

# WNTS Insight

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*IRS releases taxpayer-favorable  
guidance on examination of research  
expenditures in pharmaceutical sector*

## *In brief*

In a long-awaited, taxpayer-favorable development, IRS Large Business and International (LB&I) Commissioner Heather Maloy on December 7 issued a [memorandum](#) to all LB&I employees regarding examination of section 41 research credit claims in the pharmaceutical sector.

The memo directs LB&I employees not to challenge the amount of qualified research expenditures (QREs) claimed by taxpayers in the pharmaceutical sector that arise during Stage 1 (discovery and preclinical stage) or Stage 2 (clinical trial stage) of the four-stage pharmaceutical development process, as long as the taxpayer provides a Certification Statement -- described in the memo -- regarding those QREs. The research undertaken in Stage 1 and Stage 2 often is referred to as "core R&D."

While the memorandum applies only to examinations of taxpayers in the pharmaceutical sector, the IRS is expected to use it as a model for examinations of core R&D in other industry sectors.

## *The LB&I memorandum*

The memorandum directs LB&I examiners not to challenge the amount of QREs claimed by a taxpayer to the extent the QREs are for qualified research activities and not excluded under section 41(d)(4) that occur during Stage 1 or Stage 2 of the "Pharmaceutical Drug and Therapeutics Biologics Development Process and clinical trials required by the FDA relating to Accelerated Approvals" of such products.



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The taxpayer must provide, within the times specified in the memo, a Certification Statement providing:

- That the taxpayer's QREs were computed in accordance with section 41(b);
- That the taxpayer excluded the activities listed in section 41(d)(4); and
- The amount of the taxpayer's Stage 1 and Stage 2 QREs.

## Observations

This is an extremely positive development that has been anticipated for months. This so-called "ring fence" approach to core R&D was discussed at PwC's Global R&D Symposium in May and also during the recent PwC webcast on key developments in the research credit space. (The webcast may be viewed [here](#).)

The memorandum does not address QREs arising during Stage 3 (regulatory review stage) or Stage 4 (post-approval stage) of the pharmaceutical development process. Taxpayers now can focus on the documentation of QREs arising in these stages.

### *Let's talk*

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