

# R & D Tax Aspects of Cancer Treatment

*By Charles R. Goulding, Andressa Bonafe and Charles G. Goulding*

Charles R. Goulding, Andressa Bonafe and Charles G. Goulding discuss efforts being made to develop a cure for cancer and how the R&D tax credit can be used to support cancer innovation activities.

According to the American Cancer Society, a total of 1,660,290 new cancer cases and 580,350 cancer deaths are projected to occur in the United States in 2013. Malignant neoplasms are currently a leading cause of death in the country, second only to cardiovascular diseases. Studies show that one in every four deaths in the United States is due to cancer.<sup>1</sup> Even though progress has been made in treatment and care, the number of cancer cases worldwide is expected to increase to 21 million in 2030, causing more than 13 million deaths.<sup>2</sup>

In the face of this major public health problem, many leading agents from the public and private arenas are engaged in research and development activities aimed at achieving an eventual cure. Federal R & D Tax Credits are available to support credit eligible cancer innovation activities.

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## The Research & Development Tax Credit

Enacted in 1981, the federal Research and Development (R & D) Tax Credit allows a credit of up to 13 percent of eligible spending for new and improved products and processes. Qualified research must meet the following four criteria:

- new or improved products, processes or software;
- technological in nature;
- elimination of uncertainty; and
- process of experimentation.

Eligible costs include employee wages, cost of supplies, cost of testing, contract research expenses and costs associated with developing a patent.

On January 2, 2013, President Obama signed the bill extending the R & D Tax Credit for 2012 and 2013 tax years.

## Federal Cancer Research Funding

In addition to providing tax credits for cancer innovation activities, the U.S. Federal Government

**Table 1.**

National Institutes of Health (NIH)	The NIH invests more than \$30 billion annually in medical research nationwide mainly through competitive grants.
National Cancer Institute (NCI)	The NCI is the nation's principal institution for cancer research. It currently funds more than 6,500 research grants at more than 150 locations throughout 49 states.
U. S. Food and Drug Administration (FDA)	The FDA supports the development of cutting-edge science to the prevention and treatment of cancer. The agency's funding decisions are under the House and Senate Appropriations Subcommittees on Agriculture.
Centers for Disease Control and Prevention (CDC)	The organization is at the forefront of cancer research focused on prevention and risk reduction. Through state-based programs, the CDC provides resources for monitoring and surveillance as well as awareness initiatives. In 2012, CDC's Cancer Programs totaled \$344 million.
Department of Defense (DoD) Congressionally Directed Medical Research Programs (CDMRP)	The peer-reviewed, biomedical research programs fund research related to lung, breast, prostate and ovarian cancers. In 2012, the programs totaled \$226 million.

currently supports several cancer research initiatives. Table 1 summarizes federal agencies and programs that provide cancer research funding.<sup>3</sup>

## Basic Facts About Cancer

Characterized by the malfunction of genes that control cell growth and division, cancer is a group of diseases marked by the uncontrolled multiplication of abnormal cells that result in the formation of malignant tumors. Medically known as malignant neoplasm, the disease can be caused by both external factors, such as chemicals, radiation, tobacco and infectious organisms, and internal conditions, namely, hormones, immune conditions and inherited or metabolic mutations. Risk factors also include obesity, unhealthy dietary habits, lack of physical activities, alcohol use, sexually transmitted HPV-infection, among others.<sup>4</sup>

Most commonly, cancer treatments include a combination of interventions, such as chemotherapy, radiation therapy and surgery. Biological therapy, targeted therapy, hormone therapy and palliative care are also available for cancer patients. The choice of treatment is determined by the stage of the disease, in other words, its extent or spread at the time of diagnosis (tumor size and eventual spread to other parts of the body).

According to the World Health Organization,<sup>5</sup> lung, stomach, liver, colon and breast cancers are responsible, in this order, for the most cancer deaths. The major cause of death from cancer is denominated metastasis, a process through which abnormal cells grow beyond their originating site, spreading to other parts of the body.

## Cancer R & D

Cancer research currently involves agents from different spheres. The American Association for Cancer Research is an interesting example of this diversity—with more than 34,000 members, the organization gathers medical centers, laboratories and clinics, government, universities and industry.<sup>6</sup>

Not only are the origins of innovation initiatives diverse, but so are their nature. In general terms, they can be divided in:

- 1. Investigation of causes:** such as critical cell types for cancer growth, oncogenomics and *in vitro* research.
- 2. Investigation of treatments:** such as vaccines, gene therapy, targeted therapy and photodynamic therapy.

For the first group, an interesting example is the recent discovery of more than 70 new susceptibility loci (alterations in genomic regions) for prostate, breast and ovarian cancers. The Collaborative Oncological Gene-Environment Study's (COGS) findings represent a major step in the characterization of the genetics of cancer and the understanding of inherited susceptibility. The mega-study analyzed more than 200,000 individuals and will allow for the development of more effective preventive initiatives, such as targeted screenings.<sup>7</sup>

Concerning the investigation of treatments, there is a significant number of experimental drugs currently undergoing clinical trials. FierceBiotech recently published a list of "Top 10 Late-Stage Cancer Drugs,"<sup>8</sup> gathering what are considered to be the most promising cancer research programs, based on safety and efficacy data. See Table 2.

**Table 2.**

Drug	Developer	Indication
BB1608	Dainippon Sumitomo and Boston Biomedical	Colorectal cancer
Cabozantinib	Exelixis	Thyroid cancer
Carfilzomib	Onyx Pharmaceuticals	Multiple myeloma
Enzalutamide (formerly MDV3100)	Medivation and Astellas Pharma	Prostate cancer
Ponatinib	Ariad Pharmaceuticals	Chronic myeloid leukemia
Regorafenib	Bayer HealthCare and Onyx Pharmaceuticals	Colon cancer
Talimogene laherparepvec (OncoVex)	Amgen (Acquired from BioVex in 2011)	Melanoma
T-DM1 (trastuzumab emtansine)	Roche/Genentech and ImmunoGen	Breast cancer
Tivozanib	Aveo Pharmaceuticals and Astellas Pharma	Renal cell carcinoma
Zaltrap (aflibercept concentrate)	Sanofi and Regeneron	Colorectal cancer

## Cancer-Related Innovation

In an era of ever-evolving technology, cancer R & D is not restricted to the development of drugs or genetic investigation, comprising a wide range of related innovation. The Wall Street Journal recently presented a promising initiative that aims at using “Big Data” to increase effectiveness of cancer care.<sup>9</sup> A major driver of innovation and job creation, “Big Data” is defined as large data sets that are too large and complex to be analyzed by conventional means.<sup>10</sup> The project, launched by the American Society of Clinical Oncology, will pool patient records in an electronic database allowing doctors to evaluate treatment strategies based on how similar patients nationwide have responded. Even though there are numerous challenges to be overcome, such as patient privacy and data limitations, the potential benefits are enormous since virtually all patients would become contributors to an unprecedented clinical study. This revolutionary access to information is likely to change the face of cancer care and, eventually, medicine.

The revolutionary use of Big Data in cancer diagnosis is also on the horizon. IBM’s Watson, a language-proficient computer system initially created to answer questions on the show *Jeopardy!*, has the ability to assimilate and analyze an enormous quantity of data. Its cumulated “knowledge” includes “more than 600,000 pieces of medical evidence, more than two million pages from medical journals and the further ability to search through up to 1.5 million patient records,”<sup>11</sup> an amount of information no human doctor’s mind can match. IBM, in partnership with the Memorial Sloan-Kettering Cancer Center in New York and the American private healthcare company WellPoint, is working to enable oncology hospitals, clinics and individual doctors to

rent time with Watson over the cloud. Watson’s wider deployment would significantly increase accuracy of diagnoses while simultaneously reducing costs. When tested for lung cancer diagnoses, Watson’s success rate was 90 percent, compared to an average of 50 percent for human doctors.

Similarly, Brain Mapping activities are bound to open the way for new advancements in cancer research. The personalized diagnostics for brain tumor patients and the consequent possibility of performing more precise surgeries figure among the potential benefits. Brain Mapping techniques will prevent damage to language, visual and motor functions when removing cancerous tissue. With a \$3 billion U.S. commitment announced in 2013 called BAM (Brain Activity Mapping) and an incredible amount of University research now occurring in this domain, one should expect major progress in brain tumor treatment.<sup>12</sup>

## Conclusion

The world anxiously waits for the end of the affliction of cancer. Genetic discoveries along with drug development and the use of new technology to improve care are examples of advancements due to recent R & D activities. Federal tax credits and funding are available to open the way to more innovation.

## ENDNOTES

- <sup>1</sup> R. Siegel, D. Naishadham and A. Jemal, *Cancer Statistics, 2013*, CA: A CANCER J. FOR CLINICIANS, 63 at 11–30 (2013). Available online at <http://onlinelibrary.wiley.com/doi/10.3322/caac.21166/full>.
- <sup>2</sup> Data from the World Cancer Research Fund International, available online at [www.wcrf.org/cancer\\_statistics/world\\_cancer\\_statistics.php](http://www.wcrf.org/cancer_statistics/world_cancer_statistics.php).
- <sup>3</sup> American Association for Cancer Research, available online at [www.aacr.org](http://www.aacr.org).

[aacr.org/home/public--media/science-policy--government-affairs/resources-for-policymakers/federal-cancer-research-funding.aspx](http://aacr.org/home/public--media/science-policy--government-affairs/resources-for-policymakers/federal-cancer-research-funding.aspx).

<sup>4</sup> American Cancer Society. *Cancer Facts & Figures 2012*, Atlanta: American Cancer Society, 2012, available online at [www.cancer.org/acsgroups/content/@epidemiologysurveillance/documents/document/acspc-031941.pdf](http://www.cancer.org/acsgroups/content/@epidemiologysurveillance/documents/document/acspc-031941.pdf).

<sup>5</sup> For detailed information see [www.who.int/](http://www.who.int/).

<sup>6</sup> For detailed information, see [www.aacr.org/](http://www.aacr.org/).

<sup>7</sup> For detailed information, see [www.nature.com/icogs/](http://www.nature.com/icogs/).

<sup>8</sup> *Top 10 Late-Stage Cancer Drugs—2012*, FIERCEBIOTECH MAGAZINE, available online at [www.fiercebiotech.com/special-reports/10-promising-late-stage-cancer-drugs-2012/10-promising-late-stage-cancer-drugs-2012](http://www.fiercebiotech.com/special-reports/10-promising-late-stage-cancer-drugs-2012/10-promising-late-stage-cancer-drugs-2012).

<sup>9</sup> "Big Data" for Cancer Care, WSJ, March 26, 2013, available online at <http://online.wsj.com/article/SB10001424127887323466204578384732911187000.html>.

<sup>10</sup> Charles R. Goulding, Charles G. Goulding and Jacob Goldman, *The R & D Tax Aspects of Big Data*, CORP. BUS. TAX'N MONTHLY, May 2013, at 2315.

<sup>11</sup> *IBM's Watson Is Better at Diagnosing Cancer Than Human Doctors*, Feb. 11, 2013. Available online at [www.wired.co.uk/news/archive/2013-02/11/ibm-watson-medical-doctor](http://www.wired.co.uk/news/archive/2013-02/11/ibm-watson-medical-doctor).

<sup>12</sup> Charles R. Goulding, Andrea Albanese and Charles G. Goulding, *The R & D Tax Aspects of Brain Mapping*, CORP. BUS. TAX'N MONTHLY, Dec. 2013.



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