Capturing Pharmaceutical R&D Tax Credits

To Fund New Drug Discovery And Development

LEADING THE WAY TO TAX SAVINGS

CTI

Corporate Tax Incentives

The U.S. pharmaceutical industry spends over $100 billion annually on research and development activities in the design, development and testing of new or improved pharmaceutical drugs.

One way pharmaceutical companies can recoup some of their R&D investments is by taking advantage of lucrative tax credits and incentives to offset tax liabilities, increase cash flow and lower their effective tax rates.

The federal R&D tax credit, under Internal Revenue Code ("IRC") §§41 and 174, was enacted to incentivize business sectors like the pharmaceutical industry to invest in the development of new or improved business components (e.g., drugs/medications). The tax credit provides opportunities to create new jobs in the U.S. and encourages companies to be competitive in the global marketplace.

In addition to federal R&D tax credits, most states have incentives for research and development activities, allowing companies to receive a double benefit for their research expenditures.

Unfortunately, many pharmaceutical companies are not taking full advantage of these business incentives by significantly understating their credits or not having the necessary documentation to adequately support their credit claims.

LEADING THE WAY TO TAX SAVINGS

CTI
Corporate Tax Incentives

866.444.4880 | www.ctillc.com

R&D Tax Credit Opportunities For Pharmaceutical Companies

The U.S. Food and Drug Administration (FDA) tightly regulates the pharmaceutical industry, and companies need to follow certain processes and procedures to be in compliance. And, the detailed process provides opportunities for your pharmaceutical company to adequately identify, document and support R&D credit claims.

The typical new drug development process includes the following four stages, which include many direct and indirect research expenses:

STAGE 1: Preclinical and discovery research, where new compounds are discovered.

STAGE 2: Clinical development, which is conducted in three phases:

- **Phase I** – First trials are conducted in humans that test a compound for safety, tolerance and pharmacokinetics. The trials typically employ normal, healthy volunteers.
- **Phase II** – Pilot studies are conducted to determine efficacy and safety in selected populations of patients with the disease or condition to be treated, diagnosed or prevented.
- **Phase III** – Expanded clinical trials are conducted to gather additional evidence of effectiveness for specific indications and to better understand safety and drug-related adverse effects.

STAGE 3: Regulatory review, where the New Drug Application (NDA) is submitted to a regulatory agency, such as the Food and Drug Administration, for marketing and manufacturing approval.

STAGE 4: Post-marketing activities that occur after the appropriate regulatory agency grants approval to market. These activities include Phase IV studies that are performed to determine the incidence of adverse reactions or long-term effects of a drug, studies of patient populations not previously studied, and studies for marketing comparisons against other products and other uses.

At each stage, research and development activities are taking place, and the IRS has acknowledged that these types of R&D activities qualify for the R&D tax credit.

Due to the favorable correlation, the IRS developed a separate audit techniques guide (ATG) specifically for the pharmaceutical industry to provide general guidance for agents and managers examining pharmaceutical R&D tax credit claims.

CTI
Corporate Tax Incentives

866.444.4880 | www.ctillc.com

Helpful Guidelines For Pharmaceutical R&D Tax Credits

As you identify audit areas that have the lowest and highest probability for sustainability, these guidelines provide helpful information on qualifying research expenses:

EMPLOYEE WAGES

IRC § 41(b) (2) defines the term "in-house research expenses" as any wages paid or incurred to an employee for qualified services (either direct research, supervision or support activities). Pharmaceutical personnel perform many research activities that may be considered qualified wages for the R&D tax credit.

- **High-Level Executives**

  Pharmaceutical companies frequently hire specialized personnel who are supervisors and high-level executives with direct supervision responsibilities over employees conducting direct research activities. High-level executives are often highly educated and skilled workers, many with advanced degrees, and are commonly involved in all major drug development activities.

  High-level executives, including the founders of the company, are also often the inventors or co-inventors of their company's new drug patents, and some of their activities should be qualified as eligible wage expenses.

- **Manufacturing Personnel**

  Manufacturing personnel represent another employee group within the pharmaceutical industry that performs qualifying research activities. While manufacturers may not be the core scientists and researchers at a pharmaceutical company, they do perform an important research and development function for the company.

  Manufacturing personnel's job responsibilities frequently include:

  - New equipment setup/breakdown and cleaning
  - Hands-on manufacturing operations and materials dispensing
  - Preparation of test documentation and laboratory batches
  - Scale-up experiments to facilitate technology transfers for manufacturing
  - Procure inventory of APIs and excipients for new manufacturing techniques
  - Interaction with analytical colleagues to ensure testing of materials as needed

CTI
Corporate Tax Incentives

866.444.4880 | www.ctillc.com

CONTRACT RESEARCH EXPENSES

Another qualifying pharmaceutical research expenditure is contract research expenses, defined as 65% of "any amount paid or incurred by the taxpayer to any person (other than an employee of the taxpayer)."

For example, a company may hire a third-party scientist to conduct a study or perform a test on the company's behalf, especially if the company doesn't have the expertise in-house. In this situation, you must consider several factors before claiming these expenses as eligible contract research expenditures:

- First, the activities need to be conducted on a qualified project that meets the IRC §41 eligibility requirements. Once those tests are satisfied, the actual contract or agreement must be reviewed and evaluated under the "rights" and "risks" tests – the taxpayer takes on the economic risk of the research and has some rights to the results.
- Under the R&D tax credit regulations, the qualified research will be treated as being performed on behalf of the taxpayer only if the taxpayer has a right to the result. Regulations require the taxpayer to bear the expense even if the research is not successful. That's why it's important to review all contracts for credit eligibility when hiring outside contractors or consultants who perform your research.
- In many cases, pharmaceutical companies don't have the means and expertise to conduct all of their own research and development activities. As a result, they hire large, third-party contractors known as Contract Research Organizations (CROs), which specialize in managing and conducting clinical studies for pharmaceutical companies. As a taxpayer, you must ensure the CROs are conducting research activities in the U.S., otherwise their activities and expenditures will not qualify for the credit.

Corporate Tax Incentives

866.444.4880 | www.ctillc.com

SUPPLY EXPENSES

Another potentially qualifying pharmaceutical R&D expense is supplies, meaning any tangible property other than land, land improvements or other property subject to depreciation that is used or consumed during research.

Supply expenses must be directly linked to qualified research activities, including prototypes and testing materials. Travel, shipping or royalty expenses cannot be included as supply expenses.

Pharmaceutical companies frequently use supply expenses that might include chemicals, compounds and experimental formulations. However, companies routinely fail to properly claim their supply expenses because they have not shown how these expenses were used during research (or conversely, they failed to recognize them as an eligible expense in the first place).

Drug development companies often use both active and inactive ingredients during their research and development of new or improved drugs.

Active ingredients are components in a drug that provide some pharmaceutical value, in contrast with the inactive ingredients, which act as carriers to make the drug easier for the body to process. Many new drugs combine several active ingredients, and the interaction between them may be critical to the development and function of the medication.

Inactive ingredients, also known as "excipients," perform a number of functions:

- The body cannot absorb some active components very well, so they must be combined with soluble excipients so that the body can process them
- Active ingredients are very strong, and combining them with an excipient allows greater control over the dosage
- Without an excipient, a powerful pill might be the size of a pinhead, but with one, it can be formulated into a larger and more manageable size

It's important that pharmaceutical companies review all of their R&D ingredients, formulations and compounds to make sure they are eligible supply expenses.

ORPHAN DRUG CREDIT

Another R&D tax incentive for some pharmaceutical companies is the Orphan Drug Credit (ODC). IRC §45C(a) provides that companies may claim a credit against income taxes equal to 50% of qualified clinical testing expenses (QCTE). QTCE are eligible for this credit if they are spent in human clinical testing of drugs for treating rare diseases that afflict 200,000 people or less.

CTI
Corporate Tax Incentives

866.444.4880 | www.ctillc.com

For pharmaceutical companies to take advantage of the ODC, certain conditions and rules must be met:

- Companies need to apply for and receive orphan drug designation approval
- Once the drug receives the requisite designation, only certain expenses related to human clinical testing, up until FDA approval of the drug, will qualify
- The qualified expenditures for clinical testing generally follow the same rules for expenses that are eligible for the R&D tax credit, with the exception that contract research expenses are 100% eligible (instead of 65%)

A couple of caveats exist when claiming ODCs. First, the expenditures are only eligible from the day the drug gets its orphan drug designation to the day it receives FDA approval.

Also, only expenses related to human clinical testing are eligible. Other studies, such as animal testing, are ineligible for this credit.

Finally, you cannot claim both an ODC and the R&D tax credit for the same research expenses, so companies are required to separate the qualified expenditures between the two credit claims.

R&D Tax Credit Substantiation Requirements

Taxpayers must retain records in sufficient usable form and detail to substantiate that the expenditures claimed are eligible for the credit (IRC § 6001). That's why documentation is so critical when qualifying and quantifying your R&D activities and expenses.

Taxpayers are often unsure of the type of documentation necessary to sustain their credits and therefore come under scrutiny during an audit.

For example, a taxpayer may have filed a high-level R&D credit amount on their income tax return, and several years later faces an IRS or state taxing authority audit. Because the credit claim was computed at a high level, the company does not have the necessary books and records now to fully substantiate the credit claim.

CTI
Corporate Tax Incentives

866.444.4880 | www.ctillc.com

The following is a list of the more important documentation outlined in the IRS's audit technique guidelines for the pharmaceutical industry:

- **Tax Work Papers:** Tax work papers and other documentation used to calculate the credit include tax returns, cost schedules, project accounting data, general ledger account schedules, invoices and contracts or developer agreements.
- **Qualified Wages:** Reconciliation schedule listing of all employees' wages included in the credit claim should include each employee's full name, Social Security number, job title, grade level and the cost center/department/project to which the employee was assigned.
- **Qualified Supplies:** Reconciliation summary schedule of the supplies included in the credit claim should identify the cost center/department/projects to which the supplies were allocable.
- **Qualified Contract Research:** Reconciliation summary schedule of the qualified contract research expenses included in the credit claim should identify the contractors, the payments to each contractor, the type of research performed and the objective of the research.
- **Contemporaneous Documentation:** Pharmaceutical companies should review and organize contemporaneous documentation for each of the drug development programs for which qualified research expenditures were identified. Such documents could include executive summaries, laboratory notebooks, test results, FDA approval documents, patents and patent applications.

- **Organizational Chart:** Gather the company's organizational chart for the qualified R&D and support departments to get a better understanding of the reporting hierarchy and the research levels within each department.
- **Job Titles, Grade Levels And Position Descriptions:** Provide a summary of the company's job titles, position descriptions and grade levels within the qualified departments. This information is helpful in determining who is actually doing research or who is supervising or supporting the research activities.

LEADING THE WAY TO TAX SAVINGS

CTI
Corporate Tax Incentives

866.444.4880 | www.ctillc.com

Many activities and related expenditures in the pharmaceutical industry are eligible for significant research- and development-related tax credits and incentives. The more knowledgeable a company is about capturing the appropriate activities, the more credit benefits they will receive.

When in doubt, companies should consult with R&D tax credit and Orphan Drug Credit experts who can help them navigate through the complex nature of identifying and documenting these available credits and business incentives.

Ready to learn more about capturing R&D tax credits for your pharmaceutical company?

Call 866-444-4880 or **click here** to speak directly with an experienced Tax Navigator at Corporate Tax Incentives.

About Corporate Tax Incentives

Corporate Tax Incentives leads the way to tax savings for companies of all sizes on tax solutions ranging from employment tax incentives to R&D tax credits and cost segregation services. Working alongside CPAs and in-house accountants, CTI shows businesses the path to profit with customized tax-savings strategies that don't drag down daily operations. For more information, visit **ctillc.com**.

LEADING THE WAY TO TAX SAVINGS

CTI
Corporate Tax Incentives

866.444.4880 | www.ctillc.com