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R&D tax update

Update to Canada Revenue Agency's policies regarding clinical work

December 11, 2014 (14-5)

On November 13, 2014, Canada Revenue Agency (CRA) held one of what is anticipated to be a series of webinars about the Scientific Research and Experimental Development (SR&ED) program. This first webinar addressed the topic of clinical work, providing clarification of CRA's interpretive policy for the biopharmaceutical industry.

After the cancellation of the sector-specific application policies in December 2012 as part of CRA's policy consolidation project, the biopharmaceutical industry experienced differing interpretations of policy regarding the eligibility of work related to clinical trials, especially for work associated with multinational clinical trials. The consolidated policies introduced a five question methodology for determining the eligibility of work as SR&ED in lieu of the more familiar three criteria model that had previously been used. While this change was intended to yield the same results, the application of the new methodology has, in practice, resulted in different outcomes than previously experienced by the biopharmaceutical industry in some cases. Specifically, some projects and activities associated with multinational clinical trials were no longer accepted as eligible SR&ED by some CRA reviewers.

For the most part, the explanations presented in the webinar appear to be consistent with the previous policies, and should clarify and confirm the eligibility of SR&ED activities related to clinical trials.

Eligibility of Clinical Trials

CRA explained that, for a clinical trial conducted in Canada to be eligible, claimants must demonstrate that, in planning and undertaking this trial, they defined a scientific or technological problem to be resolved, designed a hypothesis to resolve that problem, planned and undertook tests or trials to validate the hypotheses, and finally developed logical conclusions based on the results. Specifically, to be eligible as SR&ED, the clinical trials would need to answer positively to five questions:

1. Was there a scientific or a technological uncertainty?
2. Did the effort involve formulating hypotheses specifically aimed at reducing or eliminating that uncertainty?
3. Was the adopted procedure consistent with the total discipline of the scientific method, including formulating, testing, and modifying the hypotheses?
4. Did the process result in a scientific or a technological advancement?
5. Was a record of the hypotheses tested and the results kept as the work progressed?

Normally, Canadian clinical trials that received authorization from Health Canada and Institutional Review Boards would be eligible as SR&ED based on this five question methodology as such authorization requires the scientific relationships under investigation to be specifically identified along with the hypotheses under investigation and the methodology to scientifically validate these hypotheses.

For multinational clinical trials, there are some additional considerations arising from the fact that the work is carried out in multiple jurisdictions. In these cases the purpose and methodology of the trial is first evaluated holistically to confirm the purpose of the trial to advance scientific knowledge and the presence of the scientific method. It is then necessary to demonstrate that the work undertaken in Canada embodies the systematic investigation or search, and that Canadian researchers contribute to the definition of the systematic approach and to the scientific knowledge accruing from the trial. Practically, this requires that the activities claimed contribute to addressing the scientific questions or uncertainties addressed by the research and would include work conducted in Canada by the claimant (or on their behalf) such as:

- defining a problem;
- advancing an hypothesis towards resolving that problem;
- planning and testing the hypotheses by experiment or analysis; and
- developing logical conclusions based on the results.

As in the previous application policies, it is the scientific input of Canadian researchers that determines the eligibility of activities. This input would include contribution to the development of the protocol and/or the critical evaluation of the proposed work. We note that such inputs are one of the main requirements of a Clinical Trial Application (CTA) or an Institutional Review Board / Ethical Review Board (IRB/ERB) application in Canada, and as such it should not be unusual that these requirements could be met.

As before, claimants must retain contemporaneous evidence such as emails, letters, faxes or meeting minutes documenting eligible activities performed by Canadian researchers to assist in demonstrating the systematic investigation. Typical examples of such evidence could include the critical analysis of draft protocols or protocol synopses, CTAs in Canada, pre-CTA notes, applications to Ethic Boards, participation to Data and Safety Monitoring Boards, site closure reports or scientific publication manuscripts.

Finally, once the first step of a CRA review has demonstrated that eligible SR&ED activities have been performed in Canada, the claimant must demonstrate that any support activities claimed are commensurate with the eligible activities.

In summary, the principles elucidated in the webinar appear to reaffirm the previously established policies in the domain, and should help to provide clarity to the biopharmaceutical industry.

Can we assist?

Deloitte's Global R&D/Government Incentives professionals are experienced in the implementation of the new or revised methodologies for assessing eligibility for SR&ED incentives. We would be happy to discuss how our expertise and tools can be used to your advantage.

Albert De Luca, National Leader, Global R&D/Government Incentives