R&D tax credits for the pharmaceutical industry

Accounting methods and credit services

Since their inception, companies have been able to reduce the cost of their research and development (R&D) operations through the R&D and/or orphan drug tax credits (ODC). The R&D and ODC are tax incentives for performing qualified research in the U.S. to develop new or improved business components. As companies in the pharmaceutical industry experience industry consolidation, increased clinical and manufacturing trials, and expansion of their R&D function, the credits have become an important planning opportunity for many companies and their executives.

Due to the perceived complexities in calculating the R&D and ODC, and the documentation standards in place to uphold the credits, many companies have additional opportunities to claim credits on costs that they may have overlooked in the past.

That is where KPMG's research credit service team can help.

KPMG LLP's (KPMG) Research Credit Services practice can help companies take advantage of federal, state, and even global R&D tax deductions and credits. Our national team of tax professionals has extensive experience in the pharmaceutical industry. In addition, our professionals can utilize our proprietary KPMG R&D Exchange software to help identify and quantify eligible activities, and to collect and organize financial data and documentation. Our combination of experience and technology provides a thorough and effective means of defining and documenting the R&D credit claims process.

Enhance your R&D credits claims by considering all potentially qualifying activities.

There is a wide variety of activities that pharmaceutical companies may consider when identifying qualifying activities, some of which may even be performed outside of the traditional R&D departments. Many pharmaceutical companies have invested in a wide variety of new products to fill their pipeline, with qualifying activities and associated costs incurred within each step of the new product development process that may be eligible for the R&D and/or ODC.

Qualifying activities that may not be obvious and outside of the early-stage clinical trials process may include:

- Design, construction, testing, and administering trials of new prototypes and pilot plants
- Development of new production processes, or new technologies to support existing process improvements intended to increase productivity or reduce costs
- Milestone payments related to R&D collaboration agreements
- New product manufacturing trials and packaging trials performed at manufacturing facilities
- Manufacturing process scale-up activities
- Developing technology for compliance with various regulatory agencies
- Hardware and software system development for use in R&D or other internal functions
- Developing improvements to existing products to increase performance (e.g., increased shelf life, reduced side effects)
- Core R&D direct support activities, including quality, data collection, regulatory, and facilities.

Orphan drug credit: In addition to R&D tax credit incentives, companies may also qualify for the ODC. The ODC is similar to the general R&D credit rules, except the credit is an amount equal to 25 percent of the qualified clinical testing expenses (CTEs) for the taxable year. Also, similar to the R&D credit, a section 280C election is available to claim a reduced ODC in lieu of foregoing deductions in the amount of the credit. CTEs include any human clinical testing that is carried out under an exemption for a drug being tested for a rare disease or condition. A rare disease or condition is one that affects less than 200,000 persons in the U.S., or affects more than 200,000 persons in the U.S. but for which there is no reasonable expectation that the cost of developing and making available in the U.S. a drug for such disease or condition will be recovered from sales in the U.S. Amounts only qualify after a taxpayer has received an orphan drug designation for a particular drug. Note: For CTEs paid or incurred in taxable years beginning before January 1, 2018, the ODC rate is 50 percent of CTEs but no section 280C election is available. For each taxable year, a taxpayer must elect to claim either the R&D credit or ODC for CTEs, they cannot claim both credits.

KPMG's methodology

KPMG has a wide-ranging methodology that leverages our combination of experience and technology to help you realize a greater return on your R&D investments. First, we can help you identify and substantiate your organization's qualified research costs. KPMG's specialists can help you analyze systems, data, reports, and processes to locate and extract the transactional data related to the computation of R&D and/or ODC.

Next, we can help you capture qualified expenditures for the available federal, state, and global incentives. This process includes identifying qualified research activities and related expenditures. It also includes assisting the client with implementing enhanced information-gathering processes and documentation procedures to better support R&D credit claims in future years.

Finally, we customize each review to meet your specific needs and industry parameters. This includes following a risk-based, industry-specific approach to help streamline and focus the information-gathering project on the key items to be documented that follows the IRS Audit Technique Guidelines.

Enhance your R&D and ODC today

A wide-ranging methodology, leading technology, plus a team of tax professionals who understand the intricacies of R&D and orphan drug incentives across numerous jurisdictions (federal, state, and global). Those are just some of the reasons many organizations like yours are turning to KPMG's Research Credit Services team.

Why not join them by contacting KPMG?

Contact us

Edward Jankun
Co-leader
Research Credit Services
T: 704-371-8090
E: ejankun@kpmg.com

Michael Brossmer
Co-leader
Research Credit Services
T: 408-367-4127
E: mbrossmer@kpmg.com

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