## Abstract

Project Data Sphere, LLC, an independent initiative of the CEO Roundtable on Cancer’s Life Sciences Consortium, sponsors a web-based platform through which historic data obtained from cancer clinical trials on candidate therapeutics, both positively and negatively reviewed, are made available to outside researchers. The goal of this initiative is to have patient-level, de-identified datasets produced by both academic and industry research, available for secondary analysis to generate new insights that will accelerate cancer research.

## Mission

The Project Data Sphere initiative aims to advance oncology research by enabling collaborative sharing of historical oncology clinical trial data through a universal platform (database). The initiative aims to network all stakeholders in the cancer community—researchers, industry, academia, advocacy, and other organizations—to share insights and collaborate on issues that could not be solved individually. To do this, the initiative has made efforts to address issues of data privacy, security, intellectual property, resources, and incentives as part of its effort to maximize participation.

Data contributions include control arms of clinical trials, and the Project Data Sphere platform uses...
data-security precautions and analytics to pool multiple studies associated with the same diagnosis in a manner that seeks to protect the privacy of patients and the security of the data contributed.

**Consortium History**

In 2011, the Project Data Sphere initiative was established in pilot phase and continued with beta-testing of de-identified control arm data in 2012. In preparation for the official platform launch in 2014, the initiative focused on designing and implementing the information technology infrastructure, developing policies and procedures for governance and access and addressing other legal and policy issues.

The initiative was officially launched in April 2014 with nine datasets from AstraZeneca, Bayer, Celgene, Janssen Research and Development, Memorial Sloan Kettering Cancer Center, Pfizer and Sanofi US. There are plans to include an additional 25 datasets from 10 providers.

**Structure & Governance**

Project Data Sphere, LLC, a nonprofit, limited liability company, is an independent initiative of the CEO Roundtable on Cancer’s Life Sciences Consortium with support from several members of the Roundtable. A formal governance structure has been defined with officers and with an Executive Committee that serves the officers in an advisory capacity.

**Financing**

The initiative is supported by the members of the CEO Roundtable on Cancer and its Life Sciences Consortium through voluntary, in-kind contributions.

**Intellectual Property**

Project Data Sphere, LLC has developed a uniform Data Sharing Agreement that provides for the data
provider to retain all of its rights in the provided data. In Phase I of the initiative, only control arm data is included, which allows a level of comfort and trust to be established as the first step for creating a culture of data sharing.

Additionally, a uniform Data User Agreement imposes only limited restrictions on the use of the data to facilitate the spirit of open research.

These uniform legal agreements have been developed to balance the needs of patients, data providers, and researchers.

The result of any clinical trial whose data is accessible through the Project Data Sphere platform may have already been published in summary form in a scientific journal. The Data User Agreement encourages the sharing of additional clinical trial data and the pursuit and publication of secondary analysis.

**Patent Engagement**

Feedback from patient advocacy groups, including Conquer Cancer Foundation, FasterCures, Friends of Cancer Research, LUNGevity, LIVESTRONG, Melanoma Research Alliance, Multiple Myeloma Research Foundation, Research Advocacy Network, Triple Negative Breast Cancer Foundation, Men’s Health Network, Prostate Cancer Foundation, C-Change, and ZERO—The Project to End Prostate Cancer, has been incorporated into the design of the Project Data Sphere platform. A patient advocate also consults regularly with Project Data Sphere, LLC. Engaging patient groups in the planning and implementation stages is expected to promote a culture of data sharing among the research community.

Initially, the ability of Project Data Sphere, LLC to add datasets to the platform along with indications of data use will be the key indicator for forward momentum of this initiative. In the long term, the results and findings from secondary analysis performed using the accumulated datasets will determine the value of the data-sharing effort.

**Data Sharing**
Data sharing is the key mission of the initiative and the information technology platform has been carefully designed to address privacy, security, intellectual property (IP), resources, and incentives expressed by the data providers and data users.

Privacy and security:

- Data providers are required to de-identify patient-level data before making it available for research purposes.
- Data is housed in a hardened hosting environment managed by SAS Institute, Inc.
- All data are behind the SAS firewall, accessible to users to whom rights have been granted through the Project Data Sphere application process.
- All data transmissions are encrypted via Secure Socket Layer transmission.
- User accounts have role-based permissions to make appropriate functionality and access available to varying user types.
- All data uploaded to the Project Data Sphere platform are subject to virus scanning prior to being made available to researchers.

Intellectual property (also described above):

- Uniform legal agreements support control arm data, for both data providers and data users.
- Each data provider retains ownership of all existing IP in data it provides.
- There are limited restrictions on data usage.

Resources:

- Data providers will be responsible for data preparation.
Sponsors & Partners

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