



The IQ Consortium is a not-for-profit organization of pharmaceutical and biotechnology companies with the mission of advancing science and technology to augment the capability of member companies to develop transformational solutions that benefit patients, regulators and the broader R&D community.

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CRO Outreach Working Group

The mission of the CRO Outreach Working Group is to collaboratively partner across industry to foster the highest standards of scientific excellence and animal welfare with a focus on continued advancement in application of the 3Rs.

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Development of An IQ Assessment Tool to Streamline Review of Contracted Animal Research Programs

THE CHALLENGE

Within the last 20 years, pharmaceutical and biopharmaceutical companies have increasingly outsourced animal studies to contract research organizations. With this shift, companies found that some programs, especially in developing countries, were not upholding the high standards for animal care and use expected by the biopharma industry. To address this, individual companies began creating programs and processes to standardize animal studies. This resulted in an increasingly burdensome workload for contract research programs that must complete a large number of different animal program assessment questionnaires to meet the expectations of individual companies.

OBJECTIVES & APPROACH

The objective of this project was to find a way to help ensure that CROs meet high animal care standards while reducing the burden associated with completing many different company questionnaires. To do this, the CRO Outreach Working Group invited representatives from large, global CROs to work with expert animal program reviewers from IQ member companies to develop a comprehensive animal program assessment tool. Recognizing that each set of stakeholders would contribute unique perspectives about laboratory animal care and use risks, this tool was developed collaboratively and included:

- a questionnaire that reflected CRO experience and pharmaceutical industry expectations,
- a protected template with user-friendly check boxes to facilitate collection of responses, and
- a list of questions and documents that might be reviewed during an onsite assessment.

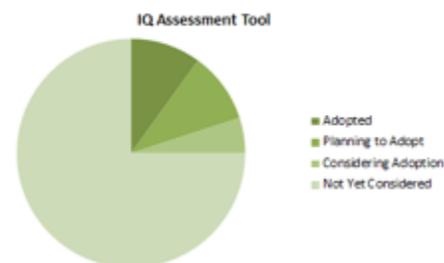
Finally, three IQ member companies agreed to pilot the assessment tool in their internal due diligence reviews of contract animal programs.

RESULTS

The three companies that piloted the assessment tool each provided a favorable report, observing that the tool was useful both because it simplifies the process for CROs and because it can readily be adapted by companies that need additional information from CROs. Although some concern was raised about the length of the questionnaire, the tool has been made user-friendly by offering simple yes/no options for many questions; the questionnaire also allows contract animal programs to provide a copy of their AAALAC program description instead of completing the questionnaire.

To increase the value of this tool for future users and provide more context for how the pharmaceutical and biopharmaceutical industries approach work with CROs, the Working Group has developed a handout on the pharmaceutical industry's use of "A Risk-Based Approach to Assessments of Contracted Programs for Animal Studies." They have also created a shortened questionnaire for animal programs that are considered "low risk." These resources are now available for on the 3Rs CRO Outreach Working Group webpage on the IQ website, for voluntary use by interested companies.

Adoption of an IQ Assessment Tool for Contract Animal Programs



IMPACT

Through creation of this tool, biopharmaceutical companies and the CRO industry build consensus on essential elements of risk-based assessments of contracted animal research programs, as well as ways to better coordinate and streamline these assessments. Pharmaceutical and biopharmaceutical companies will benefit from the tool because it offers a comprehensive, vetted assessment process that reduces the need to invest internal resources in developing other processes. Use of the tool will also benefit CRO and academic animal programs by reducing the number of complicated questionnaires that they need to complete as the industry seeks to insure that high standards for animal care and use are upheld.