Mission-oriented R&I policies: In-depth case studies

Case Study Report
War on Cancer (US)
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European Commission
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Manuscript completed in February 2018.

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Luxembourg: Publications Office of the European Union, 2018

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Mission-oriented R&I policies: In-depth case studies

Case Study Report

War on Cancer (US)

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A Study coordinated by the Joint Institute for Innovation Policy

February 2018
Directorate-General for Research and Innovation
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1 Summary of the case study

This document analyses the case study of mission-oriented R&I policy initiatives in the field of cancer in United States from 1971 to 2016.

The following table describes the main components of the case study:

| Title: | War on Cancer |
| Country: | US |
| Thematic area: | Health |
| Objective(s): | Eradicate cancer as a major cause of death by increased research to improve the understanding of cancer biology and the development of mode effective cancer treatments such targeted drug therapies. |
| Main Governing Body | National Cancer Institute |
| Timeline: | 1971-2016 |
| Budget: | USD 117.8 billion (1971-2016) (Public Budget for National Cancer Institute) |
| Brief description of the case (250 words) | War on Cancer started in 1971 with the signing of the National Cancer Act by President Richard Nixon, and reflects the national effort to find a cure for cancer by increasing research to improve the understanding of cancer biology and the development of more effective cancer treatments. |
| Implementation and organisation (a brief description of the governance and policy instruments used) | From the beginning, tools have been aimed at building a strong technological offer. First, by creating main governance bodies and supply agents and then, by developing science and technology to give an answer to the main challenges. Legislation has been a main tool to face this supply-side approach (1937 and 1971 National Cancer Acts and ALERT Act) |
| Observed / expected outputs, outcomes, and impacts | • Creation of the National Cancer Institute, National Cancer Advisory Board, research centers, networks and platforms that make up a solid supply ecosystem to give scientific and technological answers to the main challenges. • The creation in 1998 of the Comprehensive Cancer Control National Partnership: 18 national cancer organisations working in collaboration to develop and implement state, tribe and territory cancer control plans. • The creation in 2014 of the National HPV Vaccination Roundtable, a national coalition of public, private and voluntary organisations to reduce the incidence of mortality from Human Papillomavirus-associated cancer. • Since the Affordable Care Act (2010), all health plans cover any U.S. Preventive Services Task Force-approved immunisation or cancer prevention measure without out-of-pocket payments by the insured. • Federal regulation of tobacco products, state and local legislation to increase tobacco taxes, increased coverage of tobacco-cessation programmes, expansion of smoke-free workplace laws and increased access to pain medication. • Advances in technology, including imaging techniques, new drugs and treatments, therapeutic interventions and insights and discoveries into the fundamental nature and causes of cancer, have led to cures and to improved quality of life for people diagnosed with cancer. • Federal research has been essential for discovering knowledge that has later been used to develop important drugs. A study of 32 innovative drugs introduced before 1990 found that without the contributions of public institutions, 60% of the drugs would not have been discovered. • In 2017, 55% of products in the global health pipeline are supported by the US Government; 45% of total investment in global health R&D is contributed by the US Government and 70% of public sector...
investment in global health R&D is contributed by the US Government.

- Bayh-Dole University and Small Business Patent Act, and Stevenson-Wydler Technology Innovation act, enable researchers to license technologies and create spinoff companies from research funded by the public sector. There is a great flexibility for the biomedical scientists to move across public institutions and private sector, which has fostered an R&D environment that produces a high rate of commercialization.

- 23% drop in cancer mortality rate between 1991 and 2012.
- 90% of Americans with access to quality health services (including cancer prevention, treatment and care).
- Improvements in 5-year survival rates between 1975-2012 for the most common cancer.
- Improvements in 5-year relative survival for childhood cancers, 1975-2012.
- Overall cancer death rates from 2010 to 2014 decreased by 1.8% per year in men, by 1.4% per year in women and by 1.6% per year in children.
- From 2010 to 2014, death rates decreased for 11 of the 16 most common cancer types in men and for 13 of the 18 most common cancer types in women, including lung, colorectal, female breast and prostate, whereas death rates increased for liver (men and women), pancreas (men), brain (men) and uterine cancers.
- Survival varied by race/ethnicity and state. The adjusted relative risk of death for all cancers combined was 33% higher in non-Hispanic blacks and 51% higher in non-Hispanic American Indians/Alaska Natives compared with non-Hispanic whites.
- US is the most prolific producer of cancer research publications. US researchers have dominated research production for the past decade, producing more publications per annum than Japan, the UK, France, Germany, and Italy combined.
- In 2014, the number of drugs in development for Cancer was 3,073 (1,265 in phase I, 1,507 in phase II, 288 in phase III and 13 in regulatory review).
- NIH-supported research helped create the first cancer drug targeted at a family of molecules called kinases. This breakthrough launched a new wave of drug development, with drug companies creating other drugs targeting similar molecules to treat not only cancer but also other diseases.
- 49 new cancer medicines were launched between 2010 and 2014. US is the country with the highest number of medicines available.
- Between 1998 and 2000, life expectancy increased four years, and the average willingness to pay for these survival gains was USD 322,000. Improvements created USD1.9 trillion of additional social value, and health care providers and pharmaceutical companies appropriated 5-19% of this total.
- Cancer death rates have been dropping by more than 1 percent annually (2005-2015). In 2006, it was estimated that a cure for cancer would be worth USD 47 trillion, and even a 1 percent reduction in cancer mortality would be worth about USD 500 billion.
- New markets: U.S leads developed markets in the wide and early adoption of newer targeted treatments. New targeted oncologics medicines introduced globally (2010-2015) represent nearly one-third of the volumes used in the U.S.compared to 23-26% in the top five European countries, and 21-22% in Japan. In the U.S., EU5 and Japan, over 90% of oral treatments currently used were introduced since 2000, representing a near complete replacement of the treatment arsenal over that time.
- In 2002 it was estimated that 500,000 jobs in the biopharmaceutical industry in USA were created "on the shoulders of public funding and academic performance".
- A USD 1 increase in public basic research stimulates ad additional USD 8.38 of industry R&D investment after 8 years. A USD 1 increase in public clinical research stimulates an additional USD 2.35 of industry R&D investment after 3 years. More specifically, it has
been calculated that every USD 1 of NIH fund generates USD 2.21 in economic output.

- Discoveries arising from NIH-funded research provide a foundation for the U.S biomedical industry, which contributed USD 69 billion to the GDP and 7 million jobs in 2011.

- Successful oncology treatments have promised some of the highest returns for pharmaceutical manufacturers; in 2016, oncology assets represented 5 of the top 15 best selling drugs globally. The market is expected to continue to show strong growth, with a forecast CAGR of 10.9% to 2030 for oncology prescription sales, driven by factors such as an aging population and lifestyle changes predisposing to disease.

- In Kansas, the total economic impact of NCI investments is estimated in USD 931 million (2007-2012) and USD 1,088 million (2013-2016).

- The California Healthcare, Research and Prevention Tobacco Act, launched on November 2016 is expected to generate USD 664 million in total economic activity and a net increase of 8,645 jobs. A similar study launched in 2012 had calculated that California Cancer Research Act could generate 12,000 jobs and USD 1.9 billion in economic activity.

- In Texas, in 2016, the overall total current impact of Cancer Prevention and Research Institute (CPRIT) includes a gain of 79,075 jobs and USD 8 billion in output.

- In general, US government investment in global health R&D from 2007-2015 generate d an estimated 200,000 new U.S jobs and USD 33 billion in economic growth.

<table>
<thead>
<tr>
<th>Main elements of mission-oriented R&amp;I initiative¹</th>
<th>YES</th>
<th>TO CERTAIN DEGREE</th>
</tr>
</thead>
<tbody>
<tr>
<td>Directionality (links to societal challenges, industry transformation):</td>
<td>YES. War on Cancer is directly related to Good Health, that is one of the Sustainable Development Goals defined by United Nations.</td>
<td></td>
</tr>
<tr>
<td>Intentionality (specific, well-articulated targets):</td>
<td>YES. At the early part, the main targets are focused on creating capabilities, then on matching the supply and the demand and in the last stage, obtaining results and social and economic impact.</td>
<td></td>
</tr>
<tr>
<td>Clearly set timeline and milestones:</td>
<td>YES. The National Program Goal was to develop he means to reduce the incidence, morbidity and mortality of cancer in humans. The second level was composed of Seven National Program Objectives with approaches and well-defined project areas.</td>
<td></td>
</tr>
<tr>
<td>Mobilises public and private investments:</td>
<td>NO. Originally War on Cancer was a public initiative.</td>
<td></td>
</tr>
<tr>
<td>Focused on new knowledge creation (basic research, TRLs 1-4):</td>
<td>YES. Knowledge creation and basic research have a main role in the initiative to give an accurately answer to some problems. In fact, War on Cancer triggered a massive investment in basic science with the assumption that unbiased fundamental research would hold the key to unlocking the secrets of cancer cells.²</td>
<td></td>
</tr>
<tr>
<td>Focused on knowledge application (applied research, TRLs 5-9):</td>
<td>TO CERTAIN DEGREE. A certain part of the National Cancer Program was focused on demonstration of advanced diagnostic and treatment methods</td>
<td></td>
</tr>
<tr>
<td>Demand articulation (involves instruments for inducing demand):</td>
<td>YES. War on Cancer counted on private contractors, including laboratories, profit-making, universities and industry, both national and foreign.</td>
<td></td>
</tr>
<tr>
<td>Multi-disciplinary (inter-disciplinary and/or trans-disciplinary):</td>
<td>YES. Despite being an initiative deeply rooted in health sector (pharma, biotech, etc), other scientific disciplines such as psychology, economy or finances had an important role.</td>
<td></td>
</tr>
<tr>
<td>Joint coordination (multi-level and/or horizontal governance of policies/finance):</td>
<td>YES. There was an intensive vertical coordination within the Department of Health and Human Services (among different directions and centers) but also with other Departments and non-federal agents.</td>
<td></td>
</tr>
</tbody>
</table>

¹ Assessment: Yes, To certain degree, No or Not known).

Reflexivity (flexible policy design, timely monitoring): **YES.** The available information points to an effective coordination between the needs of patients and the scientific and technological activity.

Openness (connected to international agendas and networks): **YES.** One of the main functions of the Director of NCI was to support research in the cancer field outside the United States by highly qualified foreign nationals which research can be expected to inure to the benefit of the American people; support collaborative research involving American and foreign participants; and support the training of American scientists abroad and foreign scientists in the United States.

Involvement of citizens: **TO CERTAIN DEGREE.** There were few mechanisms to involve civil society in the decision-making process to identify priorities or to evaluate results. The director of NCI had the possibility of appointing one or more advisory committees composed of private citizens.

## 2 Context and objectives of the initiative

This chapter contains an analysis of the initiative against cancer since the beginning until 2016, as well as an overview of the major milestones and main objectives. Also, the analysis describes the key barriers and drivers influencing the initiative, classified according to their nature.

### 2.1 Contextual factors and origins of initiative

Even though the first initiatives in USA related to Cancer are to be found in the early 20th century, it took until **1937** when the National Cancer Institute (NCI) was established through the **National Cancer Act**, culminating several years of efforts to formalize the commitment of U.S. government with cancer research. Thus, NCI became the federal government’s agency for conducting research and training on the cause, diagnosis and treatment of cancer. Also, the Act established the National Advisory Cancer Council, now named National Cancer Advisory Board.

During the January 1971 State of the Union, President Nixon said:” **I will ask for an appropriation of an extra USD 100 million to launch an intensive campaign to find a cure for cancer, and I will ask later for whatever additional funds can effectively be used. The time has come in America when the same kind of concentrated effort that split the atom and took man to the moon should be turned toward conquering this dread disease. Let us make a total national commitment to achieve this goal.**”

On December 23, 1971, President Nixon followed through on his promise as he signed the National Cancer Act into law. The **National Cancer Act of 1971** initiated the National Cancer Program, with 15 new research centers, cancer control programs to improve the collaboration with other health agencies and an international cancer data research bank. This Act is generally viewed as the beginning of the War on Cancer, understood as the national effort to find a cure for cancer by increasing research to improve the understanding of cancer biology and the development of more effective cancer treatments.

In despite of the efforts, though there were some notable steps forward in diagnosis and treatment of cancer, a growing perception of a lack of progress in the war on cancer\(^3\) was documented in 2008 by the U.S Senate Committee on Health, Education, Labor and Pensions in the panel discussion “**Cancer: Challenges and Opportunities in the 21st**

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As a result, in 2009, The U.S Senate issued the **21st Century Cancer ALERT Act** (Access to Life-Saving Early Detection, Research and Treatment)\(^7\) to overhaul the 1971 National Cancer Act. ALERT aims to improve patient access to prevention and early detection by providing funding for research in early detection, supplying grants for screening and referrals for treatment and increasing access to clinical trials and information.

Almost at the same time (2009), Senators Barack Obama and Joe Biden presented a plan to combat cancer with a stimulus package of US 10 billion for National Institutes of Health. As a result, in 2016 Obama's government launched the federal initiative **Cancer Moonshot** to accelerate cancer research, improve access to therapies for more patients and increase the ability to prevent and detect cancer early.

To understand the **differences between War on Cancer and Cancer Moonshot**, Former Vice President Biden’s words are revealing: "President Nixon, when he declared War on Cancer in 1971, he was earnest and sincere and very committed. But what makes the difference between then and now is -- the single big difference is that he had no army. He had no resources. He had no weapons. He had no strategy to win. But after 45 years with many of you in this room doing incredible work, 45 years of progress, after decades of funding research, training scientists and physicians, treating millions of patients, we now have an army. We now have powerful new technologies and tools, like immunotherapy that -- by the way, even six, eight, ten years ago was viewed kind of as a voodoo science out there. It wasn't really an integral part of this fight that makes cancer cells visible to the immune system so our natural defenses can destroy the cancer."\(^8\)

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\(^6\) Stand Up to Cancer (2008). "Renewing the War on Cancer". YouTube. [https://www.youtube.com/watch?v=9YicA5ANmdE](https://www.youtube.com/watch?v=9YicA5ANmdE)


The following table summarizes main external drivers and barriers for facing and managing the fight against cancer:

<table>
<thead>
<tr>
<th>Drivers</th>
<th>Barriers</th>
</tr>
</thead>
</table>
| **Political** | • There were other projects before, such as Apollo Project and Manhattan Project that had demonstrated the U.S. capacity to foster big and complex scientific and technological projects.  
• There have been other more recent initiatives such as Precision Medicine Initiative (2015), that involves similar organizations and have objectives fully compatible with the ones of War on Cancer. |
| **Economic** | • In 1969, for every man, woman and child the U.S spent only USD 0.889 on cancer research.  
• The R&I of innovative cancer treatments used to be a risk-taking investment opportunity. Also tends to be a limited level of expertise amongst business angels, private funds and public equity schemes in early-stage high-technology investments and many lack competent risk capital capabilities. This lack of expertise and knowledge of the market weaknesses and opportunities, has the consequence of risking the high levels of capital investment required to see a research product through to commercialization. |
| **Societal** | • In 1969, for every man, woman and child the U.S spent only USD 0.889 on cancer research.  
• The R&I of innovative cancer treatments used to be a risk-taking investment opportunity. Also tends to be a limited level of expertise amongst business angels, private funds and public equity schemes in early-stage high-technology investments and many lack competent risk capital capabilities. This lack of expertise and knowledge of the market weaknesses and opportunities, has the consequence of risking the high levels of capital investment required to see a research product through to commercialization. |
| **Technological** | • In 1971 the incidence of cancer was increasing and cancer was the disease which Americans were more concerned about.  
• In 1971, more than 52 million Americans were at risk for cancer.  
• In 1930, one case of cancer in five could be treated and cured. The rate in 1971 was one in three and it was much room for improvement.  
• In 1971, surgery and radiation were the methods of treatment that cured most cancers. The |

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2.2 Strategic and operative objectives and milestones of the initiative

In 1971, National Cancer Program started with 1,426 employees, 37% scientific and professional, 24% administrative and clerical, and 38% technical and supporting. The objectives and milestones were achieved through the National Cancer Program Strategy, a combination of selected laboratory, field and clinical research courses of actions.

The National Program Goal was to develop the means to reduce the incidence, morbidity and mortality of cancer in humans.

The second level was composed of Seven National Program Objectives:

1. Develop the means to reduce the effectiveness of external agents for producing cancer.

2. Develop the means to modify body mechanisms so as to minimise the hazards of cancer inducing agents.

3. Develop the means to prevent transformation of normal cells to cells capable of forming cancers.

4. Develop the means to prevent progression of precancerous cells to cancers, the development of cancers from precancerous conditions and spread of cancers from primary sites.

5. Develop the means to achieve an accurate assessment of a) the risk of developing cancer in groups and in individuals and b) the presence, extent and probable course of existing cancers.

6. Develop the means to cure cancers and to retard the progress of cancers not cured.

7. Develop the means to improve the rehabilitation of cancer patients.

There were also a third level including the approaches recommended to achieve the objectives and two more levels: approach elements and project areas.
3 Resources and management

The development of War on Cancer required three major ingredients: effective administration with clearly defined authority and responsibility, a comprehensive national plan, and necessary financial resources.

3.1 Governance and management model\textsuperscript{12}

War on Cancer has been under National Cancer Institute (part of National Institute of Health, an agency of the U.S Department of Health and Human Services), established by the National Cancer Act of 1971 (see figure 1)

![NCI Organizational Diagram](image)

Figure 1: National Cancer Institute Organization (1971). Source: 1973 Fact Book. NCI.

NCI was developed with the advice of the National Cancer Advisory Board (NCAB), a committee of 23 members, including scientists, members from the general public and members from other government agencies.

The director of the NCI coordinated all the activities of the NIH relating to cancer with the National Cancer Program. In consultation with NCAB, and under the National Cancer Act, the director of NCI had the following functions:

- Plan and develop an expanded, intensified, and coordinated cancer research program encompassing the programs of the NCI, related programs of the other research institutes, and other federal and non-federal programs.

• Utilise existing research facilities and personnel of the NIH for accelerated exploration of opportunities in areas of special promise.

• Encourage and coordinate cancer research by industrial concerns where such concerns evidence a particular capability for such research.

• Collect, analyse, and disseminate all data useful in the prevention, diagnosis, and treatment of cancer.

• Establish or support the large-scale production or distribution of specialized biological materials and other therapeutic substances for research and set standards of safety and care for persons using such materials.

• Support research in the cancer field outside the United States by highly qualified foreign nationals which research can be expected to inure to the benefit of the American people; support collaborative research involving American and foreign participants; and support the training of American scientists abroad and foreign scientists in the United States.

• Support appropriate manpower programs of training in fundamental sciences and clinical disciplines to provide an expanded and continuing manpower base from which to select investigators, physicians, and health professions personnel for participation in clinical and basic research and treatment programs relating to cancer.

A three-member panel called President’s Cancer Panel (PCP) oversaw the reviews of the program and submitted an annual progress report directly to the President.

NCI director, NCAB Committee and PCP were presidential appointees.

3.2 Financing model

Yearly appropriations for National Cancer Institute are reflected in Table 1. The NCI budget was submitted directly to the President.

<table>
<thead>
<tr>
<th>Year</th>
<th>Total appropriation (USD)</th>
</tr>
</thead>
<tbody>
<tr>
<td>1938-2002</td>
<td>USD 52,940,982,220</td>
</tr>
<tr>
<td>2003</td>
<td>USD 4,622,394,000</td>
</tr>
<tr>
<td>2004</td>
<td>USD 4,770,519,000</td>
</tr>
<tr>
<td>2005</td>
<td>USD 4,865,525,000</td>
</tr>
<tr>
<td>2006</td>
<td>USD 4,841,774,000</td>
</tr>
<tr>
<td>2007</td>
<td>USD 4,797,639,000</td>
</tr>
<tr>
<td>2008</td>
<td>USD 4,827,556,000</td>
</tr>
<tr>
<td>2009</td>
<td>USD 4,968,973,000</td>
</tr>
<tr>
<td>2010</td>
<td>USD 5,103,388,000</td>
</tr>
<tr>
<td>2011</td>
<td>USD 5,058,577,000</td>
</tr>
<tr>
<td>2012</td>
<td>USD 5,072,183,000</td>
</tr>
<tr>
<td>2013</td>
<td>USD 5,072,183,000</td>
</tr>
<tr>
<td>2014</td>
<td>USD 4,923,238,000</td>
</tr>
<tr>
<td>2015</td>
<td>USD 4,950,396,000</td>
</tr>
</tbody>
</table>

When National Cancer Program started the appropriation by program was as reflected in figure 2:
Governmental funding in US for Cancer accounts for 94% of the total spend. The NCI has been the main source of cancer research funds and receives its funds from the U.S Congress.

The NCI budget distribution in 2016 (see figure 4) shows a rate of 69% for research activities (in blue) – 23% for cancer causation activities, 9% for detection and diagnosis research, 23% for treatment research and 14% for cancer biology. The budget devoted to resource development (14% in orange) is distributed within cancer centers (10%), research manpower development (3%) and buildings and facilities (less than 1%). The residual budget goes to cancer prevention and control (6%) and program management and support (11%).

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At the end of War on Cancer total public sector direct funding for cancer research was the highest of most developed countries, 19.34€ per capita. (see figure 5).
3.3 Key actors and key technologies and platforms involved in the initiative

**National Cancer Institute**

NCI is the federal government’s agency for cancer research and training. It is part of the National Institutes of Health, which is one of the 11 agencies that comprise the Department of Health and Human Services (see figure 6).

![Image of National Institutes of Health Ecosystem](image)

*Figure 5: National Institutes of Health Ecosystem. Source: United for Medical Research (2013).*

NCI leads, conducts and supports cancer research across the nation. As the largest funder of cancer research in the world, NCI supports investigators working across the US and in other countries. This support is advancing a broad portfolio of research—from basic laboratory science to clinical trials and population science—to improve our understanding of cancer and cancer prevention, diagnosis, treatment, and survivorship. NCI encourages collaboration between scientists and organizations, conducts a rigorous and accountable funding process, and works with stakeholders to ensure that the nation’s investment in cancer research has maximum impact.

**The National Cancer Act of 1971:**

- Granted the Director of the NCI broad authority to plan and develop the National Cancer Program that included the NCI and related programs, other research institutes and federal and non-federal programs.

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15 National Cancer Institute: https://www.cancer.gov/
• Provided the NCI Director with access to the President of the US and required the Director to submit an annual budget directly to the President bypassing the approval of the National Institutes of Health Director.

• Mandated that the NCO develops its programs with the advice of the National Cancer Advisory Board.

• Gave the NCI Director additional authorities to create new cancer centers and manpower training programs, expand the physical location at NIH and other research facilities across the country, award contracts for research, collaborate with other public or private organisations, conduct cancer control activities, establish an international cancer research data bank, and award research grants.

The National Cancer Institute has 30 divisions, offices and centers (figure 7). Their work consists in researching on cancer causes, treatment and prevention, training the next generation of cancer researchers, funding and supporting the nation’s network of scientists and institutions, and informing and educating people about cancer.

Figure 6: NCI-Organisation Chart nowadays. Source: www.cancer.gov.

3.4 Monitoring system and evaluation of the initiatives

The President’s Cancer Panel (PCP) monitored the development and execution of the national Cancer Program and reported directly to the President. The Panel submitted to the President periodic progress reports on the Program and annually, an evaluation of the efficacy of the Program and suggestions for improvements.\(^\text{17, 18}\)

On the other hand, the Surveillance, Epidemiology, and End Results (SEER) Program of the National Cancer Institute (NCI) is an authoritative source of information on cancer incidence and survival in the United States. SEER collects and publishes cancer incidence and survival data from population-based cancer registries covering approximately 28 percent of the US population. The main targets of the SEER Program are:

• Collect complete and accurate data on all cancers diagnosed among residents of geographic areas covered by SEER cancer registries.

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\(^\text{17} \) 1971 National Cancer Act. Op.Cit

\(^\text{18} \) President’s Cancer Panel Archive available here: https://deainfo.nci.nih.gov/advisory/pcp/archive/index.htm
• Conduct a continual quality control and quality improvement program to ensure the collection of high quality data.

• Periodically report on the cancer burden as it relates to cancer incidence and mortality, and patient survival overall and in selected segments of the population.

• Identify unusual changes and differences in the patterns of occurrence of specific forms of cancer in population subgroups defined by geographic, demographic, and social characteristics.

• Describe temporal changes in cancer incidence, mortality, extent of disease at diagnosis, therapy, and patient survival as they may relate to the impact of cancer prevention and control interventions.

• Monitor the occurrence of possible iatrogenic cancers.

• Collaborate with other organizations on cancer surveillance activities.

• Serve as a research resource to the National Cancer Institute providing for the conduct of studies that address issues dealing with cancer prevention and control as well as Program and registry operations.

• Provide research resources to the general research community including a research data file each year, and software to facilitate the analysis of the database.

• Provide training materials and web-based training resources to the cancer registry community.

Surveillance Research Program provides leadership in the science of cancer surveillance as well as analytical tools and methodological expertise in collecting, analysing, interpreting, and disseminating reliable population-based cancer statistics. This surveillance infrastructure benefits the stakeholders in understanding changes in cancer incidence and outcomes in all segments of the US population over time. One of the main output of surveillance activity is the Annual Report to the Nation of the Status of Cancer 1975-2014, that updates the rates for new cases, deaths and trends for the most common cancers in the US.

SEER Program has also other ways to disseminate such as:

• Online cancer statistics: cancer stat fact sheets, fast stats, cancer query systems and state cancer profiles.

• Data analysis tools: software to analyse SEER Data (SEER Stat), to analyse trends in data (Joinpoint, to calculate lifetime risks of getting cancer (DevCan) and to generate summary measures for evaluating and monitoring health disparities (HDCalc)

• Reports and studies: SEER Cancer Statistics Review, USCancer Statistics and Rapid Response Surveillance Studies

• Data bases: SEER Medicare Database, SEER Medicare Health Outomes Survet Database and National Longitudinal Mortality Study

Furthermore, the American Association for Cancer Research publishes yearly the Cancer Progress Report19 that capture the main advances in the year and try to urge Government and public to stay firm in the commitment to fight against cancer.

19 Cancer Progress Report 2017 is available at: http://cancerprogressreport.org/Pages/default.aspx
3.5 Level and type of citizen engagement in the initiative

Understanding society as the main beneficiary of the initiative, there are many resources created by governmental and private organisations to provide support for cancer patients, to share information with them and to give advice. Directly related with this initiative, Cancer Information Service (NCI Contact Center)\textsuperscript{20} is a federally funded cancer education program established in 1975 to provide information on cancer on a range of topics.

4 Policy instruments and wider policy-mix used for implementing the initiative.

4.1 Description of the R&I policy instruments used for implementing of the initiative

In 1971, contractors received more than USD 500,000 in NCI research contract funds. Among suppliers there were laboratories, federal and non-federal agencies, universities and industry. By NCI program, 37% of contracts were in Chemotherapy area, 26% in Viral Oncology, 14% in Etiology-Carcinogenesis, 11% in Etiology-Demography, 7% in Task Forces, 4% in General ILabs and Clinics and 1% for Cancer Research Center.

On the other hand, 31% of the contractors were profit-making, 38% academic, 18% non-profit, 5% Federal Government, 3% State and Local Government and 5% foreign contractors.

The research contract process is reflected in figure 7.

\textsuperscript{20} Cancer Information Service: https://www.cancer.gov/contact/contact-center
Figure 7: Steps leading to research contract from conception of project to contract execution. Source. 1972 Fact Book. NCI.

On the other hand, research grant application process is reflected in figure 8:
4.2 Connection with other policies

There are some recent initiatives that have synergies with the War on Cancer such as Human Genome Project that works in areas that have a clear interaction with the ones in the Cancer project.

Human Genome Project

From 1990 to 2003, Human Genome Project was an international initiative funding by the National Institutes of Health with the aim of determining the sequence of nucleotide
base pairs that make up human DNA and identifying and mapping all the genes of the human genome from both a physical and a functional standpoint.

The rise of new class of molecular technologies developed in Human Genome Project opens-up new ways to study cancer and eventually, to more effective diagnostics and therapies for cancer patients. The sequencing of genome can help to identify mutations linked to different forms of cancer or to identify the genetic variants that increase the risk for cancer. One of the main output of the project was the implementation of genetic tests that can show predisposition to a variety of illness such as cancer.

Relation with Department of Defense

Since 2009, Peer Reviewed Cancer Research Program (PRCRP)\textsuperscript{21} has been charged by U.S. Congress to fund innovative basic, applied, and translational cancer research to support service members, their families, and the public.

Members of the military are exposed to hazardous environments due to the nature of their service and deployments and, thus, are at risk for the development of many types of cancers. The mission of the PRCRP is to successfully promote high-impact research for cancer prevention, detection, treatment, and survivorship. To accomplish this task, the PRCRP seeks to fund different areas of the research landscape. Funding innovative and translational research the PRCRP offers funding opportunities directed toward the special focus of Service members and potential cancer risks; focusing on the gaps in cancer research with respect to unique situations and military environments.

Additionally, the PRCRP addresses growing and developing the future in research through targeted funding opportunities for early career investigators. With a funding program focused on military health and welfare in cancer research, the PRCRP strives to improve the quality of life by decreasing the impact of cancer on Service members, their families and the American public by funding highly relevant and innovative research.

4.3 Key turning points of the initiative and policy adaptation measures

The following table shows the major changes and turning points of the Cancer Moonshot, as well as a description of the main flexibility mechanisms and policy adaptation measures.

<table>
<thead>
<tr>
<th>Major changes / turning points of the initiative</th>
<th>Description of the flexibility mechanism / policy adaptation measures</th>
</tr>
</thead>
<tbody>
<tr>
<td>After almost three decades of efforts to fight against cancer, in 1930’s, there were not enough diagnostic and treatment centers in the US and there was a lack of coordination on issues related to cancer research.</td>
<td>The National Cancer Act of 1937 established the National Cancer Institute as an independent research institute for conducting research and training on the cause, diagnosis and treatment of cancer.</td>
</tr>
<tr>
<td>Cancer was the nation’s second leading cause of death by 1970 and cancer research needed a push to accelerate and represent the country commitment to the war on cancer.</td>
<td>The National Cancer Act of 1971 established the procedure for submitting NCI’s annual budget called the “bypass budget”, which was transmitted directly from the NCI director to the President of the US and Congress.</td>
</tr>
<tr>
<td>In despite of the efforts, though there were some notable steps forward in diagnosis and treatment of cancer, a growing perception of a lack of progress in the war on cancer was documented in</td>
<td>The U.S Senate issued the 21st Century Cancer ALERT Act (Access to Life-Saving Early Detection, Research and Treatment Act) to overhaul the 1971 National Cancer Act. ALERT aims to improve patient access to prevention</td>
</tr>
</tbody>
</table>

2008 by the U.S Senate Committee on Health, Education, Labour and Pensions in the panel discussion “Cancer: Challenges and Opportunities in the 21st Century”. and early detection by providing funding for research in early detection, supplying grants for screening and referrals for treatment and increasing access to clinical trials and information.

- Initiative continuous assessment.
- The President’s Cancer Panel (PCP) submitted to the President periodic progress reports on the Program and, annually, an evaluation of the efficacy of the Program and suggestions for improvements.

5 Realised or expected outputs, outcomes and impacts

This section is focused on the outputs, outcomes and impacts resulted from the whole initiative (from 1971 to 2016).

5.1 Outputs and New Instruments

- Creation of the National Cancer Institute, National Cancer Advisory Board, research centers, networks and platforms that make up a solid supply ecosystem to give scientific and technological answers to the main challenges.

- The creation in 1998 of the Comprehensive Cancer Control National Partnership: 18 national cancer organisations working in collaboration to develop and implement state, tribe and territory cancer control plans.

- The creation in 2014 of the National HPV Vaccination Roundtable, a national coalition of public, private and voluntary organisations to reduce the incidence of mortality from Human Papillomavirus-associated cancer.

5.2 Outcomes

- Since the Affordable Care Act (2010), all health plans cover any U.S. Preventive Services Task Force-approved immunisation or cancer prevention measure without out-of-pocket payments by the insured.

- Federal regulation of tobacco products, state and local legislation to increase tobacco taxes, increased coverage of tobacco-cessation programmes, expansion of smoke-free workplace laws and increased access to pain medication.

- Federal research has been essential for discovering knowledge that has later been used to develop important drugs. A study of 32 innovative drugs introduced before 1990 found that without the contributions of public institutions, 60% el the drugs would not have been discovered.

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22 About the CCCNP: https://www.cccnationalpartners.org/about-us.
• In 2017, 55% of products in the global health pipeline are supported by the US Government; 45% of total investment in global health R&D is contributed by the US Government and 70% of public sector investment in global health R&D is contributed by the US Government.\(^{27}\)

• Bayh-Dole University and Small Business Patent Act, and Stevenson-Wydler Technology Innovation act, enable researchers to license technologies and create spinoff companies from research funded by the public sector. There is a great flexibility for the biomedical scientists to move across public institutions and private sector, which has fostered an R&D environment that produces a high rate of commercialization.\(^{28}\)

5.3 Social Impacts

• 23% drop in cancer mortality rate between 1991 and 2012 (see figure 9).\(^{29}\)

![Figure 9: Changes in mortality rates over time (2004-2013). Source: Global Oncology Trends 2017](image)

• 90% of Americans with access to quality health services (including cancer prevention, treatment and care).\(^ {30}\)

• Improvements in 5-year survival rates between 1975-2012 for the most common cancers (figure 10).

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\(^{29}\) Union for International Cancer Control (2016). op.cit.

Figure 10: Improve in survival rates for the most common cancers (1975-2012). Source Annual Report to the Nation2017.

- Improvements in 5-year relative survival for childhood cancers, 1975-2012 (figure 11).

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Overall cancer death rates from 2010 to 2014 decreased by 1.8% per year in men, by 1.4% per year in women and by 1.6% per year in children.33

From 2010 to 2014, death rates decreased for 11 of the 16 most common cancer types in men and for 13 of the 18 most common cancer types in women, including lung, colorectal, female breast and prostate, whereas death rates increased for liver (men and women), pancreas (men), brain (men) and uterine cancers.34

Survival varied by race/ethnicity and state. The adjusted relative risk of death for all cancers combined was 33% higher in non-Hispanic blacks and 51% higher in non-Hispanic American Indians/Alaska Natives compared with non-Hispanic whites.35

US is the most prolific producer of cancer research publications (see figure 12). US researchers have dominated research production for the past decade, producing more publications per annum than Japan, the UK, France, Germany, and Italy combined.36
In 2014, the number of drugs in development for Cancer was 3,073 (1,265 in phase I, 1,507 in phase II, 288 in phase III and 13 in regulatory review).  

NIH-supported research helped create the first cancer drug targeted at a family of molecules called kinases. This breakthrough launched a new wave of drug development, with drug companies creating other drugs targeting similar molecules to treat not only cancer but also other diseases.

49 new cancer medicines were launched between 2010 and 2014. US is the country with the highest number of medicines available (see figure 13)

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5.4 Economic Impacts of cancer and biomedical research

- Between 1998 and 2000, life expectancy increased four years, and the average willingness to pay for these survival gains was USD 322,000. Improvements created USD1.9 trillion of additional social value, and health care providers and pharmaceutical companies appropriated 5-19% of this total.40

- Cancer death rates have been dropping by more than 1 percent annually (2005-2015). In 2006, it was estimated that a cure for cancer would be worth USD 47 trillion, and even a 1 percent reduction in cancer mortality would be worth about USD 500 billion.41

- New markets: US leads developed markets in the wide and early adoption of newer targeted treatments. New targeted oncologics medicines introduced globally (2010-2015) represent nearly one-third of the volumes used in the US compared to 23-26% in the top five European countries, and 21-22% in Japan. In the U.S., EU5 and Japan, over 90% of oral treatments currently used were introduced since 2000, representing a near complete replacement of the treatment arsenal over that time (see figure 14).

- In 2002 it was estimated that 500,000 jobs in the biopharmaceutical industry in USA were created “on the shoulders of public funding and academic performance”.42

41 Murphy K, Topel R (2006) "The value of health and longevity". University of Chicago and NBER.
A USD1 increase in public basic research stimulates additional USD 8.38 of industry R&D investment after 8 years. A USD 1 increase in public clinical research stimulates an additional USD 2.35 of industry R&D investment after 3 years. More specifically, it has been calculated that every USD 1 of NIH fund generates USD 2.21 in economic output.

Discoveries arising from NIH-funded research provide a foundation for the US biomedical industry, which contributed USD 69 billion to the GDP and 7 million jobs in 2011.

Successful oncology treatments have promised some of the highest returns for pharmaceutical manufacturers; in 2016, oncology assets represented 5 of the top 15 best selling drugs globally. The market is expected to continue to show strong growth, with a forecast CAGR of 10.9% to 2030 for oncology prescription sales, driven by factors such as an aging population and lifestyle changes predisposing to disease.

In Kansas, the total economic impact of NCI investments is estimated in USD 931 million (2007-2012) and USD 1,088 million (2013-2016).

The California Healthcare, Research and Prevention Tobacco Act, launched on November 2016 is expected to generate USD 664 million in total economic activity and a net increase of 8,645 jobs. A similar study launched in 2012 had calculated that

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California Cancer Research Act could generate 12,000 jobs and USD 1.9 billion in economic activity.

- In Texas, in 2016, the overall total current impact of Cancer Prevention and Research Institute (CPRIT) includes a gain of 79,075 jobs and US 8 billion in output.\(^{50}\)

- In general, US government investment in global health R&D from 2007-2015 generated an estimated 200,000 new jobs and USD 33 billion in economic growth.\(^{51}\)

5.5 Summary of the key indicators

Next table shows the main indicators related to War on Cancer:

<table>
<thead>
<tr>
<th>Key indicators</th>
<th>1971-2016</th>
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<tbody>
<tr>
<td>Timeline:</td>
<td>1971-2016</td>
</tr>
<tr>
<td>Objective and targets:</td>
<td>Eradicate cancer as a major cause of death by increased research to improve the understanding of cancer biology and the development of more effective cancer treatments such targeted drug therapies</td>
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<tr>
<td>Total budget:</td>
<td>USD 117.795 billion (1971-2016) (Public Budget for National Cancer Institute)</td>
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<tr>
<td>Annual budget:</td>
<td>1938-2002</td>
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<td>USD 52,940,982,220</td>
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<tr>
<td>Share of budget, public funding:</td>
<td>Governmental funding in U.S for Cancer accounts for 94% of the total spend</td>
</tr>
<tr>
<td>Share of budget, private investment:</td>
<td>-</td>
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<tr>
<td>Leverage effect (additional public/private investments the initiative has triggered):</td>
<td>A US 1 increase in public basic research stimulates additional USD 8.38 of industry R&amp;D investment after 8 years. A USD 1 increase in public clinical research stimulates an additional USD 2.35 of industry R&amp;D investment after 3 years. More specifically, it has been calculated that every USD 1 of NIH fund generates USD 2.21 in economic output.</td>
</tr>
<tr>
<td>Key indicators (official/public) applied for</td>
<td>Cancer death rates for men, women and children</td>
</tr>
<tr>
<td></td>
<td>Number of cancers by type.</td>
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<tr>
<td></td>
<td>Number of new anticancer therapies</td>
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</tbody>
</table>

\(^{50}\) Perryman Group (2016). “An economic assessment of the cost of cancer in Texas and the benefits of the Cancer prevention and Research Institute of Texas and its programs”.

\(^{51}\) GHT Coalition data. Available at: http://www.ghtcoalition.org/r-d-facts
monitoring the progress towards the targets:

- Number of drugs for cancer
- Anticancer therapeutics approved
- Medical costs of cancer care
- Number of new cancer cases diagnosed
- Estimated incidence and mortality for selected cancers
- Number of cancer screening tests
- Number of survivors
- Increase in life expectancy

Other key indicators (e.g. outputs/outcomes/impacts):

- Number of smoking-related deaths
- Number of people at higher risk for obesity
- Number of HPV-associated cancers diagnosed
- Cancer research publications.
- Percentage of people with cancer who participate in a clinical trial
- New jobs created
- Economic activity generated

6 Conclusions and lessons learned

6.1 Identification and assessment of key strengths and weaknesses of the initiative

<table>
<thead>
<tr>
<th>Strengths</th>
<th>Weaknesses</th>
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<tbody>
<tr>
<td>Initiative is linked to global challenges (good health and reduce inequalities) with an strong social and potential economic impact.</td>
<td>Lack of open access and rapid sharing of research data and results, allowing researchers to build on each other's success and failures.</td>
</tr>
<tr>
<td>Availability of a great amount of high-quality historical data and trends about cancer, mostly through the SEER (Surveillance, Epidemiology and End Results) Program of the National Cancer Institute.</td>
<td>Lack of involvement of civil society in the decision-making or evaluation process.</td>
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<tr>
<td>Culture of sharing medical information and scientific knowledge respecting privacy and transparency. The Cancer Research Data Ecosystem (NCI) collects and standardises cancer data allowing researches to examine complete datasets.</td>
<td>Incentive structures that do not encourage cross-discipline and cross-sector collaboration.</td>
</tr>
<tr>
<td>Cross-disciplinary. Despite being an initiative deeply rooted in the health sector (pharma, biotech, etc), the ICT technologies have also an important role, as well as other scientific disciplines such as psychology, economy or finances.</td>
<td>Insufficient collaboration and utilisation of technological capabilities to harness de vast amounts of data.</td>
</tr>
<tr>
<td>Strong focus on eliminating barriers and improving and universalising the access to novel treatments.</td>
<td>Slow dissemination of knowledge (new discoveries, new diagnosis and screening measures, new clinical trials, new treatments) equitably throughout the population.</td>
</tr>
<tr>
<td>Public-private collaboration has a very important role in the initiatives.</td>
<td>Patient privacy and different formats to process information and data present difficulties in terms of data availability and sharing.</td>
</tr>
</tbody>
</table>

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54 Ibid

55 Ibid.

56 Ibid.
• High degree of integration between scientific and technological supply.

• There is an intensive vertical coordination within the Department of Health and Human Services (among different directions and centers) but also horizontal coordination with other Departments such as Defense.

• NCI has traditionally made substantial investments in basic research because the institute recognizes that the basic research provides the foundation and the raw materials for applied research, including the translational and clinical research arising from the outstanding work of researchers.

• Patient engagement. Patients are at the centre of the treatment in order to understand their necessities and their reality and, at the same time, the patients can be educated and informed about the issues related to the disease.

• The cost of therapies is excessive compared to the benefit they deliver and combination therapies have repeatedly failed.58

• There is no easy direct, linear relationship between spending and outcomes in cancer care. The process of cancer care delivery is complex and depends on several other factors like the health-care system, adoption and diffusion of the innovations in a system, quality of the clinical guidelines, the (economic) behaviour of several stakeholders and characteristics of patients.59

• The increasing regulation has increased the unit cost of research without social benefits. Bureaucracy is absorbing too much of the global investment in cancer research.60 There is in an urgent need to reconsider the regulatory paradigms that have been built into a thriving industry around cancer research, and reverse this trend. The data from the USA should act as a warning to all global funders of cancer research.

6.2 Lessons learned and key messages for European R&I policy

• A big part of the recent successes is based in the knowledge generated during decades of fundamental basic research under the War on Cancer, which suggest the need for a broad basis of capabilities and knowledge to have successful outcomes.

• U.S War on Cancer Initiative relies on a sophisticated scientific and technological research system, with a high level of coordination between the actors. This allows to leverage most of the synergies and complementarities, and to accelerate the delivery of the results and benefits. Advanced culture of information and data sharing is one of the success factors of the initiative. The dynamic and thriving biotech industry in the U.S. has enabled bringing the research breakthroughs into the market.

• Government support is one of the main key success factors of this initiative. At the beginning, the government has acted as a leader and coordinator of the whole ecosystem, and has provided funding and key guidance to create capabilities. In the later stage, the government has reoriented the whole initiative, and has focused it towards concrete results.

• Regulatory framework is a very powerful tool that has had an important role in the initiative, both fostering the demand and by erasing the barriers for scientific and technological results to gain access to the market.


References:


IMS Institute for Healthcare Informatics: www.imshealth.com


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War on Cancer started in 1971 with the signing of the National Cancer Act by President Richard Nixon, and reflects the national effort to find a cure for cancer by increasing research to improve the understanding of cancer biology and the development of more effective cancer treatments. Since 2016, War on Cancer followed under the designation "Cancer Moonshot". To understand the differences between War on Cancer and Cancer Moonshot, Former Vice President Biden’s words are revealing: "President Nixon, when he declared War on Cancer in 1971, he was earnest and sincere and very committed. But what makes the difference between then and now is -- the single big difference is that he had no army. He had no resources. He had no weapons. He had no strategy to win. But after 45 years with many of you in this room doing incredible work, 45 years of progress, after decades of funding research, training scientists and physicians, treating millions of patients, we now have an army. We now have powerful new technologies and tools, like immunotherapy that -- by the way, even six, eight, ten years ago was viewed kind of as a voodoo science out there. It wasn’t really an integral part of this fight that makes cancer cells visible to the immune system so our natural defenses can destroy the cancer.”

Studies and reports