January 4, 2019

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, academic centers, and others to share de-identified patient-level data for creation of a small cell lung cancer (SCLC) database.

In recent years, the standard of care and overall survival of patients with SCLC has remained largely unchanged. FDA’s Oncology Center of Excellence supports Project Data Sphere’s efforts to collect, curate and aggregate relevant SCLC clinical trial data for creation of a database as a benchmark reflecting clinical outcomes.

As an independent, nonprofit, open-access repository of patient-level clinical trial data with a demonstrated track record of successful collaborations, Project Data Sphere is a platform for constructing a globally-accessible external control reference database in SCLC. Investigation of the data would be open to all interested researchers, including those from industry, the FDA, and academia.

Signed:

Richard Pazdur, MD
Director, Oncology Center of Excellence
Food and Drug Administration