ASCO and NCI Collaboration Finds Widespread Benefits of Centralizing Coverage Analyses for Multi-Site Clinical Trials

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Alexandria, VA – The American Society of Clinical Oncology (ASCO) has released findings from an ASCO-National Cancer Institute (NCI) collaboration that explored centralizing the development of coverage analyses for multi-site cancer clinical trials. In an ASCO special article published today in the Journal of Oncology Practice, “Feasibility of a Centralized Clinical Trials Coverage Analysis: A Joint Initiative of the American Society of Clinical Oncology and the National Cancer Institute,” the authors assert that developing a centralized system for coverage analysis is a feasible way to address key issues and reduce administrative burdens for cancer research sites managing billing compliance, with potential for widespread benefits across the cancer research field.

“Establishing a centralized system that provides coverage analysis to research sites participating in a multi-site cancer clinical trial before trial launch would reduce system-wide redundancies and costs, as well as time and resource burdens on sites,” said Dax Kurbegov, MD, Chair-Elect of the ASCO Research Community Forum Council and contributing author for the manuscript. “By improving efficiencies and billing compliance consistency and accuracy, centralizing coverage analysis development has the potential to increase patient accrual and site participation for multi-site cancer clinical trials.”

A coverage analysis outlines insurance coverage and billing for the full scope of procedures and care provided to patients participating in a clinical trial and helps sites ensure billing practices are compliant with regulations, verify consistency of trial documents, and assess costs for patients participating in the trial.

While important for reducing financial risk to sites and patients, the authors point out that conducting a site-specific coverage analysis can be a challenge for research sites, particularly
when participating in multiple trials and with multiple sponsors. Complexities in billing compliance and confusion regarding insurance coverage of routine care provided as part of a clinical trial makes it difficult for sites to conduct a coverage analysis. Moreover, coverage analysis development requires staff with knowledge and expertise in billing coding and compliance; it can be burdensome, costly, and resource-intensive for sites, particularly given the number of other tasks required before launching a trial.

An ASCO Research Community Forum Working Group identified centralizing coverage analysis development for multi-site trials as an effective mechanism to address these concerns voiced by cancer research sites. The Working Group then initiated a collaboration with NCI to host a symposium that provided the tools, information, and skills needed to move forward with developing such a system. Nearly 50 staff from NCI research sites and cooperative groups, including the NCI National Clinical Trials Network (NCTN) and NCI Community Oncology Research Program (NCORP) Research Bases attended the symposium.

As the authors discuss, this initiative has resulted in concrete steps that have since been taken by NCI to establish a centralized coverage analysis system, including the launch of a pilot currently underway for some NCTN and NCORP trials. As part of the pilot, NCI is developing standardized national coverage analyses for multisite trials that serve as guidance for billing compliance. Trial sites are able to take these templates and make adjustments as needed based on coverage and reimbursement specifics of local insurers. The authors note that results on the effectiveness of the pilot are still forthcoming, but initial participant feedback has been positive. The standardized coverage analyses will be made available online via the Cancer Trials Support Unit.

According to the authors, additional efforts are needed to demonstrate the value of centralizing coverage analysis to expand the creation of these types of systems to other multisite trials, including industry-sponsored trials.

Read the full article in the Journal of Oncology Practice.

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