

## R&D SPENDING

# What Has Changed With The R&D Tax Credit?

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***According to the Congressional Budget Office, the pharmaceutical industry devoted \$83 billion to R&D expenditures in 2019.***

Those expenditures covered a variety of activities, including discovering and testing new drugs, genome sequencing developing incremental innovations such as product extensions, and clinical testing for safety-monitoring or marketing purposes. The amount spent is about 10 times what the industry spent per year in the 1980s, after adjusting for the effects of inflation. Below is a small sample of potentially qualifying projects and activities driving the industry in 2022.

**Pharmaceuticals:** Over the past two years, annual spending on R&D throughout the industry has accelerated even further in response to the COVID-19 pandemic. Significant investments were made to fund drug development, clinical and human trials that resulted in innovations in the form of novel vaccines, and other therapies — all accomplished within record times.

In general, pharmaceutical companies are finding that it is critical to design with patient and regulatory constraints in mind. As such, it's important to integrate a variety of parameters from the start, such as formulation development, manufacturing process design, control strategy, and primary packaging. Anticipating issues and delivering solutions require leveraging pharmaceutical expertise and knowledge to plan and minimize risk in product development and to commercialize with speed and quality.

As drug design and scale-up have become increasingly complex, pharmaceutical companies are facing numerous challenges developing and manufacturing drug substances. More rapid innovation and production are needed to bring solutions to market faster. With the high cost of equipment — and the wide range of equipment needed for sterile liquid dosage, liquid and semi-solid dosage, and solid dosage forms — partnering with a CDMO or CMO facilitates a company's ability to bring new products or formulas to market without investing in additional infrastructure to support it.

**Biotechnology:** In the biotechnology sector, there is an increased focus and reliance on AI to enhance the early detection of a drug's efficacy in the drug discovery process. AI is being used to accelerate drug discovery and development through rapid design and iteration.

**Medical Devices:** Additionally, the development of medical devices and medical electronics has grown from simple devices to include lifesaving devices that can provide diagnostics, monitoring, and therapeutics to a physician without multiple trips to the physician's office or hospital. These devices have been miniaturized and inserted into the body to allow patients to continue with daily life uninterrupted.

Developing the next lifesaving drug or technique can be time-consuming and expensive. Fortunately, the federal government, as well as certain state and local governments, provide economic incentives to counter and help companies overcome such technical uncertainties and risks that they take on. The R&D tax credit, an often overlooked and misunderstood opportunity for taxpayers, can be used to offset the cost of drug discovery.

## **WHAT IS THE R&D TAX CREDIT?**

The federal R&D tax credit under Internal Revenue Code (IRC) section 41 was first introduced by Congress in 1981. The purpose of the credit is to incentivize U.S. companies to keep and increase spending on R&D within the U.S. The R&D tax credit is available to businesses that uncover new, improved, or technologically advanced products, processes, principles, methodologies, or materials. Correctly calculating the R&D tax credit is critical for maximizing the taxpayer benefit, which will ultimately lower the taxpayer's effective tax rate and potentially generate cash flow, and for achieving sustainability in case of IRS examination.

## **HOW DOES THE R&D TAX CREDIT WORK?**

The R&D tax credit is available to taxpayers who incur incremental expenses for qualified research activities (QRAs) conducted within the U.S. The credit primarily is composed of the following qualified research expenses (QREs):

- internal wages paid to employees for qualified services
- supplies used and consumed in the R&D process
- contract research expenses (when someone other than an employee of the taxpayer performs QRAs on behalf of the taxpayer, regardless of the success of the research)

- basic research payments made to qualified educational institutions and various scientific research organizations.

For an activity to qualify for the research credit, the taxpayer must show that it meets the following four tests:

- 1.** The activity must rely on the principles of hard science, such as engineering, computer science, biological science, or physical science.
- 2.** The activities must relate to the development of new or improved product or process intended to improve functionality, performance, reliability, or quality features.
- 3.** Technological uncertainty must exist at the outset of the development activities. Uncertainty exists if the information available at the outset of the project does not establish the capability or methodology for developing or improving the business component or the appropriate design of the business component.
- 4.** A process of experimentation (e.g., an iterative-testing process) must be conducted to eliminate the technological uncertainty. This includes assessing a design through modeling, proof-of-concept, computational analysis, or trial-and-error testing.

Examples of qualifying activities include:

- development of a new or improved drug compound
- development of new or improved medical devices, including hardware and software development and product engineering
- development of new testing methods and protocols
- development of new clinical applications for an existing drug compound
- development of new manufacturing processes or manufacturing scale-up
- implementation of new process technologies to improve production efficiencies and quality
- performance of toxicology and safety testing in animals and cell cultures
- performance of clinical testing activities

Once it is established that the activities qualify, a thorough analysis must be performed to determine that the taxpayer has assumed the financial risk associated with, and will have substantial rights to, the products or processes developed through the completed work. The next

step is to develop a methodology for identifying, quantifying, and documenting project costs that may be eligible for the R&D credit. Costs that qualify for the credit include wages of employees involved in developing new or improved products or processes, supplies used or consumed during the research process, and 65% of fees paid to outside contractors who provide qualifying R&D services on behalf of the taxpayer.

More recently, CROs are performing expanded drug development functions on behalf of life sciences companies. For life sciences companies that enter into agreements with CROs to assist with their R&D efforts, it is important to understand where the CROs are performing the research activities. It is also important to ensure that rights to the research and risks associated with failure are clearly outlined in the contracts to avoid issues regarding which entity can claim the R&D tax credit. In the current environment, life sciences companies are entering into complicated collaboration agreements for some of the later-stage development work, including clinical trials and manufacturing. Due to more complicated contracts, the determination of which company can claim the QREs and how to allocate them is not always clear.

The Protecting Americans from Tax Hikes (PATH) Act of 2015 made the R&D tax credit permanent and made the R&D tax credit more accessible to small and mid-sized businesses. The Tax Cuts and Jobs Act (TCJA) of 2017 lowered the corporate tax rate, while preserving and keeping permanent the R&D tax credit for qualifying U.S. businesses. Changes to the PATH legislation include:

- U.S. businesses and business owners with revenue less than \$50 million can use the R&D credit to offset their alternative minimum tax (AMT).
- Startup companies with gross receipts less than \$5 million may be able to use the R&D credit to reduce their payroll tax liabilities.

In conclusion, companies in this industry should closely evaluate this tax incentive. It is available to companies of all sizes in a wide variety of industries. Taxpayers will want to ensure they are taking full advantage of the R&D tax credit, optimizing the benefit at the federal and state levels, and properly and effectively documenting and substantiating projects and activities as required. The research credit is a highly effective tool in lowering effective tax rates and retaining more money in the company, thereby facilitating the refueling of the R&D innovation cycle.



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