Tax Opportunities for Life Science & Pharmaceutical Companies: Tax Savings through Research & Development and Orphan Drug Tax Credits

08.26.16

Background

The Research and Development Tax Credit ("R&D Tax Credit") was introduced in 1981 as a temporary credit to incentivize domestic research and job growth. As of December 18, 2015 the Protecting Americans from Tax Hikes Act of 2015 ("PATH") made the R&D Tax Credit permanent. The tax savings opportunities for life science and pharmaceutical companies continued when Congress enacted the Orphan Drug Act of 1983 to stimulate the development of drugs for rare diseases with small patient populations or "orphan diseases." This permanent act provides financial incentives and meaningful tax savings to encourage the life science industry—in particular pharmaceutical companies—to develop treatments for these small patient populations.

Qualified taxpayers are able to claim both the R&D Tax Credit under IRC § 41 and Orphan Drug Credit ("ODC") under IRC § 45C in the same tax year. The ODC closely follows the rules and regulations set forth in IRC § 41 for R&D. Life Science companies that have qualifying activities for the R&D Tax Credit may also qualify for the Orphan Drug Credit.

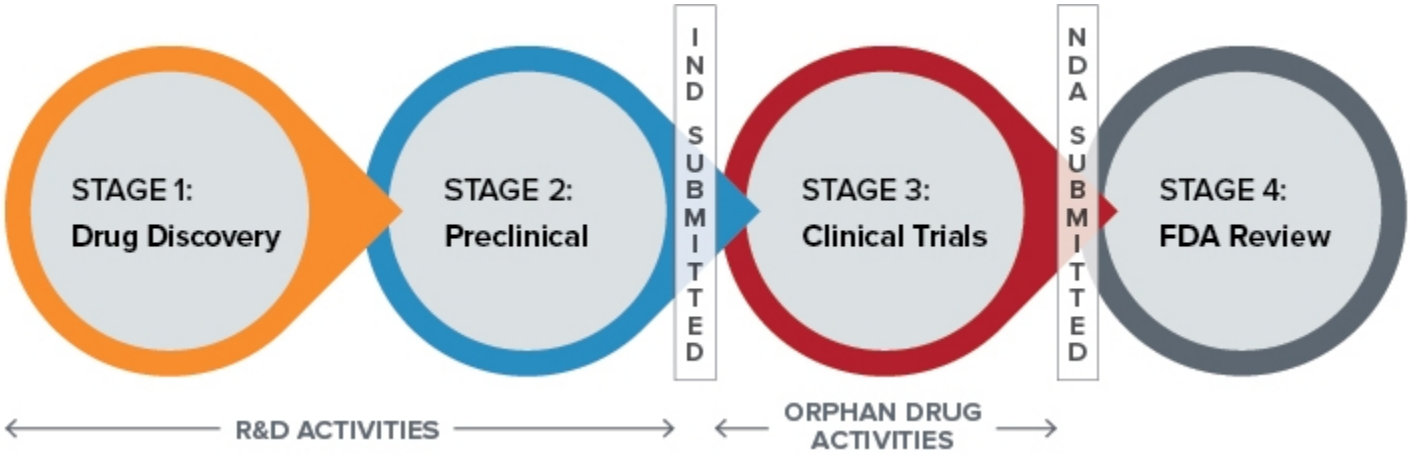
To claim an Orphan Drug Credit, a taxpayer must receive an orphan drug designation through the FDA also known as submitting the Investigational New Drug Application ("IND"). The Credit may then be claimed for qualified expenses after a taxpayer receives the orphan drug designation and prior to the FDA approval of the drug for any indication, which occurs when the New Drug Application ("NDA") is submitted.

Credit Mechanics & Benefit

Taxpayers may claim an ODC equal to 50% of qualified clinical testing expenses for the taxable year after an orphan drug designation, and prior to, the date drug is approved or receives licensing. See below for a summary of similarities and differences between the R&D Tax Credit and ODC. The ODC provides a much more significant benefit than the R&D Tax Credit, as it is not limited by the base amount and takes 100% of qualified vendor costs (as opposed to 65% allowance for outside vendor costs for R&D Tax Credit purposes). Additionally, special provisions for Orphan Drug allows for eligible testing costs outside the United States to be included in the analysis. Any clinical testing expenses claimed for ODC purposes are not eligible for the R&D Tax Credit.

Opportunity

There is a benefit to evaluate costs prior to FDA approval, which allows companies to take advantage of the significant and lucrative tax savings of the ODC in lieu of the R&D Tax Credit.



	Research and Development Credit IRC § 41	Orphan Drug Credit IRC § 45C
Credit Benefit	Credit benefit is equal to 20% of the excess (if any) of qualified research expenses for the taxable year over the base amount, the credit is used to offset regular tax. However, if the company is an eligible or qualified small business, the R&D Tax Credit may offset AMT and/or Payroll Taxes.	Credit benefit is equal to 50% of qualified clinical testing expenses. The credit is used to offset regular tax.
Credit Eligibility (see above)	Companies that can potentially qualify are in a wide range of industries such as: Financial Services, Architecture & Engineering, High Tech, Life Sciences, and Consumer Products. Any qualified activities prior to orphan designation would be deemed R&D. For a pharmaceutical company, this would typically be in Stage 1 and Stage 2 of drug development (see above).	Qualification begins (see above): •AFTER orphan designation •PRIOR to approval date of the application for the drug, anything outside of this would be potentially qualified under § 41.
Qualified Activity	Qualified research – research undertaken to discover information that is technological in nature and intended to be useful in development of new or improved business component and substantially all of the activities constitute elements of a process of experimentation. Business component means any "product, process, computer software, technique, formula or invention."	Substitutes "clinical testing" for qualified research as it appears in § 41. Clinical testing typically occurs in stage 3 of pharmaceutical research. This period is known as Clinical Trials (see image above).
Qualified Expenses	Eligible expenses related to development of business components; expenses for wages, supplies, and contractors are includible.	Eligible expenses that relate to "human clinical testing"; though not explicitly defined in the regulations, this is generally understood as the clinical trial phase.
Wages	Claim wages related to the R&D expenses for employees performing qualified activities related to direct research, direct supervision or direct support.	Similar to § 41
Supplies	Any tangible property other than land, land improvements or other property subject to depreciation that is used or consumed during research.	Similar to § 41
Contractor Costs	65% of payments to contractors for eligible expenses are qualified. Any contractor work performed outside the U.S. is not eligible.	100% of payments to contractors for eligible expenses are qualified. Exception for *foreign* testing costs to potentially be included.

Contact us today to ensure you are taking full advantage of these tax benefits.

This article was authored by Vanessa Dang and Amanda Groendal of BPM.

BPM for Life Science

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partnering with our clients is to provide financial clarity and guidance to help with their strategic planning, preparing for capital raises/liquidity events and regulatory compliance. For more information or to learn how we can provide innovative solutions to your needs, contact Scott Taylor at STaylor@bpmcpa.com or (650) 855-6882 or Julie West at JWest@bpmcpa.com or (650) 855-6881 or visit us at www.bpmcpa.com/lifescience.