NCI, NCRI and EORTC outline risk-assessment approach for biomarker-driven cancer clinical trials

April 29 2014, by John Bean, Phd

In an article published in *The Lancet Oncology*, an NCI (US National Cancer Institute), NCRI (UK National Cancer Research Institute), and EORTC (European Organisation for Research and Treatment of Cancer) working group outline a practical risk-management approach for effective integration of biomarkers into cancer clinical trials. Their work provides the international community with a set of common principles by which biomarkers can be integrated into clinical trials, exchange of data can be facilitated, quality promoted, and research accelerated while simultaneously respecting local approaches and legislation.

Their risk-assessment approach for designing and conducting cancer

clinical trials include risks to patient safety, operational risks, and biomarker development risks, and for each risk they evaluate possible consequences, provide solutions along with examples of these as well as references to helpful resources. Concerning protocol design, the working group recommends items that a protocol should include as well as items that should be assessed during protocol development. For the conduct of the trial, they make recommendations for the close monitoring of variability in test results, and they also make recommendations for particular aspects following completion of the trial.

Dr. Jacqueline Hall, who coordinated this NCI, NCRI, and EORTC working group says, "We readily acknowledge that in today's clinical trial landscape, many stakeholders play a role in clinical trials. These include regulators, public authorities, and patients, amongst others. By opening this discussion to others, we hope to find solutions to the varied challenges facing molecularly driven clinical research."

Provided by European Organisation for Research and Treatment of Cancer

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