

CEO Roundtable on Cancer and Project Data Sphere Announce New ICD-10-CM Codes for Immune-Related Adverse Events

Significant Milestone in Immuno-Oncology Achieved Through the Global Oncology Big Data Alliance

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Roundtable on Cancer and its independent, not-for-profit initiative, Project Data Sphere® LLC, are proud to announce the approval of new ICD-10-CM diagnosis codes for immune-related adverse events (irAEs) in the United States. These codes, set to be implemented nationwide on Oct. 1,

2024, are the result of dedicated research efforts conducted under the Global Oncology Big Data Alliance (GOBDA), a groundbreaking collaboration between Merck KGaA and Project Data Sphere.

Established in 2017, GOBDA aims to expand the open-access of de-identified patient data sets and enhance analytical capabilities in oncology research. By leveraging Project Data Sphere's innovative digital platform, which contains historical clinical trial data from over 250,000 patients, GOBDA has been advancing collaborative research in key areas related to cancer research.

Immunotherapies have revolutionized cancer treatment by harnessing the immune system to fight cancer cells. However, these therapies can also lead to irAEs, which occur when the activated immune system inadvertently attacks healthy tissues and organs. The lack of specific diagnosis codes for irAEs has hindered appropriate reimbursement and the accurate documentation and tracking of these adverse events, limiting the understanding of the safety profile of immunotherapies and the development of optimal management strategies.

The CEO Roundtable on Cancer and Project Data Sphere have played a pivotal role in addressing these challenges. Through their collaborative research efforts with Merck KGaA and other



partners including the National Cancer Institute and the Food and Drug Administration, they have driven the research and advocacy necessary to secure the approval of ICD-10-CM codes for irAEs.

"The approval of these codes marks an important milestone in our mission to improve the lives of patients with cancer," said Sean Khozin, MD, MPH, CEO of the CEO Roundtable on Cancer and Project Data Sphere LLC. "By facilitating the accurate documentation and tracking of irAEs, we are enabling physicians, providers, researchers, and industry to develop optimal strategies for mitigating the risks associated with immunotherapies."

The availability of irAE diagnostic codes will have far-reaching implications for the healthcare ecosystem. Clinicians will be better equipped to recognize and manage irAEs and researchers will have access to a wealth of data to conduct comprehensive studies. Moreover, the diagnostic codes can facilitate the development of personalized risk assessment tools and targeted prevention strategies, ultimately leading to improved patient outcomes.

Belén Garijo, Chair of the Executive Board and CEO of Merck KGaA, Darmstadt, Germany, expressed her enthusiasm for the achievement: "At Merck KGaA, we are committed to pushing the boundaries of cancer research and improving the lives of patients worldwide. The approval of these ICD-10-CM codes, made possible through our collaboration with Project Data Sphere and the CEO Roundtable on Cancer, represents a significant leap forward in our understanding and management of immune-related adverse events. We are proud to be part of this important initiative and look forward to the positive impact it will have on cancer care."

The approval of ICD-10-CM diagnosis codes for irAEs represents a significant step forward in the broader context of cancer care, contributing to the wider adoption of immunotherapies and the development of combination therapies. The CEO Roundtable on Cancer and Project Data Sphere remain committed to driving meaningful change and improving patient outcomes on a global scale through collaborative initiatives like GOBDA.

Kerry Reynolds, MD, Clinical Director of Inpatient Oncology Units and Director of the Severe Immunotherapy Complications Program at Massachusetts General Hospital, emphasized the significance of this milestone: "For those of us dedicated to caring for these patients, the approval of ICD-10-CM codes for immune-related adverse events is a monumental relief. It's a crucial leap forward in our ability to provide optimal care for patients undergoing immunotherapy who suffer from immune-related adverse events. These codes will empower us to accurately document, track, and manage these serious complications, ultimately improving patient outcomes and advancing the field of immuno-oncology. It's also inspiring to see institutions across the country unite to drive such impactful progress."

About the CEO Roundtable on Cancer

The CEO Roundtable on Cancer was founded in 2001, when former President George H.W. Bush challenged a group of executives to "do something bold and venturesome about cancer within

your own corporate families." The CEOs responded by creating the CEO Cancer Gold Standard®, which calls for organizations to evaluate their health benefits and workplace culture and take extensive, concrete actions in five key areas of health and wellness to address cancer in the workplace.

About Project Data Sphere

Project Data Sphere is an initiative spanning industry, academia, and government to advance cancer research. Since its inception, the organization has been developing and implementing innovative initiatives aimed at reducing the risk of cancer, enabling early diagnosis, facilitating access to the best available treatments, and hastening the discovery and development of novel anti-cancer therapies to help eliminate the burden of cancer as a personal disease and public health problem.

For more information, visit www.ceoroundtableoncancer.org.

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