications to Japan

In Japan, a "Coordination, Support and Training Program for Translational Research" that was launched by the Ministry of Education, Culture, Sports, Science and Technology in 2007 changed its name to the "Translational Research Network Program" in 2014. This program is advancing cooperation among research centers in Japan. At the same time, translational research his being accelerated under the Ministry of Health, Labour and Welfare's Early/Exploratory Clinical Trial Center Development Projects and Clinical Trials Core Hospital Development Projects. Since 2015, these undertakings have been under the integrated management of the newly established Japan Agency for Medical Research and Development (AMED). Research seeds are being generated through these hub-based projects, and the time has arrived to envision new projects that will utilize results attained thus far.<sup>81</sup>

As was presented in this chapter, clinical research support projects have a long history in the United States. However, the current CTSA program is still a new program that has been existence for fewer than ten years, having been launched in 2006. Moreover, NCATS, which oversees it, was only established in 2012. Consequently, the CTSA program can be considered the continuation of an experimental initiative. Although publication records indicate certain level of achievement of the program, those papers are not the result of the program's efforts alone, as traditional disease-specific research NIH-Institutes and Centers have had a large role to play in their production.

However, the CTSA initiative can provide a number of pointers for Japan. Specific points worth attention are its high priority on addressing data-driven research in both human resources development and development of research environments, and its efforts to apply it not only to individual hubs but also the building of a national network of national resources. Budgeting has been approved for 2016 and beyond that will allow CTSA to strengthen its research on networking methodologies (specifically, promotion of joint research, promotion of participation in research by numerous facilities and patients, and integration of the procedures used by many clinical trial review boards). As can be seen in the fact that joint research on networking methodologies is taking place among its hubs and that it is trying those methodologies in an effort to institutionalize them, the CTSA program is demonstrating a clear path forward. At the same time, with steps being taken toward establishing shared metrics for evaluating the program as a whole, it will be important for the program to take a posture oriented toward more precise project evaluation.

The environment in Japan differs from that in the United States in terms of the sizes of public medical research budgets, medical and insurance systems, the organizational structures of medical schools and university hospitals, and other factors. Nonetheless, it can be argued that Japan must fully understand the United States' CTSA program as a forerunner and study how industry, government, and academia can join together in prioritizing the evaluation of Japan's public translational research projects and realizing innovative "Japan-style" translational research.

<sup>&</sup>lt;sup>81</sup> http://www.tr.mext.go.jp/

## References

- National Center for Advancing Translational Science (NCATS) https://ncats.nih.gov/
- Clinical and Translational Science Awards (CTSA) http://www.ncats.nih.gov/ctsa
- Institute of Medicine (IOM) http://iom.nationalacademies.org/

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# Chapter 3: The Engineering Research Center Program of the National Science Foundation, USA

In this chapter, we will examine the Engineering Research Center (ERC) program, which is supported by the National Science Foundation (NSF), as an example of support for infrastructure development that bridges engineering research and innovation in the United States.

## 3.1 Background

During the 1980s, the United States faced major trade deficits as a result of the rise of Japanese companies in such fields as automobiles, iron and steel, and semiconductors. Given these circumstances, the National Academy of Engineering (NAE) and NSF jointly expressed their concern that "a technology revolution is rapidly taking place as a result of the fusion of engineering and other fields, and interdisciplinary efforts in engineering will be needed to respond," and "the separation between the engineering that is practiced in companies and the engineering for which students are being trained is growing." Against this backdrop, universities in the United States faced pressure to reform their engineering research and education. This led to the NSF's launch of the ERC program in 1985.

## 3.2 The ERC program

#### 3.2.1 Objective

The NSF states that the objective of the ERC program is to "create a culture of innovation in engineering research and education that links scientific discovery to technological innovation through 'transformational engineered systems research' and 'education.'" <sup>82</sup> The world "transformational" means have the ability to change something or have transformability. Thus, another way to state the ERC program's objective is to "create new engineered systems and train the people to lead them so as to change transform existing mechanisms."

The ERC program is considered to be a model case among strategies to support the establishment of university research bases in the United States. Many research-oriented universities in the US establish Engineering Research Centers (ERCs) that are outside of their regular research and educational organizations, normally comprised of faculties and departments. The ERCs serve as venues where researchers from disparate specialties gather to conduct interdisciplinary activities that extend beyond existing academic fields. In many cases, industrial and social needs cannot be resolved by focusing on a single academic field, and thus university ERCs serve an important role in industry-academia collaboration.

## 3.2.2 Program overview

For "transformational engineered systems" and "methods for building transformational engineered systems," the ERC program receives proposals from researchers and screens them. Then, for those that it selects, it provides support that in principle lasts ten years. The program's approach is characteristic in that consideration is given to the following points in its operation:

- Integrated promotion of education and research: Knowledge obtained through the program must be incorporated into teaching materials and curricula, and strategies for developing human resources to lead the next generation must be translated into explicit knowledge.
- Pursuit of interdisciplinarity in various ways: "Transformational engineered systems" are predicated on the execution of research that bridges different fields, and thus members from various actors must participate in their construction. For example, collaboration with other universities (and the participation of at least three instructors and three students from each university) is essential and the participation of private enterprises is desired. Moreover, whether or not the various stakeholders are cooperating in a substantial manner shall be confirmed through annual site visits. The aim is to achieve interdisciplinarity of not only fields but also of participating people.

## 3.2.3 The NSF's Directorate of Engineering

The NSF, the organization in charge of the ERC program, is a funds-distributing body that supports basic research in a broad range of scientific and engineering fields that are outside are under the jurisdiction of the National Institutes of Health (NIH). The department that oversees the entire NSF organization is the Office of the Director. Under it are seven directorates that are in charge of specific academic fields. The ERC program is administered by the Directorate of Engineering.

<sup>&</sup>lt;sup>82</sup> This report presents the ERC program's current objective. The program's original objective was "to develop a government-industry-university partnership to strengthen the competitive position of US firms in world trade and change the culture of engineering research and education in the US."

## 3.2.4 Budget

The NSF's entire budget amounts to approximately \$7.3 billion (2015, appropriation). Of this, the Directorate of Engineering's budget is approximately \$900 million (2015, actual), and of this, the budget for ERC program, which supports 19 ERCs, is \$64.5 million (2105, actual). This figure is not necessarily large when considered in terms of the entire budgets of the NSF and Directorate of Engineering.

Looking at the ERCs, the total amount of support the NSF provides to an individual center is about \$30 million over the course of ten years. The maximum amounts the NSF provides to a single center each year are shown in Figure 3-1. The amount gradually increases from the first fiscal year and reaches a maximum of \$4 million between the fourth and eighth years. From the ninth year the amount is gradually reduced as support for the center reaches its end.

## 3.2.5 ERC support period and number of centers

The period during which support is provided to ERCs under the ERC program is between five and ten years. As is shown in Figure 3-1, midterm evaluations are conducted in the third and sixth years during the support period. If one of these evaluations finds that an ERC's performance is inadequate, support from the NSF will be terminated two years later.

Figure 3-1: Amount of support (maximum amount) to individual bases of the ERC program and the mid-term evaluation schedule

Initial FY	2nd year	3rd year	4th year	5th year	6th year	7th year	8th year	9th year	finalyear
NSF su	pport	Midterm evaluation		▲ Midterm evaluation					
		Support terminated in 5th year if result is unfavorable			Support terminated in 8th year if result is unfavorable				
(Maximum) \$3.25 M	amount) \$3.5M	\$3.75 M	\$4.0 M	\$4.0 M	\$4.0 M	\$4.0 M	\$4.0 M	33% year year redu	

Source: Prepared based on NSF materials

Thus far, 56 ERCs situated throughout the United States have received NSF support as ERC program centers. As of 2015, the nineteen ERCs shown in Figure 3-2 are receiving support.

Field	ERC name	Core university		
	Synthetic Biology ERC (Synberc)	University of California, Berkeley		
	Nanosystems ERC for Nanomanufacturing Systems for Mobile Computing and Mobile Energy Technologies (NASCENT)	University of Texas at Austin		
Advanced Manufacturing	ERC for Structured Organic Particulate Systems (C-SOPS)	Rutgers University		
	ERC for Compact and Efficient Fluid Power (CCEFP)	University of Minnesota		
	Center for Biorenewable Chemicals (CBiRC)	Iowa State University		
	ERC for Power Optimization for Electro-Thermal Systems (POETS)	University of Illinois at Urbana-Champaign		
	Smart Lighting Engineering Research Center (Smart Lighting ERC)	Rensselaer Polytechnic Institute		
	Nanosystems ERC for Nanotechnology Enabled Water Treatment Systems (NEWT)	Rice University		
Energy, Sustainability,	Future Renewable Electric Energy Delivery and Management Systems Center (FREEDM)	North Carolina State University		
and Infrastructure	ERC for Ultra-wide Area Resilient Electric Energy Transmission Networks (CURENT)	University of Tennessee-Knoxville		
	ERC for Re-Inventing the Nation's Urban Water Infrastructure (ReNUWIt)	Stanford University		
	ERC for Quantum Energy and Sustainable Solar Technologies (QESST)	Arizona State University		
Microelectronics,	Nanosystems ERC for Translational Applications of Nanoscale Multiferroic Systems (TANMS)	University of California, Los Angeles		
Sensing, and Information Technology	ERC on Mid-Infrared Technologies for Health and the Environment (MIRTHE)	Princeton University		
	Center for Integrated Access Networks (CIAN)	University of Arizona		
	Center for Advanced Self-Powered Systems of Integrated Sensors and Technologies (ASSIST)	North Carolina State University		
Biotechnology and Health Care	ERC for Revolutionizing Metallic Biomaterials (RMB)	North Carolina Agricultural and Technical State University		
	Center for Sensorimotor Neural Engineering (CSNE)	University of Washington		
	Center for Bio-mediated and Bio-inspired Geotechnics (CBBG)	Arizona State University		

Source: ERC Association

## 3.2.6 Targeted technical fields at ERCs

According to an official at the NSF, public invitations for the ERC program are not limited to specific fields. Rather, they seek to obtain proposals in all interdisciplinary fields in engineering.

As is shown in Figure 3-2, the ERCs that are currently receiving support are classified into four fields: Advanced Manufacturing; Energy, Sustainability, and Infrastructure; Microelectronics, Sensing, and Information Technology; and Biotechnology and Health Care.

## 3.3 Selection of ERCs

The process of selecting an ERC for the ERC program takes between one and a half and two years. Screening takes place in four stages: preliminary screening, preparation of main proposal, site visit, and final selection. Newly selected ERCs enter into a five-year cooperative agreement with the NSF. And then begins its activities. Each of these processes is examined below.<sup>83</sup>

## 3.3.1 Preliminary screening and preparation of main proposal (document screening)

Preliminary screening is conducted to select outstanding ideas. For this reason, applications can be brief, as their ideas must be expressed in no more than seven pages. At this stage, the NSF receives between 100 and 200 applications. It then narrows this number down to around 25 through the preliminary screening. It should be noted that the NSF provides feedback to the applicants when it announces the screening results, making comments from a scientific standpoint about all of the applications it receives, even those that are not selected.

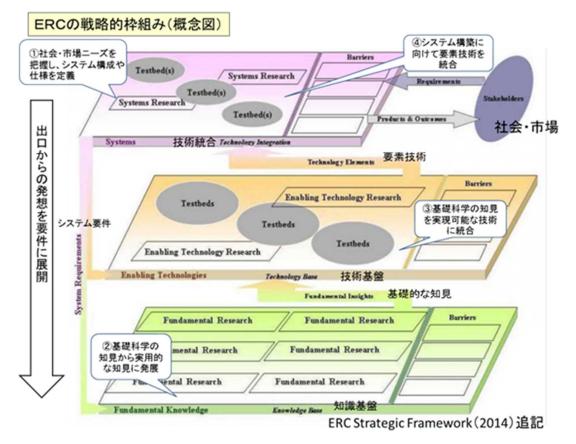
When proposals pass the preliminary screening, their applicants are asked to prepare a new "main proposal" application that notes specific details about the research plan and project implementation methods and then submit it to the NSF. Then a further round of screening narrows these main proposals down from around 25 to around seven.

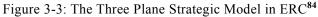
The following describes in detail the "research plan" and "project implementation method" that are characteristic of the NSF's screening of ERC documents.

(1) Research plan

The research plan must make contain specifics that are based on the NSF's "Three Plane Strategic Model." As is shown in Figure 3-3, the Three Plane Strategic Model classifies R&D conducted at ERCs into three levels ordered from the bottom as "Knowledge Base," "Technology Base," and "Technology Integration." The design of the overall system conceived as a top-down structure that is based from the top on social and market needs, while research moves up from the bottom through the integration of knowledge and technology. The model demands the advance identification of obstacles and other problems that are anticipated when knowledge and technologies are integrated. Thus the model can be seen as a guideline that lays out a strategy for formulating a research plan.

<sup>&</sup>lt;sup>83</sup> The number of applications and other details mentioned in the text are based on an interview survey with NSF that took place on December 19, 2013.





Source: Prepared based on NSF materials with additions by CRDS

## (2) Method for promoting ERC activities

Applicants must develop how they intend to promote their activities following selection as an ERC into a highly workable plan from the application stage. When an applicant submits its application, it must also submit documents signed by the persons in charge of each stakeholder. These documents must state, for example, whether the core university can provide places to install facilities and equipment, whether researchers of partner universities are committed to participating in the center's activities, and whether partner companies agree to handle intellectual property. Additional requirements are collaboration with other universities (the number of which must not exceed four) and the participation of at least three instructors and three students from each partner university.

## 3.3.2 Site visits

When a proposal passes the preliminary screening, members of the screening panel visit the candidate site and hold meetings there that last between one and a half and two days. Experts from various fields participate in this screening panel and provide comments and advice vis-à-vis the proposal based on their expertise.

## 3.3.3 Final selection (interview)

During final selection, applicants are permitted to revise their proposals based on the expert

<sup>&</sup>lt;sup>84</sup> http://www.jst.go.jp/crds/pdf/2014/RR/CRDS-FY2014-RR-02.pdf

comments made at the time of the site visit. After interviews are held, between two and four proposals are ultimately selected. The people who are primarily in charge of decision-making during selection are NSF Program Officers (PO).

## 3.3.4 Selection criteria

The NSF conducts a standardized merit review when selecting matters of all programs. The items reviewed here are as follows:

- · Intellectual merit of the proposed research activity
- Broader impact of the proposed research activity

The merit review is also conducted for the ERC program. It takes place at the preliminary screening stage. The following special criteria—which include this merit review—are established for the ERC program:

(1) Preliminary screening items

• The ERC program's mission and strategy (strategy of identifying latent possibilities for creating new industries, clearly presenting goals at each level from and engineered systems to individual projects, and developing cutting-edge knowledge)

\*Submission of a chart based on the Three Plane Strategic Model (Figure 3-3) is required.

- Activities linked to education and industry (planning of education for undergraduate and graduate students, outreach activities to students prior to university entrance exams, selection and participation of collaborative partners in industry)
- Organization-building of the ERC and its environment (validity of goals in building the center's organization; validity of team membership from the standpoint of R&D and internships; effective resource organization/integrity based on organizational structure and management plans; possibilities for securing equipment, spaces, and other resources; degree of participation in the ERC by universities themselves)
- (2) Screening items additionally established for the main proposal
  - Close study of actual proposal feasibility (location and function of the ERC's headquarters, possibilities for corporate participation, agreements with industry [handing of intellectual property, etc.])

## 3.4 Characteristics

A characteristic of the ERC program is the fact that measures for building frameworks that take "transformational engineered systems" into the real world are built into it. These measures are established from a broad range of standpoints, standpoints that go beyond putting technologies into practice by translating ERC research achievements into forms usable by private enterprises and ventures to include the education and recruitment of the human resources that will lead next-generation engineering. In this section, we will examine this characteristic in detail.

## 3.4.1 Formulation of exit-oriented research plans based on the Three Plane Strategic Model and independence after ten years

As was presented in the Three Plane Strategic Model of Figure 3-3, under the ERC program, applicants must set an overall system composition and specifications for their ERC based on social and market needs from the application stage. They must then conceive of their entire system in a top-down manner by breaking down the system requirements that were established here into the Technology Base and Knowledge Base. Consequently, they devise various ways of making the ERC program's research results easily understandable to stakeholders on the exit side from the moment they begin planning and designing their center's activities.

From the application stage, applicants must envision how, when they move forward with actual research, they will integrate knowledge from fundamental science and take it to the Technology Base layer, where it will become practical knowledge. They must furthermore consider how they will integrate technology elements for system construction and take them up to the Technology Integration layer. At the same time, they must identify the obstacles they can expect to encounter in these activities.

Moreover, applicants must, from the ERC application stage, not only recruit partner enterprises but also engage in consensus building concerning how those enterprises will contribute to the center's activities (e.g., payment of membership fees, etc.) and their handling of intellectual property. Applicants likely try various ways of asking universities to plan ERC activities, which are difficult to realize unless everyone is prepared to work seriously toward the translation of research results.

All ERCs proceed with their projects based on such carefully prepared plans. When an ERC is in its fifth or subsequent year, the NSF provides advice toward helping it diversify its financial resources by, for example, obtaining funds from industry or research support bodies situated closer to the program exit. This is for the purpose of helping the ERC gain the ability to operate independently after the ten-year support period.

## 3.4.2 Development of interdisciplinary human resources to take charge of new systems

As was mentioned in 3.3.4 above, educational activity-related planning is included among the ERC program criteria used when selecting ERCs. Moreover, as will be discussed in detail in 3.5.1, "educational and dissemination activities" are positioned as a criterion in the mid-term evaluations that take place in the third year and later after selection. One of the first things checked in a mid-term evaluation is whether or not students involved in the ERC program are given adequate opportunities to interact with various stakeholders. Questions asked here include the following: Has a multidisciplinary research culture that involves undergraduates been established? Do students have adequate opportunities to work together with industrial and business people? And, does educational collaboration exists among the major member universities? Other questions that are raised include the following: Does the ERC's research contribute to high-quality educational

materials and programs? And, does the ERC engage in educational activities that target students and instructors at the high school level and below as well as students of universities that are not participants in the ERC? In this way, measures that expand the center's base in terms of its human aspects—namely, the creation of educational programs for continuous development of the human resources that will lead "transformational engineered systems," and promotion of activities that invite a broad range of human resources to participate in those programs—are built into the ERC program.

## 3.4.3 Translating wide-ranging results in such areas as technology, human resources, and concepts

The knowledge and research results that are generated from ERC activities are taken by the business divisions of participating enterprises and used to further develop technologies for commercialization, or are transferred to industry in the form of new business startups. The fact that what is transferred to industry in this way goes beyond specific technologies to include supplies of human resources through the employment of ERC graduates and the acquirement of "new ways of thinking" is perhaps the most important characteristic of the ERC program.

## 3.5 ERC management

In addition to technology- and system-related research results, the ERC program stresses the training of human resources to lead "transformational engineered systems" and the independence of ERCs following the end of support. Accordingly, its management looks at whether government organizations that support the provision of test beds, recipient industries (including venture startups), and application-oriented research are included; whether the human resources that industry demands are being produced: and whether the fund sources of ERCs are diversified.

## 3.5.1 Evaluation

Under the ERC program, annual "yearly evaluations" as well as third-year and sixth-year "mid-term evaluations" are conducted during the support period, which lasts a maximum of ten years.

## (1) Yearly evaluations

Each ERC under the ERC program prepares an annual report, which in total can reach up to 300 pages, and submits to the NSF. The annual report must include not only the ERC's research achievements for the pertinent year but also a discussion of benchmarks together with an analysis of the center's strengths and weaknesses in comparison with rival centers.

Additionally, site visits are conducted as part of the yearly evaluation. Here, some ten experts in various fields visit each ERC. During a visit, the experts spend two days studying and discussing such topics as educational effectiveness, the roles of students, and the participation of private enterprises and partners. Even more so than technologies themselves, the site visits seek to confirm research processes. In some cases, changes are made to team compositions and other matters (and in extreme cases, the ERC's director is replaced) based on the discussions that take place during visits. Additionally, if the ERC is in the fifth or later year of support, it is advised to diversify its funding sources.

## (2) Mid-term evaluations

Under the ERC program, mid-term evaluations are conducted in the third and sixth year to determine the advisability of continuing the targeted ERC. These evaluations are conducted by teams comprised of experts in the pertinent technical fields; experts in education, technical transfer, research management, industrial technology development, and other fields; and NSF staff members.

A mid-term evaluation is conducted through a site visit lasting two days. First, ERC members make a presentation. This is followed by a discussion between stakeholders (i.e., ERC member, partner enterprises, university administrators, etc.) and the evaluators and then a visit to the ERC's laboratories. Then, based on the results of their discussions with those concerned, the evaluators conduct an analysis of the center's strengths and weaknesses (SWOT<sup>85</sup>) and identify issues. The visit is then concluded with the signing of an agreement between the ERC and NSF on measures to be executed in the following year.

The mid-term evaluations are also not focused solely on research in itself. Incorporated into them an analysis of the targeted ERC's international positioning based on the SWOT analysis as well as items concerning its education/dissemination activities and joint activities with industry and business. The following is a list of main evaluation items.

<sup>&</sup>lt;sup>85</sup> An abbreviation of "Strengths, Weaknesses, Opportunities, Threats." It is a framework for environmental analysis of strengths weaknesses, opportunities, and threats for the formulation of corporate business strategies, etc. It is utilized in the development of strategies that alleviate threats by taking advantage of strengths and overcome weaknesses by seizing opportunities.

## Intellectual merit

- (1) Is focus on a transformational engineered system?
- (2) Is the ERC's strategic plan capable of overcoming obstacles to achieving the system's goals?
- (3) Does the ERC aim to execute a comprehensive research program, and does it have the organization to do so?
- (4) How are its activities here important in promoting field-specific as well as cross-cutting knowledge and understanding?
- (5) How do those activities propose and explore creative and original concepts?
- (6) Do teams have the qualities needed to implement projects?
- (7) What good points exist in team composition and systematization?
- (8) Does the ERC have sufficient access to research resources?

## SWOT analysis

The evaluation team conducts a comparison with rival centers and analyzes each ERC of the program in terms of its strengths and weaknesses.

## ERC characteristics

- (1) Vision and impact
- (2) Strategic research plan to fulfill the vision
- (3) Research programs
- (4) Education and dissemination activities
- (5) Joint activities with industry and business
- (6) Planning of strategic fund allocation and management

## 3.5.2 Diversification of funding sources

As was mentioned above, centers of the ERC program aim to gain the ability to be operationally independent when the NSF's support ends after ten years. For this reason, their ideal is to gradually diversify their funding sources and reduce the support they receive from the NSF. As Figure 3-4 shows, in actuality the funding sources of ERC program centers as a whole cover a broad spectrum that includes other government bodies, industry, and universities. Support from the NSF amounts to about 40% of the whole.

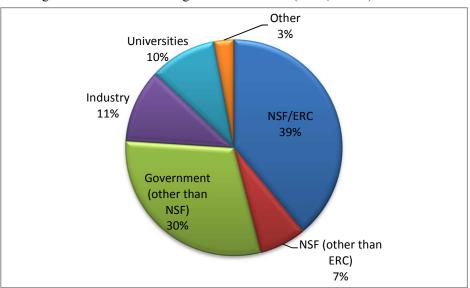


Figure 3-4: Overall funding sources of ERCs (2012, actual)<sup>86</sup>

Source: ERC Association

## 3.5.3 NSF support for ERC management

The NSF has also actively supported the operation of the ERC programs centers. For example, it has prepared a "best practices manual" for the purpose of sharing know-how among ERCs that are scattered throughout the United States and given instruction on know-how to research support staffs.

(1) Preparation of a "best practices manual"

The Committee of ERC Participants, which is a committee of people associated with the ERC program, engages in various activities under the direction of the NSF.

An activity of particular importance is its preparation of a "best practices manual" as a kind of center operation manual for the ERC program. The manual contains several hundred pages of detailed "how to" pointers for the operation of centers within the ERC program. Its content is updated and revised yearly. The manual covers a broad range of topics, including research management and ERC operations that involve industry-academia collaboration or multiple universities. It should be noted that the manual is prepared independently by the Committee of ERC Participants and is not an official publication of the NSF.

(2) Lectures for research support personnel by persons experienced with the ERC program

Administration of an ERC is complex undertaking. As an example, the core university of an ERC must pay salaries to hire researchers affiliated with its partner universities. For this reason, instruction on necessary know-how has recently started through exchanges by research support personnel. This includes dispatching staff members who have past experience managing an ERC to newly selected ERCs to provide advice based on requests from the NSF.

<sup>&</sup>lt;sup>86</sup> http://www.erc-assoc.org/about/erc data/total-erc-cash-support-fy-2012-17-ercs

## 3.6 Outcomes

#### 3.6.1 Impact surveys

Surveys on the ERC program's effects have been held at the ten-year and twenty-year marks following the program's launch. The final reports were issued in 1997 and 2008, respectively.

The 1997 survey was conducted by the NSF. It primarily focused on two items: the relationship between the ERC program and private enterprises and graduate students who are involved with the ERC program. Results of the survey that gave the program particularly high praise included the ERCs' hiring of graduate and undergraduate students, their acquirement of intellectual property rights, and their use of special equipment and facilities. This suggests that the ERC program was contributing to human resources development that was matched to corporate needs.

The 2008 survey was conducted by an American think tank called SRI.<sup>87</sup> This survey evaluated the ERC program's economic impact. It chose a number of ERCs and then attempted to demonstrate in specific numerical terms the economic effects that they had generated up until that time. However, whether the survey acquired a sufficient amount of data is questionable, and despite its original intentions, it ended up underestimating the impact of the ERCs. The survey's report includes the point of view that, because the ERC program emphasizes the development of next-generation human resources that will lead transformational engineered systems, measuring its immediate effectiveness is problematic.

#### 3.6.2 Independent ERC operation after the end of NSF support

Of the 38 ERCs whose NSF support concluded, 31, or 82%, continue to operate independently with new private or public funds.<sup>88</sup> Thus, it is appropriate to say that the program is achieving a certain level of success.

## 3.6.3 Development of educational curricula in universities and graduate schools

The development of textbooks and educational programs with the fruits of ERC activities is encouraged under the ERC program. For example, the following aggregate results had been achieved by the 17 supported ERCs as of 2012.

- Establishment of new full-degree programs based on ERC research results: 4 programs
- Establishment of new courses based on ERC research results: 52 courses (266 courses are continuing)
- ▶ New textbooks that include chapters based on ERC research results: 9 textbooks

#### 3.6.4 Supply of superior human resources to industry

As Figure 3-5 shows, more than half of ERC graduates find employment in industry. Additionally, according to a questionnaire survey of member firms of the ERC program, when asked how ERC graduates surpass ordinary graduates, respondents indicated that ERC graduates have "overall preparedness to work in industry," "breadth of technical knowledge," and "ability to work in interdisciplinary teams."<sup>89</sup> This result suggests that the program is producing human resources that can step straight into industry.

<sup>&</sup>lt;sup>87</sup> SRI "National and Regional Economic Impacts of Engineering Research Centers: A Pilot Study" Final Report (November 2008)

<sup>&</sup>lt;sup>88</sup> http://erc-assoc.org/content/status-ercs-year

<sup>&</sup>lt;sup>89</sup> http://erc-assoc.org/about/erc\_data/comparisons-member-firms-performance-erc-graduates-non-erc-hires

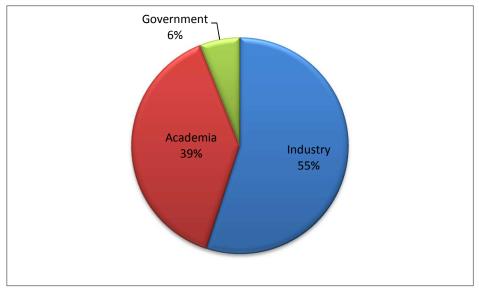


Figure 3-5: Career paths of ERC graduates (FY2012)

Source: ERC Association

# 3.7 Case study: The Center for Computer-Integrated Surgical Systems and Technology<sup>90</sup>

Here we will present the Center for Computer-Integrated Surgical Systems and Technology (CISST), which was established in Johns Hopkins University in 1998, as an example of a center of the ERC program.

# 3.7.1 Outline of the center and R&D challenges

CISST was established to develop innovative surgical processes and disseminate low-cost, highly successful surgical technologies for surgery that combines the capabilities of people and computers.

At the time of its establishment with ERC program funds, CISST began looking at robotic systems for minimally invasive surgery and asked, "How can information technology be utilized within surgical processes?" It then explored the following two approaches toward finding a solution.

- Acquirement of medical imaging in the form of data using a surgical CAD/CAM<sup>91</sup> system, formulation of a surgical plan based on those data, and then building of a mechanism for executing surgery (application of methods used in manufacturing to surgery)
- (2) Support for microsurgery

# 3.7.2 Funding sources

During the time that it was receiving ERC program support, CISST received a total of \$70 million. Of this, the NSF provided \$33 million. The remainder was comprised of \$17 million from Johns Hopkins University and \$20 million from other sources, (DOD, NIH, etc.). Although almost all of CISST's funds came from the NSF at the time of its establishment, the center later gradually diversified its funding sources.

# 3.7.3 Participating organizations

CISST is based in Johns Hopkins University's engineering faculty. Its partner institutions in the area of robotics research are Massachusetts Institute of Technology and Carnegie Mellon University, which stand at the top of this field. Its partners in medical research are Harvard Medical School's Brigham & Women's Hospital, Shadyside Hospital, and the Johns Hopkins Hospital.

Under the ERC program, the standard practice is to recruit participating companies from the application stage. However, in 1998 there was no such thing as a surgical robotics market, nor were there any companies capable of taking the lead in this field. Given this, CISST received the NSF's approval to begin its project without any participating companies.

# 3.7.4 Characteristics of NSF support

• System development that gives cohesive power to the director

The top of the chain of command at an ERC was the university faculty's dean. However, the dean generally allowed the ERC's director, who is directly below the dean, to promote the center's activities at his or her discretion. The director was not obligated to report to department chairpersons, and this made it easier to operate the ERC based on collaboration that extends beyond department boundaries.

The ERC was able to attract partners by paying the personnel costs of researchers from partner

<sup>&</sup>lt;sup>90</sup> The content appearing in this section comes from an interview with CISST ERC's director (interview on December 18, 2013)

<sup>&</sup>lt;sup>91</sup> Computer-aided design and computer-aided manufacturing. In the surgical field, this technology can prepare three-dimensional models from CT images and produce surgical simulations using those models.

organizations. On the other hand, the question of how it will be able to maintain this relationship after ERC program funds dry up is currently a topic of concern.

• Beneficial advice from experts through site visits

Considering the personnel costs that are borne by the NSF, we believe the annual site visits are extremely expensive evaluations. However, they are beneficial for us because the evaluators give us excellent feedback.

Seamless collaboration with other NSF programs

NSF officials demonstrated a posture of actively wanting to get feedback from the front lines and utilize it to augment and improve the ERC program. They also kindly gave us advice on measures that would be effective for the center. For example, they told about other NSF programs that will help link the results of our research with exit organizations.

• Troublesome ERC program operation

It was very difficult operating such a large and complex organization under the ERC program. For example, we had to hire and remotely manage instructors from other universities with ERC program funds that Johns Hopkins University received from the NSF. This was an unprecedented experience for the university. Moreover, we had to prepare annual reports that reached over 300 pages for the annual evaluation. Fortunately we were able to manage by hiring excellent managers.

# 3.7.5 ERC program effects and ripple effects

• Contribution to engineering faculty reform

Having several of the world's top researchers on its staff, Johns Hopkins University's engineering faculty has traditionally operated independently, without partnering with others. On the other hand, the ERC program makes activity in partnership with other fields and institutions a prerequisite. The faculty's execution of this kind of interdisciplinary project provided an empirical demonstration to people within it that "this is how an interdisciplinary project is implemented." The result was the emergence of an interdisciplinary atmosphere within the university and the cultivation of a culture for interdisciplinary research that stretches across faculty boundaries. Without the ERC, it is unlikely that such interdisciplinary research would have become quite so active.

• Supply of technologies and human resources for new markets

The ERC has produced a number of successes that include patents and licenses. Among them is image-guided needle placement technology that guides and sets the position of surgical needles with images. However, its biggest success is thought to be its generation of interdisciplinary human resources prepared to step straight into the still immature field of surgical robots. This has allowed it to build a good relationship with Intuitive Surgical, a company that gained fame for producing the surgical robot "da Vinci."

# 3.8 Future orientation<sup>92</sup>

Today, with the ERC program just entering its 30th year in existence, there is recognition that securing competitiveness is an important issue in an increasingly globalized economy. Given this perception of the times, the following improvements are being discussed as necessary within the program.

- More flexible support: Under the current ERC program, only those projects with a fully developed activity plan are eligible for support. However, in reality there are activities that are based on good ideas but which require time and funding to get organized. Because of this, there is talk suggesting that providing "seed funding" for partner development and other new ERC activities. Moreover, although the ERC support period is ten years in principle, depending on the field, there are some activities that can produce results in a shorter period of time and others that require longer support. Thus there is also discussion on the advisability of implementing a mechanism that could flexibly change the support period depending on the content and nature of research undertaken at individual ERCs.
- Implementation of top-down research: At the current time, all research topics are set in a bottom-up format. However, there is discussion within the program about whether a small amount of top-down research should be included for strategic fields.
- Reinforcement of international collaboration: Beginning with third-generation ERCs, collaboration with overseas institutions has been added as a requirement for ERC selection. However, in most cases, such collaboration goes no further than the holding of personnel exchanges or organization of joint symposia or meetings. Thus there is discussion suggesting that international collaboration should be deepened and that the United States should be developed into the hub of an international network.

<sup>&</sup>lt;sup>92</sup> STPI "Designing the Next Generation of NSF Engineering Research Centers: Insights from Worldwide Practice," November 2007

# 3.9 Implications to Japan

# 3.9.1 Mechanism for producing values in the form of "transformational engineered systems"

Intellectual production in the 20th century was based on reductionist research that was conducted in search of the truth. However, in the 21st century, the social issues that are targeted by research have become much larger and more complex, while at the same time S&T have become more segmentalized. The result is that issues can no longer be addressed by individual specialties. Thus, there is a need to reexamine intellectual property production from the standpoint of "creating value." Despite this, no strategies capable of pushing forward such a structural shift are to be found in Japan.

On the other hand, the ERC program could be described as an undertaking in which researchers propose hypotheses for unprecedented new value (called "transformational engineered systems"), test those hypotheses in the form of an engineering research center (ERC) for ten years, and then release them to the world. Activities during the time an ERC is being developed are not limited to just technical development. They also involve bringing together private enterprises that approve of the idea behind the ERC as well as initiatives to development infrastructure for continually sending new systems into the world, such as the development of human resources that are adapted to the new systems and preparation of curricula for developing those resources. These activities are incorporated into the NSF support process.

While it must be admitted that differences exist between the United States and Japan in terms of institutions and customs, it is likely that there are many areas in which Japan can learn from the ERC program as it aims to reform its systems for creating value.

#### 3.9.2 Review of educational effectiveness for students: Funding agency-led integrated promotion of education and research

The need to engage in human resources development through research projects has been highlighted in Japan before. Nonetheless, it would be difficult to claim that this thinking has been adequately reflected in Japan's funding agency support policies.

Although all projects that the NSF supports are premised on the integrated promotion of education and research, the ERC program receives particularly high marks in terms of the effectiveness of its human resources development. The site visits that are conducted annually at each ERC of the program could be seen as one reason for this. With the site visits, top-level experts in various fields are sent to ERCs to engage in meticulous discussions in which students are among the participants. At this time, students make presentations describing the circumstances of their ERC and details of their research to the visiting experts, and have ample opportunities to discuss matters with them. Being blessed with such opportunities while still young can only give students great encouragement. On the other hand, the NSF evaluates the degree to which the ERC's education has permeated among students by checking if they can discuss the ERC's objectives in the same way that center directors can. The NSF has indicated that it learns a lot from students in this way. Thus, this program represents one way in which a funding agency guides the integrated promotion of education and research, and as such it will serve as a useful reference.

### 3.9.3 Fine-tuned and seamless support for the creation of innovation

Under the ERC program, a variety of policy tools—namely, education, research, and industry-academia collaboration—are incorporated into the support policy for individual ERCs. However, because the ERC program establishes its bases in universities, support policies for the practical application of research results, such as the creation of venture businesses or development outsourcing, are not part of the program menu. It is our impression that when, in the process of meticulously ascertaining and monitoring the circumstances of each ERC, the NSF determines that an ERC requires support that is outside the scope of the ERC program, it introduces the ERC to other support policies and links programs, thus providing seamless support for the creation of innovation. How and upon what processes such linkage of programs is accomplished could not be identified in this survey. However, we believe that the building of mechanisms that make flexible operation feasible should prove effective when studying ways of improving Japan's funding system.

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# **Chapter 4: The Catapult Programme of the United Kingdom**

In this chapter, we will present the Catapult Programme as an example of academia-industry collaborative framework for promoting translational research in the UK. The programme is intended to establish business-focused technology and innovation centre called as "Catapult centre". The Catapult centres can enable businesses to exploit new and emerging technologies, by closing the gap between concept and commercialization to drive UK economic growth in key technology areas where the UK has strengths. We will look at the programme's background, objectives, characteristics, operational structure, funding scheme and challenges.

# 4.1 Background

## 4.1.1 High level of scientific excellence but relatively weak commercialisation

One of the challenges the UK government has been tackling is the fact that there is a lack of effective scheme with a long-term vision and certainty to translate outcome of scientific research into commercial propositions. Although UK universities have traditionally enjoyed a strong international reputation for world-class strengths in research excellence, and charity-led R&D is significantly active in the UK compared with other countries, several deficits in the UK science and innovation system have been not improved in an appropriate matter. First, there is relatively weak cross-sectoral technical transfer. And then, R&D activities in the UK private sector are comparatively less active. Finally, a sustained, long-term pattern of underinvestment in public and private R&D as well as its smaller percentage of GDP resides in the UK. Having been taken austerity measures, the government is confronted with the pressing challenges of efficiently and effectively distributing limited science budget, and of maximizing possible outcome of S&T investment and enhancing UK economic growth.

# 4.1.2 Technology and Innovation Centres: TICs

Prior governments over decades have been gone ahead with a range of innovation policies that can contribute to translate research outcome into commercialization with a view to fully capitalizing on excellence of the UK's research base. Over 50 business-focused Technology and Innovation Centres (TICs) have received over £150 million in public support since 2008. The TICs have been pro-active in developing and commercializing their specific technologies and relevant IP with highly qualified staff who can best figure out the market needs. The activities within the TICs can be categorized in the following two types. One is focused on technology and capability where TICs seek to develop a specific technology and promote its exploitation. Example includes the Printable Electronics Technology Centre (PETEC) which is an R&D facility for printed electronics represented by organic EL displays. The other is focused on sector and marked with examples including MediaCityUK, which has been established to provide a place for cooperation in creative and digital businesses.

However, the TICs could not ensure long-term, sustained and predictable flow of public funding. The activities of most TICs do not also appear to be adequately integrated into the national innovation system. Investment in TICs has, therefore, resulted in highly dispersed patterns without additional investment from businesses.

# 4.1.3 The Hauser review

The March 2010 independent review<sup>93</sup> prepared by Dr. Hermann Hauser<sup>94</sup> titled "The Current and Future Role of Technology & Innovation Centres in the UK" highlighted the need for the UK to make intermediate technology & Innovation centres for the purpose of bridging research findings and technology commercialization. His review made a case for long-term UK investment in a network of technology and innovation centres, based on best practice in other countries, such as the Fraunhofer Institutes in Germany and TNO in the Netherlands to 'deliver a step change in the UK's ability to commercialise its research'.

The conclusion of the review was that the UK was indeed missing a key piece of an intermediate infrastructure which can be expected to provide business with access to the best technical expertise, infrastructure, skills and equipment. It also concluded that the creation of such a centre would encourage the development of new technologies and ultimately contribute to the UK economic growth. It is told that industry sector took an initiative in designing and creating such a new framework for a sustained investment and joint working between business and the UK research base.

## 4.1.4 Launch of the Catapult Programme

The Conservative Party then in opposition also consulted Sir James Dyson who endorsed the approach. He reinforced the rational and arguments for such an infrastructure with his March 2010 report titled "Ingenious Britain"

Recommendations in those reports were supported by both of the Labour Party and the Conservative Party, and their governments shared the fact that the UK lacked an R&D platform with long-term perspective and finance, which could contribute to and even enhance the national economic growth.

In September 2010 the UK government announced funding for such technology and innovation centres and asked for public comments about the programme's name. Any suggestions for appropriate names were welcome through email, and eventually the name "Catapult" was chosen as a suitably prestigious and globally recognized one.

The word "catapult" refers to a device used to "propel things forward with great force." It is used for devices that launch planes from aircraft carriers as well as for bows and slingshots that serve as children's toys. It was deemed that the sense of "to expel with great force" was completely suitable for an image of overcoming the so-called "valley of death."

<sup>&</sup>lt;sup>93</sup> "Independent review" refers to a report containing recommendations for improvements and other items that is prepared after the UK government establishes a committee to look into a particular matter, and the committee conducts a comprensive survey and evaluation of the matter. Although government ministries are under no obligation to abide by the review's recommendations, they must make some kind of response, such as clarifying the reasons for not abiding. Many organizational and institutional improvements are spurred by independent reviews, and it is not unusual to see the results of a review serve as the basis for promoting policy reforms. The committees are established outside of the government, and their surveys are conducted with attention to keep their independence.

<sup>&</sup>lt;sup>94</sup> Dr. Hauser is an entrepreneur who has personally launched/supported many computer- and communications-related venture companies and attained success with almost all of them. He is also a private investor. He established the investment company Amadeus Capital in Cambridge and invests in high-tech venture companies among other activities.

# 4.2 What is the Catapult Programme?

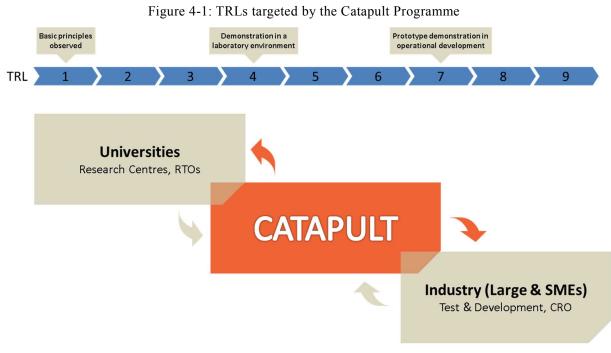
## 4.2.1 Outline and objectives

The Catapult Programme aims to build a network of technology and innovation centres in specific areas where the UK has strengths and remains the world leading power. Serving as a platform for academia-industry collaboration, each centre is intended for closing gap between concept and commercialization to drive UK economic growth in key areas where private enterprises, engineers and scientists can work together to promote R&D activities with a view to effectively translating outcome of basic research to innovation and contributing to the UK's growing wealth.

Under the programme, "Catapult centres" are established as a venue for boosting collaboration between business, academia and researchers in specific technical areas (currently 11 areas). The Catapult centres are a place for producing world-leading technical capability, where industry can resolve its technical challenges. Simultaneously they form a platform for delivering long-term investment that will allow businesses to supply new products and services though such collaboration.

Industry is supposed to be a main stakeholder of the programme to design an integrative R&D platform as well as a main booster of business-led approach on R&D. The Catapult is not a funder so public investment in the programme is not basically to use for research projects but rather to manage and operate the centres, however, there are exclusive cases where public money can be used to support infrastructure projects or projects that build capability in the centres.

As Figure 4-1 shows below, the Technical Readiness Levels (TRLs) focused on by the Catapult centres are those between TRL 3 (Proof-of-concept) and TR7 (Prototype demonstration in operational development).



Source: "Review of the Catapult network" by Dr. Hermann Hauser

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Each centre has different goals. The Cell and Gene Therapy Catapult has, for instance, the goal to build a £10 billion industry that will contribute to the UK economic growth and generate the critical mass needed to compete effectively in global value chains and high growth markets. The Satellite Applications Catapult also stresses contribution to economic growth, and one of its basic goals is to generate economic impact in the UK through the development of satellite applications.

On the other hand, the Nuclear Advanced Manufacturing Research Centre (Nuclear AMRC), which is one of 7 facilities operated under the High Value Manufacturing Catapult, is aiming to become the catalyst for building industrial technical capabilities in the civil nuclear power field and other innovative energy sectors.

As is seen here, the goal of each Catapult centre has almost nothing to do with productivity of academic papers, which can be traditionally stressed as an indicator of scientific research output.

## 4.2.2 Promotion scheme

Innovate UK, the UK's innovation agency, funds, supports and connects UK innovative businesses through a unique mix of people and programmes to accelerate economic growth. The Catapult Programme is managed as one of an integrated series of programmes and portfolios to R&D&I support in Innovate UK to key sectors in the UK economy. Figure 4-2 shows below R&I landscape in the UK.

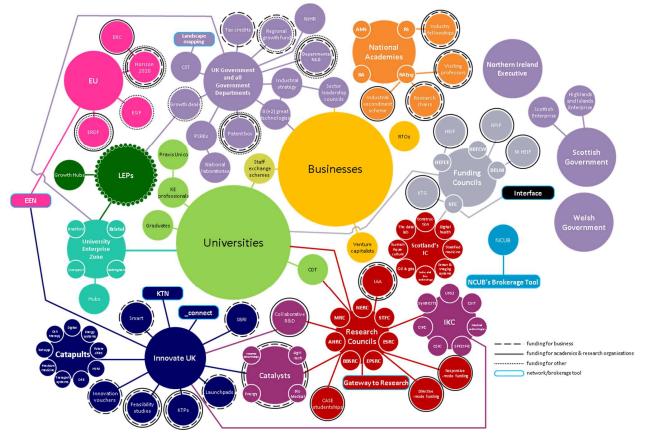
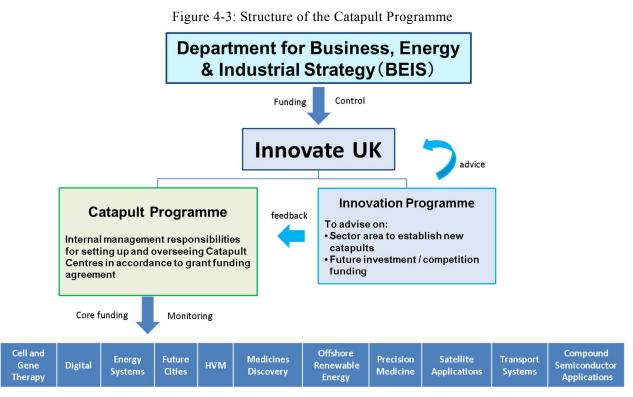


Figure 4-2: Research and innovation landscape map in the UK

Source: "The Dowling Review of Business-University Research Collaborations" by Professor Dame Ann Dowling

Innovate UK works with business, academia and government to identify and prioritise support for areas where the UK has business strengths and academic capability that can address global challenges and create opportunities for the UK economic growth. The Catapult centres were established and overseen by Innovate UK. Innovate UK serves functions partly similar to those of New Energy and Industrial Technology Development Organization (NEDO) in Japan, and works with the relevant stakeholder community in each of those areas to identify barriers to innovation and to address them through the appropriate use of tools within its portfolio.

The Catapult centres are independent entities from Innovate UK so that they can respond to the needs and trends if their industry sector. The Catapults' activities are aligned with those of Innovate UK and create a positive feedback circle between industry-Catapults-Innovate UK and the Research base. The overall structure of the programme is shown below in Figure 4-3.



Source: Prepared by the authors based on available materials

# 4.2.3 The Catapult centres

The selection of centres made by Innovate UK is guided by the following five criteria.

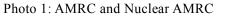
- (1) The existence of potential global markets which could be accessed through the Centres that are predicted to be worth billions of pounds per annum
- (2) World-leading research capability in the area in the UK
- (3) UK business ability to exploit the technology and make use of increased investment to capture a significant share of the value chain and embed the activity in the UK
- (4) Potential for the Centre to enable the UK to attract and anchor the knowledge-intensive activities of globally mobile companies and secure sustainable wealth creation of the UK
- (5) Close alignment with national strategic priorities

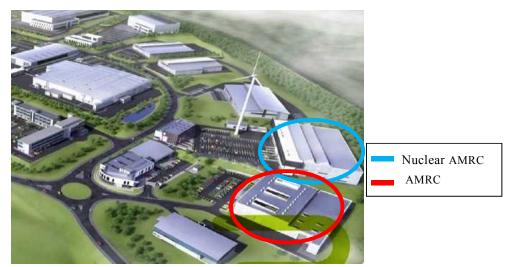
As these five criteria demonstrate, the programme places greater emphasis on economic impact and effect as well as academic evaluation.

Regarding selecting a centre site, several candidates are considered among existing research infrastructures, and those candidates are narrowed down to the last one finally selected. Centre sites are not limited to the same type of facilities: from universities to hospitals, research institutes and other organizations.

The site selected for the Cell and Gene Therapy Catapult is Guy's Hospital in central London. This site was selected also based on consideration for its high accessibility for many people, availability of space for R&D and tests, and feasibility for becoming a global centre.

On the other hand, the Advanced Manufacturing Research Centre (AMRC), which is one of 7 facilities operated under the High Value Manufacturing Catapult, was established in 2001 with collaboration between the University of Sheffield and Boeing. AMRC subsequently moved into the Advanced Manufacturing Park and has been also the site of a project implemented with the participation of major domestic and overseas companies: Rolls Royce and Airbus. AMRC currently forms the core of the University of Sheffield AMRC group, along with Nuclear AMRC mentioned above (Photo 1).





Source: © Presentation materials by Nuclear AMRC

AMRC was established with public investment worth £15 million, with additional support from Yorkshire Forward and the European Regional Development Fund.

In 2014, when the Digital Catapult newly opened an innovation centre in central London, its site was considered as the ideal location at the heart of knowledge in the digital related field, as the Alan Turing Institute and the Francis Crick Institute.

At the present time, the network of Catapult centres is located throughout the UK in 11 areas of strategic important to each sector. The Catapult programme still has small history because it was launched only in 2011. Figure 4-4 below shows the locations of the existing Catapult centres.

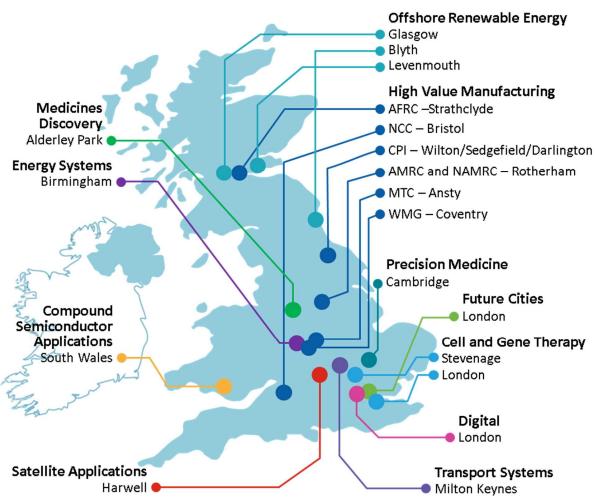


Figure 4-4; Locations of Catapult centres in 11 areas

Source: Prepared by the authors based on available materials

#### 4.2.4 Budget

In autumn 2010, the UK coalition government provided funding worth over £200 million to Innovate UK to establish seven Catapults over the four-year Spending Review period from 2011 to 2015. These seven centres include High Value Manufacturing, Cell and Gene Therapy (then called "Cell Therapy Catapult"), Satellite Applications, Offshore Renewable Energy, Digital (then called "Connected Digital Economy"), Future Cities and Transport Systems.

The government has also provided additional funding worth £328 million since the 2010 Spending Review settlement, both to grow the capabilities of the first seven Catapults and to establish two more Catapults, identified as Precision Medicine and Energy System. Total initial public funding thus reached £528 million. And the total amount of initial public and private sector investment was £1.4 billion.

Some of the Catapults received additional funding except initial core funding. The Cell and Gene Therapy Catapult, for instance, received £55 million funding to establish large-scale advanced therapies manufacturing centre in Stevenage. The High Value Manufacturing Catapult has also gotten a total of £28 million to build the National Formulation Centre for the development of next-generation technologies and products.

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The latest is the Compound Semiconductor Applications Catapult, to be based in Wales, which will receive £50 million funding over the next 5 years.

The Catapults operate on a 1/3, 1/3, 1/3 funding model, whereby one third of their funding is core government funding, one third is competitively won from national and EU funding and the final third comes from commercial, contract research with business, and fee for service. However, this is no more than an ideal model, as actual budgets are handled flexibly in accordance with the circumstances of each Catapult. If you look at a breakdown of the Annual Review 2014-2015 of the High Value Manufacturing Catapult, it shows that 48%, or roughly half, comes from contracts with industry. Competitive R&D accounts for 33% and core grant through Innovate UK accounts for 19% of the total.

For core/government funded portion, each Catapult centre agrees a five-year plan for achieving increased economic growth in their respective sector with Innovate UK. The agreement stipulates that this institutional grant can not be used for research but used for the actual operation of the centre itself. Funding for research project is only covered by contracts with industry or competitive R&D. Innovate UK has set up a representative office in Brussels, Belgium in 2014 to encourage UK businesses to participate in European research programmes within the Catapult framework. Such efforts to acquire competitive research funds in the Catapult Programme may help drive more active participation of UK businesses. The February 2015 report by Innovate UK titled "Catapults contributing to Europe 2020" summarizes the significance of Catapults' participation in European programmes and projects.

### 4.2.5 Human resources

In the Catapult Programme, recruitment of human resources has been ongoing, either openly or unofficially. Each Catapult centre has broad range of employees with different background in terms of operation planning, strategy development, and the programme management. Employees from industry sector accounts for a relatively high proportion of the total. Some of the Catapults accept interns from universities.

Employees with such diverse backgrounds are managing research projects in close consultations with business, academia and researchers in both formal and informal settings.

Some of the Catapults have a special training centre with a focus on human resources development. AMRC, for instance, has the AMRC Training Centre, which opened in autumn 2013 to provide advanced apprenticeship and higher training for manufacturing companies. The courses on "Engineering Apprenticeships" and "Business Services Apprenticeships" can be used for those who apply through electronic application procedures.

# 4.2.6 Time span and project types

There is an expectation that public funding for the Catapult Programme will continue for at least ten more years.

Project numbers and its implementation period in the centres are different by each Catapult areas. In the Digital Catapult, from seven to ten projects are ongoing as of November 2015, with different time spans between several months and half a year. SMEs in the projects account for around 60 - 70% of the total participation.

The High Value Manufacturing Catapult has more than 1,000 projects being implemented among its seven research facilities, with project periods including two or three years. SMEs account for approximately 40% of the total project participation.

# 4.2.7 Targeted areas

Figure 4-5 below shows the Catapult timeline.

Catapult centres	Data operational			
High Value Manufacturing	October 2011			
Cell and Gene Therapy	October 2012			
Satellite Applications	December 2012			
Offshore Renewable Energy	March 2013			
Digital	June 2013			
Future Cities	June 2013			
Transport Systems	August 2013			
Energy Systems	April 2015			
Precision Medicine	April 2015			
Medicines Discovery	TBD			
Compound Semiconductor Applications	TBD			

Figure 4-5: Cat	apult time	line
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Two Catapults in the areas of Precision Medicine and Energy Systems were newly established in spring 2015. And it was announced in July 2015 that a new Medicines Discovery Catapult would be established on the grounds of Alderley Park, located in Cheshire County of southern Manchester. Additionally, it was only recently announced in January 2016 that a Catapult focused on Compound Semiconductor Applications would be built in Wales.

Innovate UK is always considering candidate areas for new centres and updating its candidate list. Examples include robotics, quantum technology, and food production. While close alignment with national strategic priorities is emphasized in the setting of such areas, they have connections with "the Eight Great Technologies" presented in 2013 by then Minister of State for Universities and Science David Willetts, identified as Big data, Satellites, Robotics and autonomous systems, Synthetic biology, Regenerative medicine, Agri-science, Advanced materials, and Energy storage. The Eight Great Technologies were decided based on certain standards, namely, growth of the UK economy, Interdisciplinarity, and UK research capability, and its aim is to accelerate commercialization in those technology areas, which would highly compatible with one of the Catapult Programme.

# 4.3 **Programme characteristics**

The specific role of TICs varies according to the innovation system and economic and social landscape of the countries they operate in. However, a shared rationale exists for developing TICs that bridge the gap between academic discovery and commercial exploitation. There are actually countries which benefit from a translational infrastructure that bridges the gap.

Before taking any action to introduce a new translational infrastructure in the UK context, international comparisons were conducted to evaluate the roles and performance of TICs overseas, to identify international best practice. The roles of the TICs were explored in 12 countries: Germany; South Korea; Sweden; France; China; Denmark; the US; Japan; Singapore; Israel; Belgium, and the Netherlands. Germany's Fraunhofer model was paid special attention to the UK, however, the programme the UK launched is not the same as Fraunhofer's framework in Germany which has a different historical background. We will figure out what kind of characteristics is featured in the UK Catapult Programme.

#### 4.3.1 Sustainable Catapult development

The first point thought to be important here is to promote sustainable research base development, harnessing existing research infrastructure. One of the aims in the programme is considered to form translational infrastructure where business, academia and researchers collaborate to undertake R&D and create innovation contributing economic growth. This would be achieved by eliminating overlap among R&D facilities scattered around the UK through their integration into a "big umbrella" of the Catapults.

It is told that direct public investment in R&D to support innovation leverages extra investment from the private sector. One third of the total budget in each Catapult is covered by government funding. However, as mentioned above, core government funding can not be used for implementing R&D projects so when they want to conduct projects, it is necessary to secure research funds through contracts with industry or competitive R&D. This scheme is important for thinking an institutional design of sustainable developments in Catapult programme. There is an expectation that if a centre happens to be not a Catapult, and public funding is terminated, this centre will be able to survive as a R&D platform.

#### 4.3.2 Promotion of industry-led R&D

The Catapult Programme is intended to establish business-focused technology and innovation centre, where an initiative of the private sector is inevitable to promote R&D activities. This framework enables each Catapult to take into account industry needs and to realize industry-academia-government collaboration in the earlier stage of R&D.

Over the years Innovate UK has provided funding support for matching with universities, public research institutes, and businesses. Between 2007 and 2015, Innovate UK cooperated with about 5,000 companies, and roughly 150 universities have participated in Innovate UK-funded projects. Innovate UK provides good opportunities for business and academics to engage with the Catapults.

Germany's Fraunhofer has the total of 66 research institutes, almost of which are located on the same territory of a university or adjacent to a university. It is notable that the cross appointment system of institute directors is operating well in Fraunhofer model. In fact, 74 of the 79 directors combine their status with professors<sup>95</sup>.

<sup>&</sup>lt;sup>95</sup> The total number of institute directors exceeds the number of research institutes, as some institutes have two directors.

On the other hand, almost all Chief Executives in the Catapult Programme come from industry<sup>96</sup>, and this successfully leads to clear understanding on more industry-oriented mindsets and to suitable assignment of high-quality personnel. Chief Executives' background would be important in terms of management of the centres.

All projects in each Catapult require a significant industry investment in parallel with public sector grants. It is vital that businesses are prepared to invest their money alongside public funding. In Catapult context, therefore, employees from industry sector accounts for a relatively high proportion of the total.

In Catapult centres, outcome of basic research in universities can be quickly tested on an industrial scale to promote R&D activities in subsequent stages. The Catapults enable university to access to conduct large-scale experimentation that might be usually difficult at the university laboratory level. Through the programme, Catapults can get public grants intended for expanding existing facilities or establishing new ones and the infrastructure is operating with equipment provided by industry sector. The fact that it is possible to seamlessly prove research results at an industrial scale is particularly attractive to university researchers.

## 4.3.3 SMEs involvement

The strengthening of S&T capabilities among the SMEs in the UK is an important issue of the Catapult Programme. SMEs are happy to participate in Catapult projects because large corporations can become valuable customers/clients from their perspective. Large corporations are also positive about working with SMEs. SMEs are pivotal as subcontractors for large corporations, and simultaneously, are necessary for the expansion of their supply chains. SMEs account for a major portion of supply chains, particularly in manufacturing, and thus their presence in the programme is considered to be inevitable.

However, SMSs involvement carries a certain degree of risk because they have problems in terms of cost and technical challenges. Having in mind the current circumstances, Innovate UK set up the condition that cooperation with SMEs is one of the requirements for receiving public funding. The strategies, implementation plans, annual reviews, and other documents that each Catapult has to prepare are required to mention SMEs involvement.

The Catapults takes different approaches with SMEs. The Digital Catapult sees SMEs participation in all cooperative operations as important matter. It includes active participation in workshops, data service, and new product demonstrations. This is because projects in the digital area are at the forefront of the times and involve contents that large corporations do not actually handle. SMEs and start-up companies make major contributions in this area, and large corporations welcome their fresh and innovative ideas and insight. The Digital Catapult has a scheme in place through which it displays noteworthy SMEs research accomplishments within its centre, which are free of charge for a limited time of three months, even if those accomplishments have no connection with ongoing projects in the Catapult. This provides SMEs with an excellent venue for highlighting their own outcome, and at the same time, offers opportunities for acquiring possibilities for promoting and improving R&D.

With centres of this nature, it could be said that Catapults in Digital and Future Cities areas better provide environments that facilitate participation by SMEs, and particularly start-up companies.

On the other hand, the situation differs in the High Value Manufacturing Catapult. Given that

<sup>&</sup>lt;sup>96</sup> The one exception is Mr. Peter Madden, who is Chief Executive of the Future Cities Catapult. He has no background in industry sector. Previously, he was Chief Executive of Forum for the Future, Head of Policy at the Environment Agency, Ministerial Adviser to the British Government, Director of Green Alliance and Head of Policy at Christian Aid.

SMEs tend to want to tackle immediate problems rather than long-term issues, many projects with SMEs participation in the High Value Manufacturing area would be short-term projects with limited cost and size. The High Value Manufacturing Catapult prepares small-scale projects designed with SMEs cooperation in mind in order to encourage their support. As Figure 4-6 shows, the total amount of collaborative R&D funding for the Catapult's projects in which SMEs participate is growing steadily.

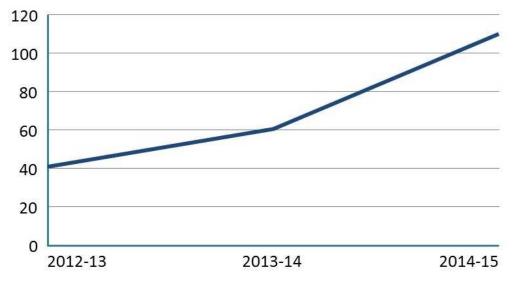


Figure 4-6: Total collaborative R&D funding accessed by SMEs (unit: million pounds)

Source: Annual Review 2014-2015 of High Value Manufacturing Catapult (p. 11)

In the ways described above, the Catapults proactively invite not only large corporations but also SMEs to participate in their projects as settings for promoting industry-led R&D. In general, participation in the Catapults provides an opportunity for SMEs to access internationally top-level technologies and expertise the UK's universities and large corporations have. This may help drive forward R&D in the UK's private sector.

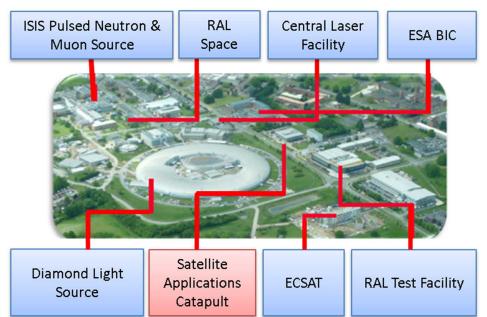
# 4.3.4 Reinforcing regional R&D capability

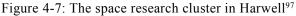
One of the aims of the Catapult Programme is to reinforce R&D capability in the nation's outlying regions. Under it, important technical areas in which the UK has an advantage are selected and research bases are formed by utilizing existing infrastructure. As was mentioned previously, these bases are selected so that investment is not concentrated in London and its periphery but is also distributed to outlying regions. It is anticipated that this approach will ultimately lead to stronger regional economies and industrial power. The willingness and cooperation of local governments are essential to the programme's success, and political lobbying efforts local governments and others have gained notice.

As can be seen in Figure 4-4 above, Catapults in only three areas: Digital, Future Cities, and Cell and Gene Therapy are located in London. Catapults in six areas: Medicines Discovery, Precision Medicine, Energy Systems, Transport Systems, Satellite Applications, and some facilities of High Value Manufacturing are distributed throughout the UK's central and southern regions. Catapults in

two areas: Offshore Renewable Energy and the remaining facilities of High Value Manufacturing are situated in the north.

The Satellite Applications Catapult, for instance, is located in Harwell. Harwell once supported the UK's nuclear power R&D as the home of the Atomic Energy Research Establishment, which was famous for its nuclear power research, and other facilities. However, its reactors have been shut down in recent years, and portions of its decontaminated grounds have been opened to the public and are being developed as housing districts. Against this backdrop, Harwell is now being reborn as an R&D cluster in the space area, and the Satellite Applications Catapult is operating as a part of it. Figure 4-7 shows the space research cluster which has been established in Harwell. As a player in the effort to reinforce the space cluster in Harwell, the Satellite Applications Catapult is gathering land and sea data using satellites and conducting climatic and environmental simulations among other activities.





Source: © Presentation materials by Satellite Applications Catapult centre

The Satellite Applications Catapult is building a regional R&D network for land and sea data by linking with other research bases in central and northern England and in Scotland. The network is shown in Figure 4-8. It is thought that the formation of this network is an important element in the effort to reinforce R&D in the UK's regions.

<sup>&</sup>lt;sup>97</sup> However, a number of facilities, including Diamond Light Source, are used as multipurpose facilities in ways that are not limited to space research.

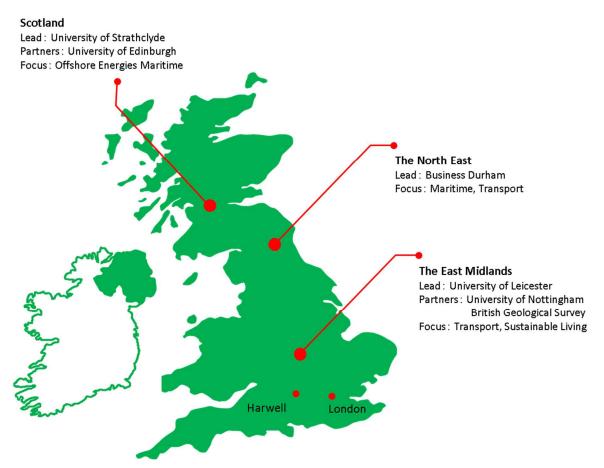


Figure 4-8: Satellite Applications Catapult's regional network

Source: © Presentation materials by Satellite Applications Catapult centre

# 4.3.5 Overall programme evaluation

The first Catapult is the High Value Manufacturing Catapult that started to operate in 2011. This means that, at the present time, only five years have passed since the programme's launch. There are some cases that only one or two years have passed since centre operation and project implementation began. These points make the Catapult Programme an extremely young undertaking, and thus it might be probably too early to conduct an overall programme evaluation.

The Catapult Programme is a significant and complex long term policy intervention that requires a long term impact evaluation. It is told that this will be conducted by both an external contractor along with the individual Catapults collecting the data.

As shown below, the indicators or data to be collected would be under one of 4 categories divided into sub-categories with specific indicators.

#### 1. Inputs

- a. Public investment
- b. Staff knowledge and expertise
- c. Facilities and equipment
- d. Collaborative R&D funding
- e. Commercial Income

## 2. Project activities

a. Project based accounting

#### 3. Other activities

- a. Providing access to facilities and equipment
- b. Stakeholder engagement
- c. Knowledge sharing
- d. Business support

#### 4. Outputs

- a. IP registration
- b. New businesses created
- c. Private finance raised

#### 5. Outcomes

a. High values jobs and activities anchored in the UK. Typically measured as GVA. However, these benefits will take several years to be realized in the UK economy.

# 4.4 Case study of the Catapult centres

We will here explore the High Value Manufacturing Catapult, which is said to be the most successful of the 11 Catapults created. The ideal budget model that was mentioned previously does not apply to this Catapult. R&D funding through contracts with industry accounts for roughly half of the total, meaning that the Catapult enjoys a high commercial return.

The High Value Manufacturing Catapult was the first one, and a large number of projects are being implemented within 7 research facilities. There is an expectation that the UK government places on manufacturing as it seeks economic growth. This expectation comes from UK manufacturing's position as a priority area that will lead the nation's economy in the coming generation.

## 4.4.1 The High Value Manufacturing Catapult

The High Value Manufacturing Catapult is comprised of the following manufacturing-related research facilities:

- (1) Advanced Forming Research Centre (AFRC)
- (2) Advanced Manufacturing Research Centre (AMRC)
- (3) Centre for Process Innovation (CPI)
- (4) Manufacturing Technology Centre (MTC)
- (5) National Composites Centre (NCC)
- (6) Nuclear Advanced Manufacturing Research Centre (Nuclear AMRC)
- (7) Warwick Manufacturing Group (WMG)

The Catapult has cutting-edge research equipment that cannot be obtained through investment by individual companies and universities. It provides a broad range of support to diverse manufacturing sectors, including pharmaceuticals and biotechnology, food and beverages, health care, aircraft, automobiles, energy, chemicals, and electronics, and endeavors to quickly commercialize research outcome.

The Catapult employs more than 1,600 engineers, scientists, technicians and other staff to support companies and push the boundaries of high-end manufacturing. According to the annual review 2014-2015 of the Catapult, there are 1,259 projects underway in which the 1,514 private companies are involving. SMEs account for approximately 40% of the total companies. The total amount of public funding invested into the High Value Manufacturing Catapult since 2011 has reached £107 million.

These 7 research facilities are located throughout the UK between Strathclyde and Bristol. None of the facilities is in London. The location of each facility was established after considering the existing bountiful environment and potential. It was also selected based on the need to secure sufficient land to contain industrial-scale research and testing facilities.

Chief Technology Officers (CTOs) are assigned to each of the facilities that comprise the high Value Manufacturing Catapult. They drive technical advancement within the Catapult and promote and undertake large-scale cross-centre projects, with the purpose of integrating manufacturing and technical capability among the facilities. Technical capabilities cover the hundreds, and those technologies are classified into 27 key technology groups as shown in Figure 4-9. Many of the key technologies are incorporated into multiple facilities.

Additive Manufacturing	Advanced Assembly	Automation	Biologics	Biotechnology	Characterisation	Composites	Design	Electronics
Flexible Manufacturing	Formulations	High Temperature Processing	IT For Manufacturing	Joining	Machining	Metal Casting	Metal Forming and Forging	Metrology
Modeling and Simulation	Polymers	Powder Metallurgy	Power and Energy	Printable Electronics	Resource Efficient and Sustainable Manufacturing	Surface Engineering	Tooling and Fixtures	Visualisation

Figure 4-9: The 27 key technology groups

Source: Annual Review 2014-2015 of High Value Manufacturing Catapult (pp. 15-19)

#### (1) Warwick Manufacturing Group (WMG)

The Warwick Manufacturing Group (WMG) is located on the University of Warwick campus in Coventry. It is a research centre that was established in 1980 primarily in the School of Engineering with participation from Warwick Medical School, Department of Computer Science, and others. More than half of its budget is provided with contributions from industry. Its main activity is translating advanced technology and knowledge of the university into industry. With the launch of the Catapult Programme, WMG's R&D facilities were greatly expanded, and it received public funding in a staged manner to ensure its sustainability. Because of the availability of industry-scale testing facilities on campus, WMG can be said to enjoy an advantageous environment in terms of verification and demonstration.

WMG is well known for two fields of Lightweight Technologies and Energy Storage & Management. Using modeling software that creates lightweight structures by combining metals, alloys, polymers, composite materials, ceramics, and hybrid materials in various ways, the former conducts research to produce materials with lightweight structures that are strong yet inexpensive from new combinations and to identify manufacturing processes that can those materials. The latter mainly focuses on the development of new battery chemistries.

A wide variety of organizations from industry, academia, and government, from the UK and other countries, participate in WMG's projects. They include India's major steel company, Tata Steel; Johnson Matthey, Land Rover, and other major and medium-sized enterprises of the UK; such research organizations as the Argonne National Laboratory of the US; and a number of UK universities, among them Imperial College London and Lead University.

As was mentioned earlier, reinforcing the S&T capabilities of the UK's SMEs is one of the Catapult Programme's aims. WMG provides a number of schemes designed to give special support to SMEs.

First there is the Innovation Vouchers scheme. This is a voucher programme designed to promote industry-academia collaboration and technical transfer between universities, public research organizations, and SMEs. The scheme is managed by Innovate UK. It is intended to allow private companies to explore new knowledge that exists outside their own networks. The scheme provides guidance for applications to the High Value Manufacturing area and disseminates information via the WMG website. Under the scheme, SMEs and start-ups can receive up to £5,000 as a voucher that they can use to pay for knowledge or technical transfer that they desire from experts affiliated with a university or public research organization. Companies eligible to use the vouchers are those SMEs and start-ups that have never used the Innovation Vouchers by Innovate UK. The scheme can help a company get expert advice on an idea to resolve a problem. An important condition is that the company's idea must be applicable to a theme designed by Innovate UK.

applications for a specified theme every three months. Approximately 100 companies are successfully selected to receive vouchers.

Another scheme provides assistance to a maximum of 12 graduate students for short-term research activity at an SME during the summer break: 6-8 weeks. This scheme is offered as part of an internship support programme. The research themes are limited to the two fields of Lightweight Technologies and Energy Storage & Management. The scheme not only serves as a way to place graduate students in employment but also helps advance R&D in SMEs.

WMG's staff numbers some 350 people, of whom roughly half are researchers or others who have a connection to academia.

#### (2) Manufacturing Technology Centre (MTC)

The Manufacturing Technology Centre (MTC) is located in Ansty. With a high-quality environment for the development and demonstration of new technologies at an industrial scale, MTC provides private enterprises with low-risk opportunities to develop innovative technologies and processes. MTC engages in R&D that is centered on the following three fields:

- Assembly: intelligent automation, advanced assembly, etc.
- Components: net shape, additive manufacturing, non-traditional machining, etc.
- Data: measurement, non-destructive testing [NDT], manufacturing informatics, etc.

It has a staff of about 40 people. Companies, which are more than 70 firms, participate and cooperate in the implementation of projects at MTC. As an example, under a project called the Embedded Sensing Feasibility Study that was undertaken in 2014, companies worked to develop high-tech "smart fixtures" that control and automatically respond to the various elements of manufacturing processes in real time. The aim was to achieve optimization and control of manufacturing processes, shorten process times, and prevent all possible malfunctions. The project was split into two phases to facilitate SMEs involvement. In the first phase, support was provided to help engineers who were not sufficiently versed in sensor technology select and decide on the right sensors to use. And during the second phase, sensor installations were demonstrated with consideration for various applications and environments.

# 4.5 **Programme achievements**

### 4.5.1 Follow-up review by Dr. Hauser

Dr. Hermann Hauser published a follow-up review titled "Review of the Catapult network" in November 2014. In the review, He presented four challenges, identified through site visit at each Catapult centre that should be addressed going forward. They include: increased SME engagement; increased university engagement; improvement in the method for selecting new Catapults; and additional funding models. He also made the following nine recommendations for tackling these challenges.

- (1) The UK must maintain its focus and commitment to investing in the existing Catapults, subject to effective performance and relevance, over the long term.
- (2) In keeping with international best practice, public sector funding must be prioritised to maintain the current 1/3, 1/3, 1/3 funding model for existing, successful Catapults.
- (3) Innovate UK should grow the network of Catapults through a clear and transparent process, based on the current criteria, at no more than 1-2 centres per year, with a view to having 30 Catapults by 2030 with total core funding for the network of £400 million per annum.
- (4) Growth of the Catapult budget requires increased funding for Innovate UK in line with recent calls to double UK innovation spend, bringing the Innovate UK budget closer to £1 billion per annum by 2020, such that it can explore and invest in a wider portfolio of emerging opportunities and support the most promising areas at scale.
- (5) Each Catapult should work with Innovate UK to develop more effective SME engagement strategies. Approaches should include working with local authorities and business groups to reach potential high growth SMEs and important clusters of activity in regions across the UK.
- (6) Catapults should develop a stronger more coherent engagement model for working with Universities (national and international), building on best practice, with a view to drawing on and commercialising knowledge to help UK industry gain competitive advantage.
- (7) Innovate UK and the Catapults should work together to develop more sophisticated Key Performance Indicators (KPIs) that sit within Catapults' Grant Funding Agreements, that incentivise impact and engagement with industry whilst still ensuring that Catapults work ahead of the market. These should reflect the difference in the sectors and the maturity of the relevant centre
- (8) Once established, Catapults should take advantage of their role as a neutral convenor to identify and help address wider barriers to innovation and commercialisation, and work with relevant parties to inform and deliver solutions. These could include regulatory and non-technological barriers such as business models and skills requirements.
- (9) Government should ensure that the 'Catapult process' developed by Innovate UK is used when deciding whether a business-led, physical infrastructure based initiative should be supported.

These recommendations will be reflected in government policy and will promote further expansion of the Catapult Programme.

#### 4.5.2 Handling of IP and economic impact

Research paper productivity is not an important evaluation indicator in the Catapult Programme. The fact that the words "research papers" do not appear in the above-mentioned recommendations suggests the strong likelihood that research papers will not be included in the programme evaluation method currently being developed. Additionally, given that the programme is still new, using the total number of patents and similar indicators in quantifiable form is difficult at the present time. Similarly, clear mention of specific outcomes in terms of economic impact, which is the highest priority of the programme, is problematic.

In the following, we present the mechanism for handling IP in the programme, the number of which is expected to grow in the future. We also look at economic profits as a possible indicator of whether or not a Catapult is operationally sound or not. Finally, we examine the kinds of economic impact that are currently expected to be generated through the Catapult Programme.

## (1) Handling of IP

Catapults have a duty to disseminate knowledge to grow the industry. IP can be distributed according the different types of funding of a project. IP are primarily divided into the following three cases:

- (a) If an infrastructure-led project is funded by Catapult core grants, then the IP remains with the Catapult.
- (b) If the funding is from the company, then the IP belongs to the company.
- (c) If it is via Competitive R&D, then the IP has to be negotiated between all parties involved before the project commences.

## (2) Economic impact

No data on the Catapult Programme's overall economic impact are available at the present time. Consequently, economic impact must be viewed in terms of individual Catapults. Looking at the Annual Review 2014-2015 of High Value Manufacturing Catapult, for instance, the Catapult's economic impact has reached £1.6 billion since 2011 until the present time. Looking to the future, it is anticipated that this figure will be each £6.1 billion by 2020.

The Cell and Gene Therapy Catapult Annual Review, this Catapult's impact has not been as great, reaching £0.83 million in 2014 and £3.15 million in 2015.

The forms in which the economic impact generated by each Catapult will contribute to the UK's economic growth remain unclear.

#### (3) Expected economic impact

Looking at the space field, it is said that the international space market, which was worth £150 billion in 2013, will grow to £400 billion by 2030. The UK Space Agency has set up the goals that the UK will share 10% of the international space market, which is worth £40 billion annually, and create 100,000 new jobs by 2030. The UK Space Agency's Space Growth Action Plan notes that reaching these goals will require expanding exports of space technologies and services from the current £2 billion to £25 billion. It further states that the Satellite Applications Catapult will, as a developer of applications, play a major role in achieving this. Thus expectations are high for the Satellite Applications Catapult in terms of its contribution to growth in the UK's space industry.

# 4.6 Future orientation

## 4.6.1 UK government policy

When the UK government published the 2015 Spending Review in November 2015, then Chancellor of the Exchequer George Osborne announced the government's intention to continue providing support for the Catapult Programme and increase funding for expanding the network of Catapult centres. The statement to expand the programme's budget even at a time when budget cuts are being sought across government demonstrates the government's focus on the Catapults' success.

#### 4.6.2 Issues and considerations

The Catapult Programme is an extremely young undertaking, and thus it is not yet time to conduct an overall programme evaluation. At the present time, the biggest question for the programme is thought to be how far industrial initiatives will succeed with academia's involvement. The role that industry plays in R&D near the output side is critical in efforts to put the superior research seeds of universities and research institutes to practical use by tying them to social needs.

R&D expenditure and researcher numbers in the UK are small compared to other developed countries, and the input in terms of S&T is not very large in the UK. Nonetheless, the UK's international share of the top 1% of research paper citations suggests that it is contributing to high-quality S&T. On the other hand, looking at trends in patent applications and registrations, and high-tech industry exports, one must conclude that the UK's strength in the area of industrial technology is relatively weak compared to other developed countries.

Thus, focusing on innovation policy for translating excellent scientific research outcome into commercialization to drive innovation forward remains a priority issue for the UK government. The Catapult Programme is undoubtedly playing a role in tackling this issue.

# 4.7 Implications to Japan

We will finally look at possible implications of the Catapult Programme to Japan.

### 4.7.1 Selection and concentration

The total of public and private R&D investment in the UK is relatively not large, amounting to no more than one-fifth of that of Japan. The investment also continues to be low as a percentage of GDP, accounting for about 1.8%, however, even against the backdrop of such limited R&D investment, learning about what the UK is doing to maintain its internationally top-level R&D and, in particular, how it is using public funding as an investment for the future should provide some implications to Japan, considering that Japan's public R&D investment is not necessarily abundant.

The Catapult Programme provides a number of viewpoints concerning the effective use of limited R&D budget. The programme's approach generally involves utilizing existing research infrastructure that has potential and investing public funding to augment facilities or expand their scale. This is important from the standpoint of effectively using limited resources and, simultaneously, deserves attention in that it represents investment that is based on "selection and concentration", something that could be described as a characteristic of the UK's R&D scheme.

Public funding that Innovate UK provides to support the Catapult Programme is operational expenditure grants that cannot be applied directly to R&D. This inevitably provides incentive, as centres that wish to conduct R&D must procure funding via other resources to do so on their own. If, as a result, a Catapult centre regularly can acquire contracted research from industry and get outside competitive R&D funding, it may be able to survive as an R&D base even if core government fonesunding ends or the label "Catapult" is removed.

#### 4.7.2 Ensuring the diversity of human resources

Human resources play a major role in determining the success of the programme. It is told that meticulous attention is given in the Catapult Programme to the placement of high-quality personnel in the right posts. Some people have pointed out how the programme maintains diversity even in its executive ranks in order to promote industry-academia collaboration.

If you look at the Innovate UK's Governing Board, it shows that its membership, including its chair, comes from both industry and universities. This demonstrates Innovate UK's effort to gain participation from all communities.

The Project Manager of Nuclear AMRC, for instance, has experience as an R&D engineer at both the University of Sheffield and an automaker before being hired by Nuclear AMRC of the High Value Manufacturing Catapult. Being well versed in the workings of universities and industry is an important factor in smooth project operation.

For Japan, as well, emphasizing diversity among those who operate and supervise programmes and projects will undoubtedly produce benefits, while maintaining flexibility among the human resources that manage overall the programme should also prove important.

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# Websites

- BEIS: Department for Business, Energy & Industrial Strategy https://www.gov.uk/government/organisations/department-for-business-energy-and-industrial-strategy
- Innovate UK https://www.gov.uk/government/organisations/innovate-uk
- The Catapult Programme https://www.catapult.org.uk/

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# **Chapter 5: Carnot Institutes of France**

In this chapter, we will examine Carnot Institutes ("Institute Carnot") program<sup>98</sup> as an example taken from France. Carnot Institutes program often regarded as a successful one. After describing the overall picture of the program, we will examine the factors make the program work. And we will also point out some gaps to be filled for further success of the program.

# 5.1 Background

French government recognized it as a matter that French research system did not well turn results of basic research into marketable products. That recognition was reflected on one of the six pillars of "Le pacte pour la Recherche" (pact for research)<sup>99</sup> a policy document that was published by the government in 2005. It proposed "reinforcement of the driving forces of innovation and strengthening of ties between public research and private-sector research." Concretely, it points out the need to activate business-led research. And it makes recommendations that include supporting the growth of young and innovated companies, reinforcing SME-led research, developing interfaces between public research and business-led research, and improving France's attractiveness (in research fields).

The policy document mentioned the Carnot Institutes program within that context as a scheme to promote joint research with private enterprises (and particularly SMEs) by certifying the laboratories of public research institutes. Taking the pact's recommendations, the French government approved the establishment of a program and then launched it in April of 2006.

To grasp a characteristic of French research system is useful to understand Carnot Institutes program. It is characterized as active public research institutes and inactive private enterprises. For example, this characteristic is reflected on several rankings. France ranks third in Europe (sixth in the world) in terms of research paper production<sup>100</sup>. However, France ranks tenth on the Innovation Union Scoreboard, which is a measure of the research and innovation capabilities of EU members. According to OECD data, France's public-private R&D investment ratio is around 1:1.5, indicating the company-led R&D is less vigorous compared to Germany (1:2.3) and the United States (1:1.9).

Since France has strong capabilities in public research, it should be an important strategy to mobile them to address the issue. We will find many built in devices to the program that motivate public research institutes to promote R&D collaboration with private enterprises.

<sup>&</sup>lt;sup>98</sup> We use the term "Carnot Institute program", although it is not officially used. We think the word well describes the nature of the system as to support temporary institutes by additional funding.

<sup>&</sup>lt;sup>99</sup> Ministère de l'Enseignement supérieur et de la Recherche (MESR) (2005), "Le pacte pour la Recherche"

<sup>&</sup>lt;sup>100</sup> Saka, Ayaka, et al. (2015), "Kagaku Kenkyu no Benchimakingu 2015" (benchmarking of scientific research 2015) National Institute of Science and Technology Policy

## 5.2 Program overview

#### 5.2.1 What are the Carnot Institutes and the Carnot Institute program?

Carnot Institutes are research institutes that have earned a "Carnot label." Carnot Label is a certification that is granted to research institutes and higher education institutes that promote joint research with private enterprises.

Carnot Institute program is a word that the auther uses for describing the selecting and supporting system of Carnot Institutes. It is a selection and supporting system of Carnot Institutes provided by a national funding agency, ANR.

The name of the Carnot Institutes is taken from Nicolas Léonard Sadi Carnot (1796-1832), who is known for developing Carnot's theorem (a theorem on the maximum efficiency of heat engines). He arrived at the theorem while conducting research toward improving steam engines. Application of the theorem continues even today in various products, such as automobile engines, refrigerators, and heat pumps.

#### 5.2.2 Objective and Methods

The Objective of Carnot Institute program is to generate innovation by promoting technology transfer and collaboration between public institutes and private enterprises.<sup>101</sup> In other words, the program has public institutes work together with privates and to transfer their technologies to private enterprises.

The program firstly selects and labels research institutes and higher education institutes with the ability to work with private enterprises. And then it provides funding to them based on their performance. Thus the program supports Carnot Institutes to expand their scientific and technical skills, to sharpen specialized skills needed to strengthen partnerships with private enterprises, and to provide research based services to private enterprises.

#### 5.2.3 Stakeholders of the Program

The stakeholders of the Carnot Institute program are largely classified as follows; decision-making organizations, a funding agency, a collaboration-promoting organization, and the program recipients typically research institutes and universities.

The following figure is a schematic representation of the stakehodlers of the Carnot Institutes program.

<sup>&</sup>lt;sup>101</sup> Programme Carnot Appel a Canditatures Carnot Édition 2011 (a document for a call for proposals)

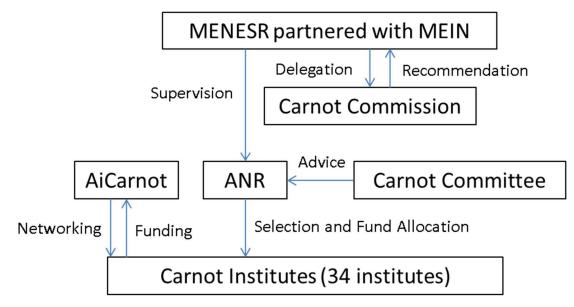


Figure 5-1: Stakeholders of the Carnot Institutes program

Source: Prepared by the authors based on available materials

#### (1) Decision-making organizations

The organizations that determine the policy of the Carnot Institutes program are the Ministère de l'Éducation nationale, de l'Enseignement supérieur et de la Recherche (MENESR; English name: Ministry for National Education, Higher Education and Research) partnered with Ministère de l'Economie, de l'Industrie et du Numérique (MEIN; Ministry for the Economy, Industry and Digital Affairs). The Commission Carnot, a temporary council of experts reporting to the ministries, provides recommendations on the program operation.

The latest Commission Carnot is comprised of eight members that include Chairman Jean-Luc Bélingard (President of bioMérieux Industry) and members from French technical academies, companies, and public institutes.

Overall responsibility for the Carnot Institutes program rests with the State Secretary to the Minister of National Education, Higher Education and Research.

#### (2) A funding agency

The Agence Nationale de la Recherche (ANR; National Agency for Research) handles the selection of Carnot Institutes. ANR is a research funding agency under MENESR. It selects institutes with receiving advice from the Comité Carnot, a temporary body.

The Comité Carnot had 23 members in the second period of the program. The Chairperson was Mr. Christian Collette (R&D Vice President of Arkema). Other members were representatives of companies and public institutes, the majority of which are French. One member came from Fraunhofer of Germany.

ANR is also in charge of allocating funds in the Carnot Institutes program. ANR allocates two types of funds. The first one is the annual funds for the operation of Carnot Institutes. Since 2007, the funds have been allocated in accordance with the formula to be described in the following section from an annual fixed budget. Second one is the funding allocated through the "Programme d'Investissements d'Avenir (PIA; Investments for the Future Program)" administered by the

Commissariat Général à l'Investissement (CGI; Commissariat-General for Investment), which is an organization placed directly below the Prime Minister.

#### (3) A collaboration-promoting organization

Ai Carnot promotes collaboration among Carnot Institutes. It gives quality standard of the institutes' activities to make the institutes popular among industry partners. Also it provides event opportunities to meet with each other and to share best practices among them.

Ai Carnot is a non-profit organization that was established in 2006, the year that the program was launched. The steering committee comprised of 15 representatives of individual Carnot Institutes decides operational policy. The secretariat with six full-time employees handles its administrative functions.

The way of financing Ai Carnot is designed to motivate Carnot Institutes to use it. The annual budget of 1.2 million euros is covered by contributions of each Carnot Institute. They have to provide 2% of the funding that is allocated by ANR for the operations of Ai Carnot. Because each institute individually contributes a portion of the budget, they intend to use Ai Carnot.

#### (4) Program receipients

The Carnot Institutes as program recipients typically consist of public research institutes, universities, and Grandes Écoles.<sup>102</sup> Many of them are consortiums comprised of those organizations.<sup>103</sup> Thirty-four institutes were selected for the second period of the program.

The geographical distribution of Carnot Institutes is presented below. The largest concentrations of institutes are found in the Île-de-France region, which is centered on Paris, and the eastern Rhône-Alpes region, which is home to Lyon and Grenoble. Many institutes are also located in the Midi-Pyrénées region of southern France, Alsace region in the north, and Loire in the west.

The number of locations marked on the map exceeds 34, as some Carnot Institutes have more than one research base.

 <sup>&</sup>lt;sup>102</sup> The Grandes Écoles are French educational institutions for the training of highly specialized professionals. Some 200 exist. École nationale d'administration (ENA), École Polytechnique, and École Nationale Supérieure des Mines de Paris (MINES ParisTech) are among distinguished institutions.

<sup>&</sup>lt;sup>103</sup> Refered to the Ai Carnot website.

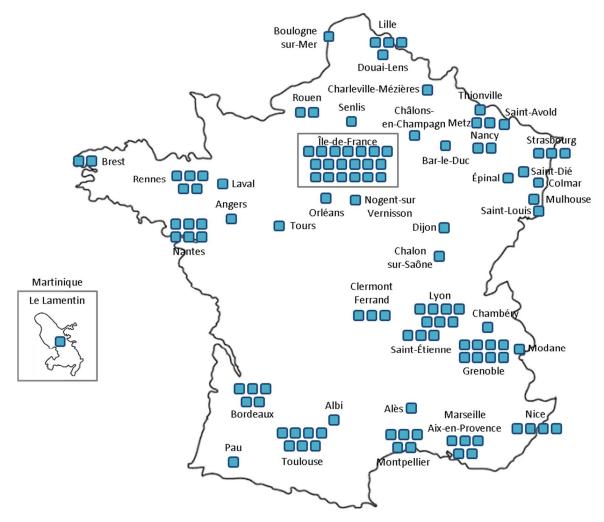


Figure 5-2: Distribution of Carnot Institutes

Source: Prepared by the authors based on the MENESR website

# 5.2.4 Selection criteria

The selection criteria of Carnot Institutes in the second period of the program are summarized as follows<sup>104</sup>. In short, they give consideration on organizational capacities (e.g. operational structure and strategy) and on track records (e.g. name recognition and experience in collaborative activities). Emphasis was placed on not only ability to engage in joint research with private enterprises but also academic capabilities.

- (1) Name recognition of candidate institution in the research field, consistency with research policy in the region, etc.
- (2) Contribution to social issues, strategy for promoting joint research, etc.
- (3) Governance, solid organization structure
- (4) Mechanisms for improving activity quality: acquirement of ISO and other certifications, human resources development strategies, etc.

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<sup>&</sup>lt;sup>104</sup> ANR (2011) Programme Carnot Appel à candidatures Carnot Édition 2011 (public invitation document)

- (5) Intellectual property policy: intellectual property management, utilization strategy, etc.
- (6) Social and economic partnerships, including experience partnering with SMEs
- (7) Scientific and technical capabilities
- (8) Actual experience in international collaboration, quality of international partnerships, etc.
- (9) Consistency with activity objectives, the Carnot Charter, etc.

It should be noted that call for proposals for the third period (from 2016) had already begun at the time that this report was being prepared. Thus, we are able to observe the plan for this third period to some extent and will touch on it in the "future orientation" section.

# 5.2.5 Number of selected institutes

Carnot Institutes were selected for five years in the first and second period of the program. If an institute was found to be eligible, the institute was reselected and the Carnot label was renewed.

The first period of the program selected 33 institutes; 20 institutes in 2006 and 13 additional institutes in 2007. The latter 13 institutes were selected for four years for adjustments.

Thirty-four institutes were selected in the second period of the program. Eight institutes from the first period were not reselected during this process.

# 5.2.6 Funding allocation

There are four sources of the funding that is allocated to the Carnot Institutes. First one is the ANR's Carnot Institutes program. The allocation of funding from this program is in itself a characteristic of the Carnot Institutes and will be looked at in more detail later on. The second one is the funding from the Investments for the Future Program (PIA). Several call for proposals have been held under the themes of SME support and international collaboration. The third one is institutional funding through the parent organization that is allocated to laboratories of the Carnot Institutes. And finally, there is competitive funding that is outside the Carnot Institutes do not have corporate status and thus cannot apply for such competitive funding independently, they obtain it under the name of their parent organization.

The following figure presents a schematic representation of funds allocation.

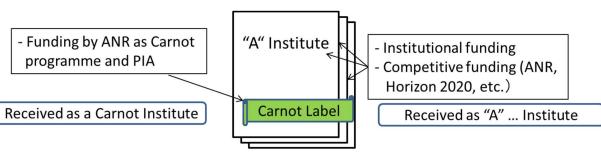


Figure 5-3: Schematic diagram of funds allocation to the Carnot Institutes

Source: Prepared by the authors based on available materials

# 5.2.7 Targeted technological fields

There is no limit in the technological fields imposed on the applicants to the program. But there is virtually a limit that the technological fields should be connected with markets since one of the aims of the program is to promote joint research based on corporate needs. There is consequently a certain concentration of the technological fields of selected institutes. According to Ai Carnot's website, the largest volume belongs to the environment and energy field, followed by ICT, chemistry and materials, and future factories (manufacturing). There are also institutes working in the fields of automobiles, construction, aviation and space, health, and bioproducts.

# 5.3 Incentives for "translation"

The Funding allocation of Carnot Institute program works as a source of incentives for translation through knowledge and technology transfer. Carnot Institutes obtain more funding as they increase direct R&D contracts with private industry. And they are able to freely use the funding if a certain coditions are met. They will work hard to obtain funds that enable them to expand their activities.

## 5.3.1 Determination of allocated amounts

The funds of the program are allocated to individual Carnot Institutes in accordance with the following formula:<sup>105</sup>

Amount allocated to a Carnot Institute

- = 20% of the value of direct R&D contracts with private enterprises in the previous year
- + An additional amount if the partner enterprises were SMEs (10% of the direct contract value)
- + 20% of the appraised value of intellectual property rights generated from activities as a Carnot Institute (maximum of 120,000 euros per right)

Here, the "value of direct R&D contracts" means the amount to be paid by the private enterprise for R&D service by a Carnot Institute that is performed without any public competitive funding. If the enterprises procured money through public competitive funding, that amount is not included in the direct contract.

ANR prepares an annual budget of 60 million euros as funding for the Carnot Institutes program. The figure has not changed since 2007, and that works as a ceiling. In case the amounts that are calculated with the above-mentioned formula exceed the ceiling, the 60 million euros are allocated using a proportional distribution method.

In fact, the shortage of annual budget appears to have happened in recent years. For example, the Commission Carnot  $3.0^{106}$  shows that the amount allocated to Carnot Institutes in 2013 was no more than 13% of the values of direct contracts with private enterprises of the previous year. The percentage cannot be below 20% if it follows the formula.

In addition to the funding based on the formula, smaller funding was allocated through three calls for proposals in the Investments for the Future Program. First, two calls for proposals were made in 2011, from which four projects were selected and a total of 31 million euros were allocated over the course of five years.<sup>107</sup> One of these projects involved international activity, while the remaining three involved support for SMEs. An additional call for proposals was held in 2014 for which a maximum total of 120 million euros was allocated to a number of projects that involved support for SMEs.<sup>108</sup>

## 5.3.2 Use of funds

Carnot Institutes need to use the funding from the program for their activities as Carnot Institutes.<sup>109</sup> Firstly, they use it for activities that are necessary to promote collaboration with private enterprises; i.e. establishment of a joint laboratory with an enterprise, technology maturation

 <sup>&</sup>lt;sup>105</sup> ANR (2011) Programme Carnot Appel à candidatures Carnot Édition 2011 (call for proposals document)
 <sup>106</sup> Commission Carnot 3.0 (2015) Commission Carnot 3.0 Rapport final

 <sup>&</sup>lt;sup>107</sup> ANR (2011) Investissement d'Avenir Action "Valorisation – Institut Carnot"Édition 2011 (call for proposals document)
 <sup>108</sup> ANR (2014) Programme Carnot Appel à candidatures Carnot Édition 2014 (call for proposals document)

<sup>&</sup>lt;sup>109</sup> ANR (2011) Programme Carnot Appel à candidatures Carnot Édition 2011 (call for proposals document)

projects, or marketing. Secondly, they use it for activities to expand the institute's own capacity; i.e. execution of basic research projects, establishment of a joint laboratory with other research institutes, or acceptance of excellent researchers and students. Thirdly, they use it for "professionalization" or improvement of the quality of provided services; i.e. the improvement of joint research management methods, expansion of legal assistance schemes, and improvement of delivery date management. And finally, they use it for contributing to the Carnot Institutes network; i.e. investing in Ai Carnot or engaging in collaborative activities with other Carnot Institutes.

A number of funding usages are prohibited; using them to cover the the cost of joint research that should be covered by the partner private enterprises, using them in activities that cannot be supported with public funds (e.g., activities that violate antitrust laws), and using them to invest in real estate.

# 5.4 Management

We will look at two types of management: Management by Ai Carnot and of individual Carnot Institutes. Those two hierarchies consist of the management system of Carnot Institutes program.

# 5.4.1 Ai Carnot's activities

Ai Carnot plays an important role in the management of Carnot Institutes. It means that Ai Carnot sets and implements the policies for integrated activities of Carnot Institutes.

Ai Carnot's activities are classified into three categories. First, it establishes the Carnot Charter and The Carnot institutes' code of best practices for Intellectual Property and Knowledge & Technology Transfers. Those are action guidelines for each Carnot Institute.

Next, it provides opportunities for Carnot Institutes to share their know-how with other Carnot Institutes. For example, it holds two-day training camp-style seminars at which institutes share best practices for smooth project implementation. Topics include methods for partnering with SMEs and procedures for concluding contracts with private enterprises.

And finally, it organizes events that bring Carnot Institutes and private enterprise together. One of which is an annual event called "Rendez-vous Carnot". At Rendez-vous Carnot, individual institutes present their own technologies to participants from private enterprises. At the same time, numerous opportunities for business meetings between individual institutes and enterprises are created. Moreover, the gatherings present the initiatives of Carnot Institutes and feature seminars for consideration of future directions.

# 5.4.2 Ai Carnot's guidelines

"The Carnot Charter" lays out an activity policy to be observed by Carnot Institutes and provides guidelines for improving the quality of institutes' activities and inter-institute sharing of information. For example, it requires institutes to improve their calculation of project costs and to secure access to legal support in order to maintain activity quality. Additionally, it requires them to formulate research strategies that take synergetic effect with other institutes into account, and to transfer their know-how and skills to other institutes. Moreover, it requires them to have members of the socioeconomic stakeholders in their managing committees.<sup>110</sup>

"The Carnot institutes' code of best practices for Intellectual Property and Knowledge & Technology Transfers" lays out a basic policy for managing intellectual property rights that are generated through joint research by Carnot Institutes and private enterprises. For example, it establishes that intellectual property rights that were generated as a result of research by individual institutes (so-called "background rights") are to be kept by those institutes, and that intellectual property rights that are the result of joint research are to be shared by both partners. It also states that institutes must give their partners permission to use their background intellectual property rights free of charge, so long as the rights will be used for the joint research.<sup>111</sup>

## 5.4.3 Individual Carnot Institutes

Carnot Institutes led by Ai Carnot are diverse. They range in size from small organizations with a workforce of around 200 to large ones with 1,500. The scale of their joint research also varies, with some spending around 2.9 million euros annually, while other approach 150 million euros.

<sup>&</sup>lt;sup>110</sup> Ai Carnot, Charte des Instituts Carnot

<sup>&</sup>lt;sup>111</sup> Ai Carnot, Charte des bonnes pratiques de Propriété Intellectuelle, et de Transfert de Connaissances et de Technologies des Instituts Carnot

According to data released by Ai Carnot in June of 2015,<sup>112</sup> the average value of joint research (including that conducted with public competitive funding) is 23.9 million euros, with the median standing at 13 million euros. Thus, institutes with small joint research spending have a large percentage overall.

Carnot Institutes can be divided into two types: institutes comprised of a single research organization, and institutes comprised of a consortium of multiple research organizations. As a whole, the latter constitute the majority. Carnot Institutes comprised of consortiums include *unités propres de recherche* (UPR; solely operated research units) that are separate laboratories of CNRS or other national research institute; *unités mixtes de recherche* (UMR; mixed research units), which are joint laboratories operated by a national research institute and a university; *grandes écoles*; and university federations. There are also cases in which a consortium becomes a member of a consortium, such as when a regional consortium of *grandes écoles* forms part of a consortium.

Consequently, it is an important issue in the management of individual Carnot Institutes that to make institutes of such complex compositions work.

## 5.4.4 The forms of joint research with enterprises

Joint research between Carnot Institutes and private enterprises takes two main forms.

The first is through a "direct contract" in which a private enterprise and a Carnot Institute conduct joint research without using public competitive funding. Only the partnership with this form is eligible for the funding based on the above-mentioned formula. In other words, the institute's budget for the next year is determined by the size of the direct contract.

A partnership of this form has the following advantages for both parties. First, they are able to start a research project with a simple process. Because there is no need to apply for competitive funding, joint research can be started from the moment that both parties reach an agreement. There is also an advantage of being able to freely select the method of partnership. A truly wide variety of partnership options are available. They range from partnerships of several months during which a Carnot Institute provides a service to the enterprise in order to solve a particular technical problem to joint research of several years or even the establishment of joint laboratories.

For a private enterprise, a partnership of this form has an important advantage: it allows the enterprise to keep research achievements confidential. When joint research is undertaken with competitive funding, the results of the research must be made public. However, no such conditions are imposed on the projects based on direct contracts.

On the other hand, direct contract-based joint research has the disadvantage of requiring that all necessary funds be secured by the parties involved.

The second form is a "joint project", which is a joint research with obtaining competitive funding from the national government or other source. With this form, the advantages and disadvantages become exactly reversed vis-à-vis the direct contract method. In other words, while this form offers the advantage of cutting expense with the use of public research funds, it also comes with the disadvantages of requiring a longer lead time for a project and publicizing of research results.

It should be noted that the interests of the two sides do not always match. Through our interviews with several Carnot Institutes, we learned that private enterprises tend to prefer "joint projects" that are conducted with competitive funding from the national government, while Carnot Institutes prefer "direct contracts" that directly influence on the funding allocation to them.

<sup>&</sup>lt;sup>112</sup> See Ai Carnot (2015) Les Instituts Carnot, La Recherche pour les Entreprises. It should be noted that only data for CEA LIST (a Carnot Institute) was missing in these data.

## 5.4.5 Management of consortium-based Carnot Institutes

We will discuss the management of consortium-based Carnot Institutes, since many of the institutes take this form. The information in this section is obtained mainly through our interviews with several Carnot Institutes.

First, individual Carnot Institutes have a collegial body that is in charge of making basic decisions for the institute. The heads of organizations in the consortium as well as representatives of industrial groups usually serve as members. Occasionally Carnot Institutes also have bodies that make decisions or provides advice concerning scientific research or that formulates institute strategy. The institute's strategy is formulated and decisions on its activities are made by these collegial bodies.

Second, typical R&D of an institute can be categorized in two. One is basic research to enhance the institute's own S&T potential. The other is joint research with private enterprises together with initiatives to support it. Resource allocations to R&D vary from institute to institute.

In the case of the former, often internal calls for proposals are made based on the institute's strategy, and then teams to conduct the research are selected from within the consortium that participates in the institute.

In the case of the latter, often specialists to liaise with private enterprises meet potential partners to know their needs and propose R&D based services. And then a contract is signed with those enterprises. R&D projects of various types (ranging from, for example, research of just several months to resolve a specific technical problem to joint research covering several years) are started afterward. That process is reinforced by an activity called "professionalization", which is to provide quality services related to R&D projects to private enterprises. That involves, for example, assigning people in charge of negotiations and contracts, marketing, and commercialization to find partner companies and smoothly advance contract-related administrative procedures.

It affects the management of Carnot Institutes that they do not have corporation status. For example, a Carnot Institute cannot be a party in a joint research contract and cannot be the holder of intellectual property rights. Thus enterprises that desire to enter into a joint research contract with them must conclude the contract with individual organizations that are members of the institute. In the case of intellectual property rights, individual member organizations become the holders of those rights, and those rights are used through mutual licensing or other means. In some cases, those organizations do not manage rights on their own, but rather outsource management to an organization that specializes in intellectual property rights management.

Third, individual Carnot Institutes participate in matching events with private enterprises that are organized by Ai Carnot (Rendez-vous Carnot). They also advance joint research projects with other Carnot Institutes and share best practices with other Carnot Institutes.

It should be noted that many of the researchers that are affiliated with a Carnot Institute do not engage in the institute activities described above on a full-time basis. Only a very small number of people are fully dedicated to their Carnot Institute duties. In most cases, they take on institute activities as something that is added on to their duties at their parent organization.

#### 5.4.6 Evaluation of the Carnot Institutes

There are three main methods for evaluating individual Carnot Institutes.

First one is an evaluation based on the volume of direct contracts with private enterprises. That evaluation is conducted by ANR each year for the purpose of determining funding allocation to the institutes. The formula previously mentioned is used for the evaluation. It is most important for the Carnot Institutes, as it is the most frequently conducted evaluation and is directly linked to their

budgets for the following year.

Next one is an institute evaluation that is conducted at the midpoint of the program. For example, a midpoint evaluation was conducted on each Carnot Institute in 2013.<sup>113</sup> A committee was organized to conduct it. The evaluated items include position of the institute within its technological fields, efficiency and effectiveness of IPR management system, contribution to the Carnot network, and status of activities toward commercialization.

And the third one is an evaluation connected with the renewal of Carnot label. It is periodically conducted when the program is renewed. That means that each Carnot Insitute need to again applay to a call for proposals when they wish to move on to the next period of the program. The evaluation looks a broad range of items that include academic achievements and ability to provide services to private enterprises.

Additionally, there is a related evaluation system to the above. That is the evaluation conducted by an evaluation organization<sup>114</sup> targeting on the parent organizations of Carnot Institutes. For example, UPR and UMR, which are CNRS laboratory units, are targeted by evaluation, and if those laboratories engaged in activities as Carnot Institutes, those activities are also subject to the evaluation. As the evaluation focuses only on the parent organization and does not have an impact on the funding allocation through the Carnot Institutes program.

<sup>&</sup>lt;sup>113</sup> Based on the annual report of each Carnot Institute (It appears that midpoint evaluation reports are not released to the public.)

<sup>&</sup>lt;sup>114</sup> Haut Conseil de l'évaluation de la recherche et de l'enseignement supérieur (HCERES; High Council for the Evaluation of Research and Higher Education)

# 5.5 Case Studies of Carnot Institutes

Here we present two cases. The first is Énergies du Futur, which is comprised of a consortium and one of the largest Carnot Institutes in the amount of joint research with private enterprises. And the second is CIRIMAT, which is comprised of a single mixed research unit (UMR) and one of the smallest Carnot Institutes in the amount of joint research with private enterprises.

The points of those case studies are as follows. The former establishes a department dedicated to providing services to private enterprises and provides services that meet their needs. The institute uses its abundant resource to build service providing capacities. The latter takes a long-term strategy that builds relationships with private enterprises through producing PhD with the skills needed by companies. It is one way of knowledge transfer that is achieved with relatively limited resource.

## 5.5.1 The case of Énergies du Futur

Énergies du Futur is a consortium comprised of four organizations in Grenoble that began activities as a Carnot Institute in 2007. It is formed by Grenoble INP (a *grandes école* consortium of the Grenoble region), CEA-Liten (a laboratory of CEA-TEC that studies energy and materials), Joseph Fourier University, and CNRS.

It develops new technologies in energy-related fields, including energy efficiency, energy storage, hydrogen, biogas and other biofuels, materials and elemental technologies for solar power generation, and modeling.

The scale of the organization and its activities is as follows.<sup>115</sup>

In 2014 its overall budget amounted to 185 million euros. And its joint research with private enterprises amounted to 97 million euros (of which 53 million euros were attributable to direct contracts with private enterprises<sup>116</sup>). The institute spent 7 million euros, or the equivalent of 91% of the funds that were allocated to it from ANR, in research projects; three-fourths of that amount went to basic research.

The institute has 1,688 researchers and engineers numbered in full-time equivalent basis (of whom, 468 were PhD candidates). The institute has eight people assigned to "professionalization" to enhance the quality of its services to private enterprises. For example, one person is in charge of negotiations and contracts, one is marketing, and one is commercialization. Additionally, the institute is also training some 40 people to work at "professionalization" with part of their effort.

In 2014 the institute filed 252 patent applications and held 1,364 patents.

A characteristic is the institute's effort to strengthen its ability to provide services to enterprises, as it also allocates a large portion of its resources to basic research, and then to eventually tie the results to larger direct contract amounts. Through our interview, we learned that, because of its low percentage of research seeds that can be linked to innovation, the institute is focusing on creating more seeds from basic research. At the same time, it is fine-tuning its functions as a service-providing institute by easing the burden on its joint research partners by integrating its contract contact points.

It should be noted that Énergies du Futur does not think that being a consortium is a hindrance to operation. Research management and organizational management are separated—for example, there is a framework in place whereby individual researchers assigned to research teams are

<sup>&</sup>lt;sup>115</sup> Énergies du Futur (2015) Rapport d'Activité 2014 Institut Carnot Énergies du Futur

<sup>&</sup>lt;sup>116</sup> According to ANR data for 2011, the value of the institute's direct contracts with private enterprises was 42 million euros. Thus, this value more than doubled in about four years.

evaluated by their own organizations—and no particular problems have emerged. What makes that management possible is Énergies du Futur's long history of building teams that extend across organizational barriers.

# 5.5.2 The case of CIRIMAT

CIRIMAT is a laboratory in Toulouse that was certified as a Carnot Institute in 2006 (a single laboratory is certified as a Carnot Institute). It is a mixed research unit (UMR) of CNRS, which was established in 1999. Participants in the UMR are Paul Sabatier University and Toulouse INP.

It conducts R&D centered on materials engineering; namely, nanomaterials, functional films, protective coatings, polymer behavior laws and change over time.

In 2014, its budget amounted to approximately 6 million euros and the value of its joint research with private enterprises stood at roughly 2.9 million euros. When converted to a full-time basis, it had a staff of 223 researchers and engineers (of whom 95 were PhD candidates). During the five years between 2009 and 2014, it published 746 research papers in international journals, produced 132 PhDs, and submitted 41 patent applications.

The majority of CIRIMAT's research is at TRL 1 or 2 (basic research). It is engaged in some research at TRL 4 or 5, most of which through joint research with private enterprises.

Its direct contracts with enterprises are mainly prepared from a medium- to long-term perspective, as they are normally valid for between one and three years and are often renewable. When it signs contracts that utilize the Convention industrielle de formation par la recherche (CIFRE; Industrial Agreement of Training through Research),<sup>117</sup> it tends to conclude a joint research project for the same number of years as that CIFRE contract.

Additionally, approximately two-thirds of CIRIMAT's researchers also teach at a university, where they build extremely good relationships with their students. Often, those same students, after graduating and finding employment in companies, become joint research partners as CIRIMAT's clients.

There should be two reasons why CIRIMAT, with its relatively strong character as a basic research institute, succeeded as a Carnot Institute. One is that CIRIMAT can meet industrial needs at a certain level even through activities approaching basic research, as the distance between basic research and the market is short in its research fields. Additionally, CIRIMAT makes a cyclical pattern that it provides PhD holders to private enterprises that need them, and then ties the results to future joint research.

<sup>&</sup>lt;sup>117</sup> A program operated by Association Nationale de la Recherche et de la Technologie (ANRT; National Association for Research and Technology), which is a semi-governmental organization. ANRT pays a yearly sum of 14,000 euros to private enterprises that hire PhD candidates on three-year contracts; the money is intended to help cover remuneration for those candidates. The enterprises pay remuneration to the candidates and provide them with research instruction in partnership with their own university laboratories.

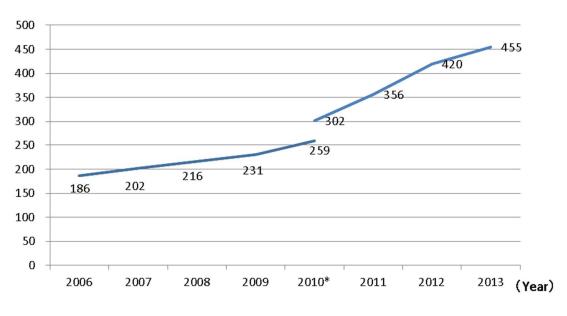
# 5.6 Program outcomes

#### 5.6.1 Outcomes corresponding to the program's objectives

The main objective of the Carnot Institutes program is to change the culture in public research institutes, whose focus was primarily on basic research, and to promote joint research with private enterprises. It encourages joint research with SMEs with the aim of supporting innovative SMEs. Through these activities, the program seeks to achieve its ultimate aim; to generate innovation.

The program's achievements toward this end are measured primarily from the size of direct research contracts between Carnot Institutes and the scale of joint research that is based on greater use of competitive funding. It is widely acclaimed as an achievement of the Carnot Institutes program that the value of direct research contracts between Carnot Institutes and private enterprises more than doubled from 186 million euros at the start of 2006 to 455 million in 2013.

Figure 5-4: Changes in the values of direct research contracts between Carnot Institutes and private enterprises



(€ Million)

\*Two types of data are used for 2010 due to a change in the calculation method. Source: Ai Carnot's annual report<sup>118</sup>

Looking at SMEs, results show that 900 out of 2,000 contracts that are signed with private enterprises each year are with SMEs. In terms of the value of direct contracts, in 2014, 24% of the total was based on contracts with SMEs.

It should be noted that, according to Ai Carnot, Carnot Institute-private enterprise collaboration accounts for 55% of contributions to France's public research from private enterprises. And Carnot Institutes' overall percentage of the workforce of France's public research sector is 15%. This means that Carnot Institutes have a noticeably high share in collaboration with private enterprises per

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<sup>&</sup>lt;sup>118</sup> Ai Carnot (2015) Rapport d'activité 2014 - AiCarnot

researcher compared to the average public research institute in France.

So then, has innovation been generated in line with the ultimate objective of the program? The answer depends on how innovation is defined. If innovation is defined as products and services that are innovative in the sense that they break down existing frameworks and have achieved great success in the market (in other words, "discontinuous innovation"), then it is thought that the program has not yet produced results. We did not find any examples of innovative products or services that were originated from the activities of Carnot Institutes.

However, if innovation is defined as "continuous innovation," which includes major improvements to existing products and services,<sup>119</sup> it could be said that the Carnot Institute program has achieved certain results. As it is thought that the solutions provided by Carnot Institutes are proving useful in resolving the technical challenges private enterprises face and contributing to the development of new products.

## 5.6.2 Research papers, intellectual property and startups

The Carnot Institutes are organizations that simultaneously conduct academic research and joint research with private enterprises, and thus they announce their outputs in terms of both research papers and intellectual property.

According to Ai Carnot, of the 40,000 A-ranked research papers that were produced throughout France in 2013, more than 20,000 came from Carnot Institutes. "A-ranked research paper" refers to a paper that was graded at a certain level or higher by a peer review by international members.

At the same time, looking at intellectual property, as of 2014 1,050 registered patents are held by 34 Carnot Institutes. Additionally, Carnot Institutes earn approximately 51 million euros a year from their intellectual property.

Moreover, recently about 60 startup enterprises are born each year from Carnot Institutes' activities.

Carnot Institutes balance results in academic research and in technology transfer and innovation.

<sup>&</sup>lt;sup>119</sup> For example, the OECD's Oslo Manual states "[innovation is the introduction of] new and significantly improved products (goods and services) and processes."

# 5.7 Characteristics of the Carnot Institutes

Characteristics of the Carnot Institutes program include the following.

# 5.7.1 A framework based on actual circumstances in France: Differences with Fraunhofer

Carnot Institutes much differs from Germany's Fraunhofer, although it is designed with reference to it. The following examines notable differences.

Carnot Institutes are not regal entities, while Fraunhofer is. This fact produces significant differences in terms of their organizational operation.

First, there is a difference in how funding is allocated to individual institutes. In the Carnot Institutes' case, basic expenditures related to organizational operation are covered with institutional funding to the parent organizations. Then additional funding is allocated within the Carnot Institutes program based on the formula. In Fraunhofer's case, a large portion of funding is allocated in accordance with the so-called "Fraunhofer model" (a performance based funding allocation system: see chapter 1). That difference means that Carnot Institutes program partly uses the institutional funding to the parent organizations and thus requires relatively small additional investment. It also means that the impact of the performance based funding is relatively small in Carnot Institutes program.

Next, there are differences in how IPRs generated from research projects are owned and utilized. IPRs are owned by their parent organizations in Carnot Institutes, while by a single division for intellectual proparties management in Fraunhofer. The difference reflects the fact that Carnot institutes have no right capacities to own IPRs, while Fraunhofer does. It influences how those IPRs are utilized. Carnot Institutes utilize IPRs on individual institute basis, while Fraunhofer does in an integrated manner. Carnot Institutes cannot take advantages of the integrated management as to utilize IPRs for future projects cross-cutting to the institutes as the institutes belong to Fraunhofer can.

Another difference is that, while individual research institutes of Fraunhofer are single organizations, the Carnot Institutes are sometimes consortiums comprised of multiple research institutes and universities. A Carnot Institute takes advantage of mustering different sources of knowledge and technology and creates an organization that optimally suited a particular purpose. It should be noted that the advantage can invite complexity in organizational management.

And second, there is a major difference in terms of research policy. Carnot Institutes usually balance fundamental research and applied research, while Fraunhofer does not generally engage in basic research. Carnot Institutes see basic research as important in maintaining and promoting their own capacity. They therefore invest a portion of their budget into basic research even as they keep their main focus on joint research with private enterprises. In Fraunhofer's view, basic research should be conducted by universities. Instead, it focuses on how it can find useful basic research outcomes. Additionally, it takes an approach that identifies the inventions needed for commercialization from the perspective of private enterprises.

# 5.7.2 High results triggered by low additional investment

Carnot Institutes program can be described as one that produces high results with low additional investment. It means that the program has successfully expanded the value of its direct contracts with private enterprises from 202 million euros in 2007 to 455 million euros in 2013 by additionally investing fixed 60 millions euro each year. In other words, the program mobilizes existing big institutional funding with small additional funding to academia-industry collaboration.

We think the following factors are important for the success.

First one is the finantial incentives that correspond to outcomes. The institutes are able to receive additional funding and expand its activities accordingly if it achieves higher performance. This mechanism should be attractive to funding recipients. Although the funding from Canrnot Institute program is relatively small, it can have a big impact on the institutes. The reason is that much part of institutional funding through the parent organization is used for salaries or other fixed expenditures, and there is a need for funding for research activities.

Second one is the management that sees all 34 Carnot Institutes as a single organization. Such management makes it possible for the institutes to enhance their capacities to provide good services to the private enterprises. As Carnot Institutes usually are not familiar with those activities, the opportunities sharing best practices much contribute to improving their capabilities.

Third one is Carnot Institutes program's policy that balances both basic and applied research. The balance should work as a source of motivation for the researchers. Most of the researchers in Carnot Institutes have the motivation to write academic papers since they have been evaluated with them. While providing R&D service to private enterprises usually does not contribute to it. The allowance for fundamental research is able to fill the gap. It gives the researchers the motivation to work on giving service to private enterprise so that they are able to increase the funding for fundamental research for the next year.

The balance has other effect. Doing basic research within Carnot Institutes enables them to easily transfer the results of the basic research, since they don't need to search for them in other organizations.

On the other hand, the balance also has a shortcoming. That is the relatively slow speed of turning inventions into marketable products. Fraunhofer shortens the period between invention and commercialization by not conducting basic research on its own. The Carnot Institutes cannot match Fraunhofer in this regard.

And fourth, the generation of synergy with other schemes is also important. This means close collaboration with other public frameworks such as "Pôle de compétitivité (competitive clusters)" and "Société d'accélération du transfert de technologies (SATT; French Technology Transfer Accelerator Company)"<sup>120</sup>, and use of CIFRE (education of PhD candidates at private enterprises) and CIR (research tax credit). In many cases, Carnot Institutes are situated adjacent to a competitive cluster and thus can become acquainted with enterprises that need technologies through their participation in the cluster's initiatives. Additionally, in some cases Carnot Institutes entrust the management of their intellectual property rights to a French Technology Transfer Accelerator Company, thus achieving smoother rights management. Also observed are cases in which institutes used the opportunity presented by having their own phD students study at private enterprises under the CIFRE scheme to sign joint research contracts with those enterprises. Furthermore, the CIR's existence provides incentive for enterprises to sign joint research contracts.

<sup>&</sup>lt;sup>120</sup> A private-sector organization established with public funds that is operated as a scheme of the Investments for the Future Program based on fund raising from large-scale issuances of government bonds. A SATT works to tie the research seeds of universities and others to private-sector needs. There are 14 SATTs established throughout France.

# 5.8 Issues

Addressing the following two issues are important to lead the program to the further success.

#### 5.8.1 Mismatch of the interests between Carnot Institutes and private enterprises

The first is a mismatch in the interests: carnot Institutes prefer to have direct contracts with private enterprises, while private enterprises prefer joint projects that make use of competitive funding. Carnot Institutes can increase the amount of additional funding in the following year by signing direct contracts with enterprises. However, private enterprises cannot make use of competitive funding if they conduct joint research in this way. They prefer to use competitive funding to alleviate their financial burden. Consequently, the interests of the two sides do not always match.

Eliminating this mismatch would naturally smooth out the partnering process, and thus it is expected that measures to narrow it will be included in the future Carnot 3.0 program. The share of joint projects will be included in institute evaluations to be conducted every two years under the new program. Although a Carnot Institute's share of joint projects that use competitive funding will not directly change its funds allocation even if it rises, this share will become an important factor when renewing the institute's Carnot status. As a consequence, that will provide incentive to individual Carnot Institutes to increase their share of joint research projects and help adjust the mismatch in interests between the two sides.

It should be noted that when a private enterprise wishes to keep the results of research confidential, they have to choose direct contracts. Since joint research projects are helped by public competitive funding, certain disclosure of results is required. The mismatch is eliminated in that case.

## 5.8.2 The technological potential of SMEs

The second issue is that SMEs tend not to have enough technological capabilities to absorb Carnot Institutes' technologies. Technologies of Carnot Institutes might not be transferred to those SMEs in that case, while Carnot Institute program is aiming at innovation through technology transfer. It is a matter since the program is focusing on involoving SMEs.

During our interviews we heard comments indicating that this is not a problem when an SME was given technical capability at time of its inception, as is the case with spinoff enterprises from universities, or when an enterprise is technically an SME but is actually closer in size to an intermediate-sized enterprise (*entreprise de taille intermédiaire*; hereinafter "ETI") and has an excellent technical development department.

However, in general, French SMEs are not known to have high technological capabilities, and the cases presented above are exceptional. Accordingly it can be said as a challenge for the Carnot Institutes program.

The program has sought to tackle that challenge by providing support to SMEs in a broad range. That is evident in the allocation mechanism through which institutes can obtain greater funding by partnering with SMEs, and its promotion of partnerships with SMEs by holding multiple call for proposals that provide funds for SME support initiatives. That seems to be based on a strategy to have the SMEs accumurate experience to work with Carnot Institutes. It is expected that the accumuration enables the SMEs become technologically competitive in a longer time frame.

Will success be achieved in raising the overall technical level of SMEs through such support? Or will the program's aims be nullified as a result of the mass production of collaborative projects that do not involve substantive technical transfer? How the Carnot Institutes program moves forward from here will bear watching.

# 5.9 Future orientation

Two sources are important to infer the future orientation of the program. One is a report by the Commission Carnot 3.0, which evaluates the existing program and gives recommendations for the future program. The other is the document for call for proposals for the next Carnot Institute program (Carnot 3.0), which has released in November 2015. The findings are as follows.

# 5.9.1 Program evaluation in Commission Carnot 3.0's report

With regard to the overall Carnot Institutes program, Commission Carnot 3.0's report states that "the Carnot Institutes program is a successful framework for reinforcing collaboration between public research institutes and private enterprises and supporting such institutes in multiple technical fields that is simple, fulfills its responsibilities, and undergoes regular ex-post evaluations."

Looking first at the report's evaluation of the program's simplicity, this refers to its mechanism for allocating funds to the Carnot Institutes. It is a simple mechanism through which the amount an institute will receive in the following year is determined automatically in accordance with the value of its direct contracts with private enterprises. The program avoids the complicated process of establishing an evaluation committee, evaluating each institute, and then determining funds allocation amounts based on the results.

Next, regarding the report's appreciation of the program's fulfillment of responsibility, the program is fully carrying out its responsibility of transferring the technologies possessed by public research institutes to private enterprises.

Finally, with regard to the report's point concerning regular ex-post evaluations, this refers to the yearly funds allocation calculations that correspond to the value of direct contracts with private enterprises.

On the other hand, the report points out a number of problem areas in the program. First, it notes that large disparities in performance exist among Carnot Institutes. It also states that the program scheme is rigid. For example, as an area requiring improvement, it identifies the five-year program period during which the Carnot Institutes are set and no replacements take place. Moreover, the report points out that the indicators used to measure the Carnot Institutes' performance are inadequate in their present state. It also questions the current circumstance in which only amounts that are lower than the amounts calculated with the formula can be actually allocated.

# 5.9.2 Recommendations in the Carnot 3.0 report

The Commission Carnot 3.0 makes the following four recommendations based on the above points.

Firstly, the commission recommends the separation of the overall Carnot program and the Carnot label's effective period. Specifically, it recommends making the overall program a 10-year program but making decisions on the advisability of granting of the Carnot label every two years or adopting new institutes every two years. This would give the program a long-term perspective and stimulate its renewal.

Secondly, it makes a number of suggestions to improve the program's benefits for private enterprises. They include speeding up the contract process while setting up a single contact point for private enterprises in each Carnot Institute, reinforcing Ai Carnot's activities to raise enterprises' awareness of it, and improving the quality of joint research. It stresses raising private enterprises' recognition of the Carnot Institutes.

Thirdly, it recommends introducing governance by a collegial body, the majority of whose

membership will come from industry. That is to ensure that Carnot Institutes are matched to private enterprises' needs.

And lastly, the commission recommends increasing the Carnot program's funding. It recommends the certain payment of at least 15% of the value of direct contracts to institutes, and the application of the increased funds allocation amount to not only SMEs, as is the case now, but also ETIs.

## 5.9.3 Selection requirements in call for proposals document

The requirements for selection that were provided in the call for proposals documents of Carnot 3.0 differed from those of the second period in the following ways.

First, it has changed to specify the requirements to the candidates regarding to the service quality to the private enterprizes. For example, the concrete phrase "immediate response to external inquiries" was included in the selection requirements pertaining to the improvement of institute activities. This requirement is a reflection what was touched on in the Carnot 3.0 report.

And second, items pertaining to international collaboration were deleted from the selection requirements. Despite the fact that the Carnot Charter calls on institutes to pursue international activities, experience in international collaboration is no longer required for selection.

It should be noted that the call for proposals for Carnot 3.0 is looking to select two organization types: "Instituts Carnot" and "Tremplin Carnot". While the Instituts Carnot (Carnot Institutes) framework remains the same as in past years, a new type (Tremplin Carnot) is being added, a new Tremplin Carnot framework—which involves the selection of organizations that do not currently meet the requirements to become a Carnot Institute but which have the "potential to meet those requirements within three years"—is being added. Organizations selected as Tremplin Carnot institutes will receive 200,000 euros a year plus an additional 600,000 euros (maximum) that is based on their performance.

## 5.9.4 Funds allocation formula in the documents for call for proposals

Calculation of funds allocation under Carnot 3.0 will differ from that of Carnot 2.0 in the following way.

Amount allocated to a Carnot Institute (Carnot 2.0)

- = 20% of the value of direct R&D contracts with private enterprise the previous year
- + An additional amount if the partner enterprises were SMEs (10% of the direct contract value)
- + 20% of the appraised value of intellectual property rights generated from activities as a Carnot Institute (maximum of 120,000 euros per right)

Amount allocated to a Carnot Institute (Carnot 3.0)

- = 35% of the value of direct contracts with private enterprises the previous year (portion of the contract value up to 2.5 million euros)
- + 25% of the value of direct contracts with private enterprises the previous year (portion of the contract value from to 2.5 million euros to 5 million euros)
- + 15% of the value of direct contracts with private enterprises the previous year (portion of the contract value exceeding 5 million euros)
- + When a contract was with an SME or ETI, an additional allocation equivalent to 10% of the contract's value

A minimum allocation of 300,000 euros will be guaranteed in case allocation based on the above formula will not be possible when Carnot Institutes have excellent performance.

Significant changes are as follows.

First, the most important change is the introduction of a mechanism that lowers the amount allocated based on direct contracts with private enterprises in a stepped manner, from 35% to 15%. With it, when a contract value exceeds 5 million euros, the allocated amount associated with it will become smaller than what it would have been with the Carnot 2.0 formula. This arrangement will, as a result, better protect allocations for Carnot Institutes that conduct joint research of a moderate scale or smaller.

In addition, while only direct contracts with SMEs were eligible for additional allocations under Carnot 2.0, eligibility was expanded to include direct contracts with ETI under Carnot 3.0. It should be noted that "SME" refers to a company of between 10 and 250 employees, while "ETI" refers to one with between 251 and 5,000 employees.<sup>121</sup>

Moreover, under Carnot 2.0, the appraised value of intellectual property rights that were generated from Carnot Institute activities were included in the funds allocation calculation; however, this item was removed in Carnot 3.0.

 <sup>&</sup>lt;sup>121</sup> Décret n° 2008-1354 du 18 décembre 2008 relatif aux critères permettant de déterminer la catégorie d'appartenance d'une entreprise pour les besoins de l'analyse statistique et économique
 It should be noted that certain financial standards are also applied in addition to the employee number standards; however, those standards were abbreviated here.

# 5.10 Implications to Japan

Here we will consider items from the above-described initiatives in France that may have applicability in Japan.

#### 5.10.1 Introduction of a framework that is distinct from Fraunhofer

The process through which France has introduced a framework that is modeled after Fraunhofer and is significantly distinct from Fraunhofer is rich with hints for Japan.

First, the Carnot Institutes program's ingenuity can be seen in its introduction of a new framework by utilizing existing frameworks and with much smaller investment than would have been required to start from scratch. Namely, the strategy behind the program is to change the culture of the strong public research institutes that places overall stress on basic research, not to build a completely new framework. Here, it is thought that if France had attempted to establish a Fraunhofer-like research organization from scratch, the cost of building and operating it would have been enormous. And as a result it would have been unable to build the kind of large-scale research organization of 34 institutes that the Carnot Institute program is today.

Another point that stands out is the program design that makes Carnot Institutes conduct not only applied research but also basic research. That is unlike Fraunhofer. That is an attempt to gradually change the mindset of researchers who have always focused on basic research. It is difficult to significantly change researchers' attitude in a short time period. In that case, it is a good way to have them gradually change. When institutes participate in the Carnot Institutes program, their laboratories gradually take on more and more joint research with private enterprises, and more of their employees are assigned with full-time responsibility for such research. It appears that this approach works at researchers through such changes in their research environment.

These points—namely, the process of using another country's scheme as a model and adapting it to one's own circumstance and the method of introducing a new framework by utilizing existing organizations with relatively little investment and few changes—can serve as a useful reference for Japan.

## 5.10.2 A program that effectively uses a network

The method makes the Carnot Institute program's operation network based offers a great deal to consier. That is the establishment of Ai Carnot and building of a network around it to manage 34 Carnot Institutes in an integrated manner and successfully provide joint research that meets or exceeds a certain level to private corporations while also raising each institute's capabilities.

The Carnot Institute program is strengthening its network by preparing the Carnot Charter and other guidelines, demanding that individual Carnot Institutes comply with those guidelines, and promoting inter-institute information exchanges and joint research.

Moreover, through its network it is sharing know-how on collaboration with business, an area in which individual research institutes had little experience, and is thus successfully building Carnot Institutes' capabilities as organizations that promote joint research with the private sector.

This network is embedded with incentives to actively use it. As a specific example, Ai Carnot's operating funds are supplied by 2% of the Carnot Institutes program budget from ANR. However, this money is not deducted prior to budget allocation to the individual institutes, but rather first allocated to the institutes and then sent to Ai Carnot. This arrangement reinforces the institutes' awareness that they are making contributions to Ai Carnot.

Additionally, Ai Carnot is established as an independent non-profit organization rather than a

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public body of ANR or other parent organization, and Carnot Institute representatives have a say in its decision-making. This serves to encourage institutes' commitment vis-à-vis Ai Carnot's activities.

The application of a framework that makes similar effective use of networks will likely be an important consideration when designing a program for Japan.

# 5.10.3 A history of inter-organizational partnership cultivated in mixed research units (UMR)

One of the Carnot Institutes program's strengths is its framework in which people from different organizations engage in R&D jointly under the roof of a single organization.

At such times, a concern is how to manage research teams that are comprised of researchers from organizations with different environments and cultures so that they produce results. With regard to this point, France has a history of operating what are called *unités mixtes de recherche* (UMR; mixed research units). The UMR framework brings together CNRS researchers and university researchers to conduct studies in a CNRS laboratory (UMR) that is established within a university. This laboratory also serves as a venue for education of the university's PhD candidates.

Those backgrounds are thought to be a factor in the effective functioning of frameworks for R&D conducted by teams of people with different backgrounds and specialties.

Because no similar frameworks exist in Japan, particular attention to differences between Japan and France in terms of background and circumstances will be required when using the Carnot Institute program as a reference

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# Authors

# Yukihide HAYASHI

Principal Fellow (Overseas Research Unit), Center for Research and Development Strategy (CRDS), Japan Science and Technology Agency (JST). Received M.S. from School of Engineering, Department of Nuclear Engineering, University of Tokyo in 1973. Assigned to his present post in 2010 after having served as Director-General, Science and Technology Policy Bureau, Ministry of Education, Culture, Sports, Science and Technology (MEXT), Cabinet Office Director-General for Science and Technology Policy and Deputy Minister for MEXT. Literary works: "*The Antiscience Society: The Decline of Math and Science in Japan*," *China: A S&T Superpower – from Manned Space Flight to Nuclear and iPS Cells,*" and "Peking University and Tsinghua University – History, Current Situation, School Life, Advantages and Challenges."

# Tomoko SAWADA

Fellow (Overseas Research Unit), CRDS, JST. Graduated from the Department of Law (Faculty of Sociel science and Geoscience), Ludwig Maximilians University Munich in 2000. After returning to Japan, engaged in web marketing and a regional resource revitalization program in an IT venture company and was assigned to her present post in 2013.

## Masamichi MINEHATA

Fellow (Overseas Research Unit), CRDS, JST. Received his PhD and MA from the Department of Peace Studies of the University of Bradford UK. Previously worked for the Center for Strategic and International Studies (CSIS) US as a SPF Fellow, Brocher Foundation Switzerl as a visiting researcher, and the UK Prime Minister's Initiative (PMI-2) and UK-DSTL fellow at the University of Bradford. Recent publication includes Minehata, M., and Walther, G. (2014) 'Biosecurity Education and Awareness in Neuroscience', in Jens, C., and Levy, N. (Eds) *Handbook of Neuroethics*, Dordrecht Netherlands: Springer. pp.1773-1783.

## Yuko TSUDA

Fellow (Overseas Research Unit), CRDS, JST. Completed the doctor's program without a doctoral degree in the Graduate School of Political Science, Waseda University in March 2010. Assigned to her present post in 2014 after having served as Research Associate, Faculty of Political Science and Economics, Waseda University, Adjunct Researcher in Overseas Legislative Information Division, Research and Legislative Reference Bureau, National Diet Library, Part-Time Lecturer, Department of Russian Studies, Faculty of Foreign Studies, Sophia University, Researcher in the Embassy of Japan in Moscow and Senior Technology Coordination Manager of International Science and Technology Center in Moscow.

## Izumi YAMASHITA

Fellow (Overseas Research Unit), CRDS, JST. Dismissed from the Department of Environmental Studies, Graduate School of Frontier Sciences, University of Tokyo in 2006. Assigned to her present post in 2012 after having worked in private companies.

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K's Gobancho, 7, Gobancho, Chiyoda-ku, Tokyo 102-0076 JAPAN TEL: +81-3-5214-7481 FAX: +81-3-5214-7385

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