

FREQUENTLY ASKED QUESTIONS



Q: What is the *Project Data Sphere* initiative?

A: *Project Data Sphere, LLC* (PDS), an independent, not-for-profit initiative of the *CEO Roundtable on Cancer's Life Sciences Consortium* (LSC), operates the *Project Data Sphere* platform (www.ProjectDataSphere.org) which was specifically designed to provide one place where the research community can broadly share and analyze historical, patient-level cancer phase III comparator arm data with the goal of advancing future research to improve the lives of cancer patients and their families around the world.

Q: How did the *Project Data Sphere* initiative get started?

A: In 2001 the *CEO Roundtable on Cancer* was founded by President George H. W. Bush. It comprises chief executives from more than 30 U.S.-based organizations representing diverse industries. Their charge was to accomplish together what no single company might consider alone to address issues in cancer prevention, diagnosis, and treatment. In 2005, the *Life Sciences Consortium* (LSC) taskforce was launched to bring together member companies that could collaborate on transforming research and development in oncology to deliver more effective therapies to patients faster. In 2011, the concept for the *Project Data Sphere* initiative was born from the LSC's vision of a novel effort to make historical cancer data broadly accessible with the objective of advancing future research to improve the lives of patients.

Q: What types of data are being shared?

A: The *Project Data Sphere* initiative is open to historical patient-level comparator arm data from phase III cancer clinical trials across all tumor types. In addition to the data set, the data provider will share the case report form template, data descriptors and study protocol.

Q: What are some potential benefits of data sharing?

A: Some potential benefits of data sharing include: a clearer understanding of disease progression and endpoints, more efficient trial designs, and development of research standards, as well as reduced duplication of efforts.

Q: Are there plans to expand the *Project Data Sphere* initiative beyond oncology?

A: Not at this time.

Q: What is the governance structure of *Project Data Sphere, LLC*?

A: The *Project Data Sphere, LLC* officers include: Christopher A. Viehbacher, President; William C. Weldon, 1st Vice President; Robert A. Ingram, 2nd Vice President; Dr. Martin J. Murphy, Jr., Treasurer; and John N. Dornan, Assistant Treasurer. Governance includes the Executive Committee, which functions in an advisory capacity.

The officers may call upon the Executive Committee to advise on ethical and scientific matters. The Executive Committee includes

Dr. Victor Dzau, President of the National Academy of Medicine

Dr. Stephen Friend, President, Co-Founder and Director, Sage Bionetworks

Sir Dennis Gillings, Executive Chairman, Quintiles

Dr. Richard Goldberg, Physician-in-Chief, James Cancer Hospital and Solove Research Institute

Dr. Martin J. Murphy, Jr., CEO, CEO Roundtable on Cancer

Dr. Charles A. Sanders, Executive Chairman, Foundation for the National Institute of Health

Dr. Elias Zerhouni, President, Global R&D, Sanofi

Q: Who will have access to the *Project Data Sphere* database?

A: All interested in gaining access will be directed to fill out a user application and agree to the terms specified in the Online Services User Agreement, which can be found in the Resources section of the *Project Data Sphere* website. Parties whose applications cannot be accepted include individuals on the FDA debarment list and individuals to whom data cannot legally be exported.

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Q: Is there a cost to use the *Project Data Sphere* platform?

A: There is no cost to access and use the *Project Data Sphere* platform or data.

Q: What information is needed for access?

A: Details on what is required when applying for access can be found in the Resources page of the website.

Q: Do I have to submit a research proposal?

A: A summary of initial research goals is requested during the user application process.

Q: Will I need to request access for each data set?

A: Once access is granted, the registered user has the ability to access all data in the *Project Data Sphere* platform.

Q: Does it need to be a research team who applies for access?

A: Access is granted on an individual basis. If you are part of a research team, each individual on the team will need to apply for separate access.

Q: How long will acceptance take for users?

A: Requests for access are reviewed in the order they are received. The estimated time frame to review a request to become a registered user is expected to be fewer than 7 days.

Q: As a registered user, for how long do I have access to the data?

A: Once you have been granted access to the *Project Data Sphere* platform as a registered user, the data will be available to you for one year. Users will be notified about the need to renew their annual application prior to the end of the term.

Q: What analytics tools are available on the *Project Data Sphere* platform?

A: The following SAS analytics tools are available for use with data in the *Project Data Sphere* platform at no cost to registered users:

SAS® Clinical Data Integration

SAS® Visual Analytics

SAS® Drug Development

Q: Is technical support available to users?

A: Technical support is available. All inquiries should be sent through the "Contact Us" feature on the *Project Data Sphere* website.

Q: Is the registered users' information ever shared publicly?

A: The privacy policy is available on the *Project Data Sphere* website for additional information.

Q: How does one go about providing data?

A: Please visit the Resources page on the *Project Data Sphere* website to learn how to become a registered user and data provider.

Q: What data standards are in place within the *Project Data Sphere* database?

A: The Clinical Data Interchange Standards Consortium (CDISC) Study Data Tabulation Model (SDTM) format is the recommended format to share data. Specific details about any format used will be provided in the data descriptor document.

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Q: What legal agreements are in place to govern how data will be shared?

A: All registered users enter into an Online Services User Agreement with *Project Data Sphere, LLC*. Additionally, each data provider enters into a Data Sharing Agreement for each data set provided. These agreements can be found in the Resources page of the *Project Data Sphere* website.

Q: Will users be required to submit research results?

A: The Online Services User Agreement encourages users to publish results of their research in a peer-reviewed publication and to report the results of their research through scientific presentations, and it requires users to only disclose data that is reasonably necessary to publish or report the research results.

The Online Services User Agreement requires users to acknowledge *Project Data Sphere, LLC* in their publications and presentations (the specifics of the acknowledgement can be found in the Online Services User Agreement available in the Resources page of the *Project Data Sphere* website).

Q: How is the *Project Data Sphere* initiative funded?

A: *Project Data Sphere, LLC* is an independent initiative of the *CEO Roundtable on Cancer's Life Sciences Consortium*, and as such is supported by the members of the *CEO Roundtable on Cancer's Life Sciences Consortium* through voluntary, in-kind contributions.

Q: Where can an individual or organization find additional information about supporting the *Project Data Sphere* initiative in ways beyond data sharing?

A: All inquiries should be sent through the "Contact Us" feature on the *Project Data Sphere* website.