FDA U.S. FOOD & DRUG ADMINISTRATION
ONCOLOGY CENTER OF EXCELLENCE

April 19, 2017

Martin J. Murphy, DMedSc, PhD, FASCO
Chief Executive Officer
Project Data Sphere, LLC

Subject: Letter of Support

Dear Dr. Murphy:

We are issuing this **Letter of Support** for *Project Data Sphere, LLC*, to encourage industry sponsors and academic centers to share their de-identified patient-level data from adult and pediatric cancer clinical trials and other research studies with *Project Data Sphere*.

The *Project Data Sphere* cancer research platform is an open-access repository of de-identified patient-level data from industry and NCTN-sponsored Phase II and Phase III cancer clinical trials that may then be aggregated from multiple research organizations. The platform contains data from more than 41,000 patients spanning more than 70 clinical trials and research studies. As a collaborative platform, data from *Project Data Sphere* has generated more than 15 peer-accepted manuscripts in high-profile journals, as well as posters and abstracts. Additional publications are in progress.

The *Project Data Sphere* platform provides an opportunity to enhance many types of investigations across different cancer therapies, but could be particularly useful in investigating the rare but clinically significant adverse events that have emerged as a result of PD-1/PD-L1 immune checkpoint inhibitors (CPIs). While CPIs have altered care for many patients with otherwise fatal cancers, rare adverse events such as myocarditis have been reported. Because the relatively small number of reported cases of serious autoimmune disorders in association with the CPI of any single sponsor is limited, it is difficult to determine whether any particular risk factors correlate with or predict these events.

We believe that there is great potential value for sponsors engaged in CPI development to upload, on a voluntary basis, critical de-identified data into a common clinical trial data-sharing environment such as *Project Data Sphere*, enabling a more robust analysis of aggregated,

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patient-level data on immuno-related adverse events, as well as other outcome measures, including efficacy endpoints.

Project Data Sphere would serve as the independent, third-party recipient of these data derived from a sufficient number of patients to enable a robust and detailed analysis of risk factors for adverse events. Investigation of these data would be open to all interested researchers, including those from industry, the FDA, and the NCI. The analytical and data visualization tools freely embedded in *Project Data Sphere* will further facilitate these analyses.

Groups from industry, academia, and government that would like to join this effort or who would like further information may contact Dave Handelsman at *Project Data Sphere*, LLC: Dave.Handelsman@ProjectDataSphere.org; O: 919-531-2694; C: 919-592-0607.

Signed:

Richard Pazdur, MD
Director, Oncology Center of Excellence
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