

Project Data Sphere®: Progress & Promise

Single-arm Trials in Cancer Drug Evaluation Workshop

June 30, 2016

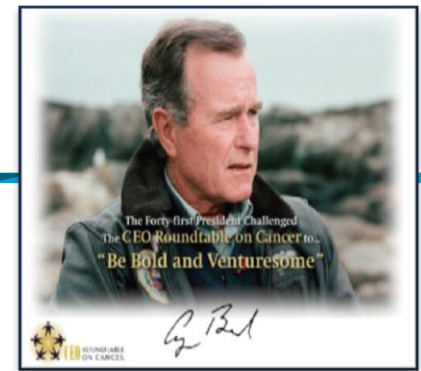
Martin J. Murphy, DMedSC, PhD, FASCO

- **Founded in 2001** at the request of *President George H.W. Bush, 41st U.S. President*
- **Founding Chairman** Robert A. Ingram, former CEO of GlaxoWellcome
- **Comprised of CEOs** from major American companies, representing diverse industries and institutions
- **Non-profit organization** - 501(c)(3)



CEO Roundtable on Cancer's Life Sciences Consortium (LSC)

- LSC founded 2004
- *Mission: "Bold and Venturesome"*
- *Accomplish together what no single company might consider alone*



AMGEN

Boehringer
Ingelheim

EMD Serono

Lilly

NATIONAL
CANCER
INSTITUTE



SANOFI

astellas

Celgene

HELSINN

MERCK

NOVARTIS

sas

AstraZeneca

COVANCE

INSTITUTE OF MEDICINE
OF THE NATIONAL ACADEMIES

MERRIMACK
PHARMACEUTICALS

Pfizer

SYNTA
PHARMACEUTICALS

Bayer HealthCare

DukeMedicine

Johnson & Johnson

THE UNIVERSITY OF TEXAS
MD ANDERSON
CANCER CENTER
Making Cancer History®

QUINTILES
TRANSNATIONAL

Takeda

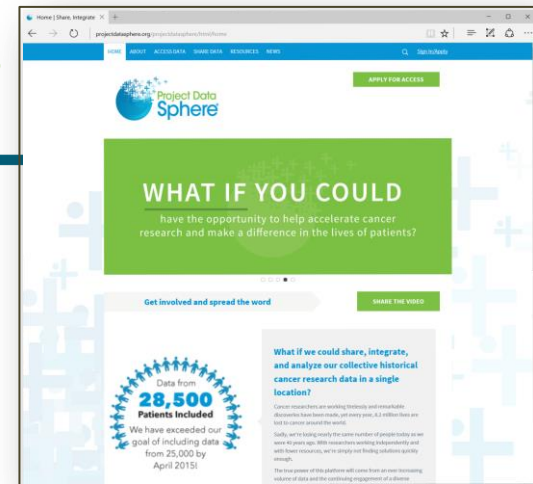
PDS: Open Access Cancer Data-Sharing Platform

- **Voluntary, not-for-profit platform**

- Broadly share, integrate, and analyze cancer data
- Sophisticated analytic tools
- Free, easy-to-use, with favorable IP
- Industry and NCI-NCTN comparator-arm phase III trials
- De-identified patient data, dictionary, protocols & CRFs

- **To benefit cancer patients**

- **Public Launch: April 8, 2014**



Project Data Sphere, LLC

Executive Committee



- **Dr. Victor Dzau**; President, *National Academy of Medicine*
- **Dr. Stephen Friend**; *Apple, Inc.*; Chairman, *Sage Bionetworks*
- **Sir Dennis Gillings**; Retired Executive Chairman, *Quintiles*
- **Dr. Richard Goldberg**; Physician-in-Chief, *The James Cancer Hospital*
- **Dr. Martin J. Murphy**; Chief Executive Officer, *CEO Roundtable on Cancer*
- **Dr. Charles A. Sanders**; Chairman Emeritus, *Foundation for the National Institutes of Health*
- **Dr. Elias Zerhouni**; President, Global Research & Development, *Sanofi*

Project Data Sphere® ... Ongoing FDA and EMA Engagement

- FDA meeting on *Sharing Clinical Trial Data*, May 2012
- IOM Data Sharing Workshop, October 4, 2012
- FDA Office of Hematology & Oncology Products, May 3, 2013
- EMA Presentation, *Hans-Georg Eichler & Francesco Pignatti, et al.*, Canary Wharf Offices, February 19, 2015
- Presentation to Office of Hematology & Oncology Products, *Richard Pazdur, Paul Kluetz, Gregory Reaman, Sean Khozin, Geoff Kim, et al.*, June 22, 2015
- FDA Meeting, *Sean Khozin, Gregory Reaman, Max Ning, Geoff Kim*, July 27, 2015
- FDA Meeting at SAS Institute, *Sean Khozin*, August 25, 2015
- FDA Meeting, *Robert Califf*, October 16, 2015
- *LSC-PDS Symposium I* with FDA, November 30, 2015
- *LSC-PDS Symposium II* with FDA, NCI, and White House, May 3, 2016
- EMA-ESMO Workshop: *Single-arm trials in cancer*, June 30, 2016

LSC-PDS Symposium II : New Project

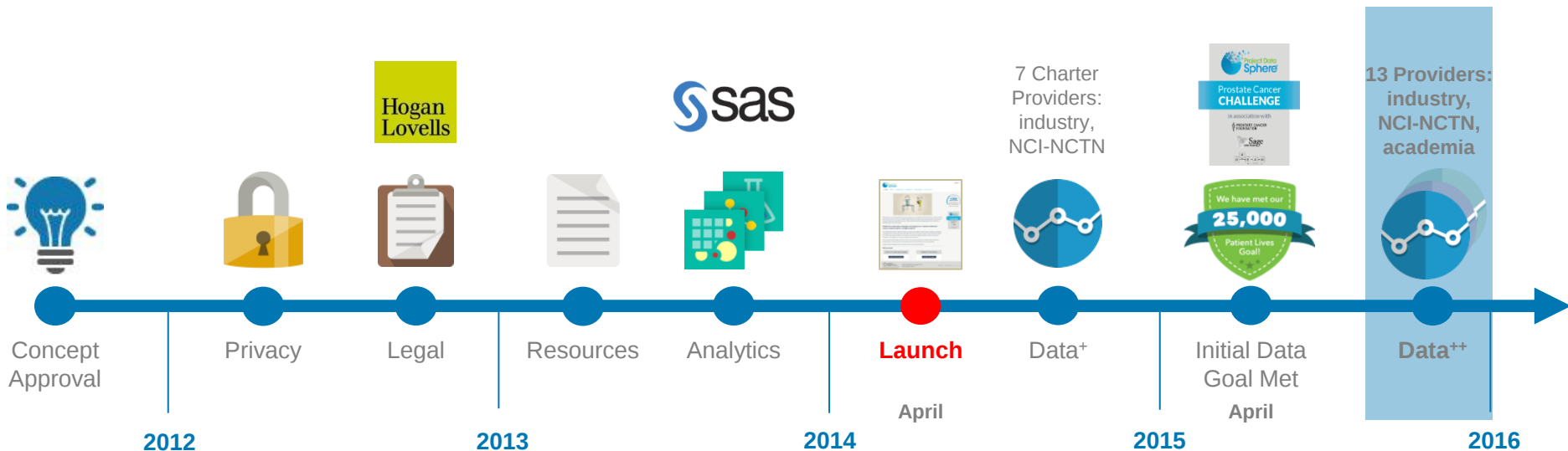
Proposed research program: “**New intermediate endpoints in Prostate Cancer**”. Project Data Sphere will support data gathering and online library-laboratory.

Investigators: **Michael Morris** and **Howard Scher**,
Memorial Sloan Kettering Cancer Center

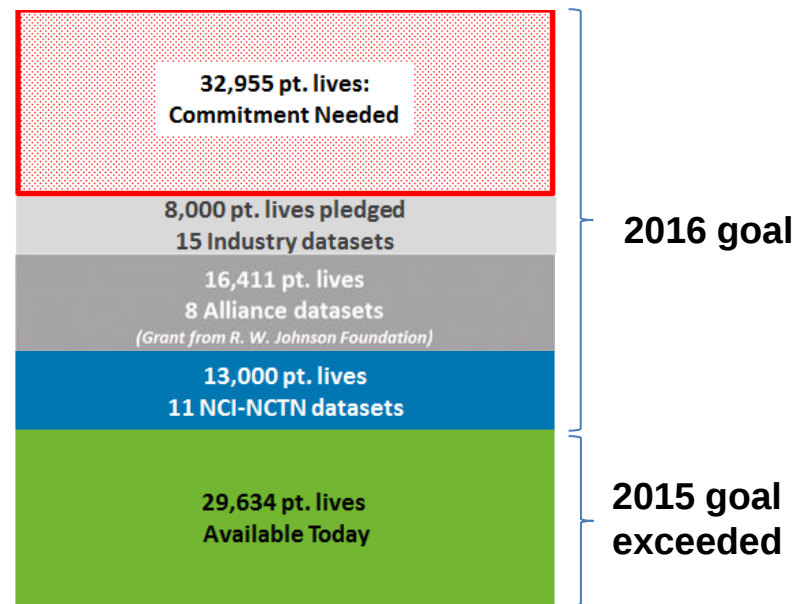
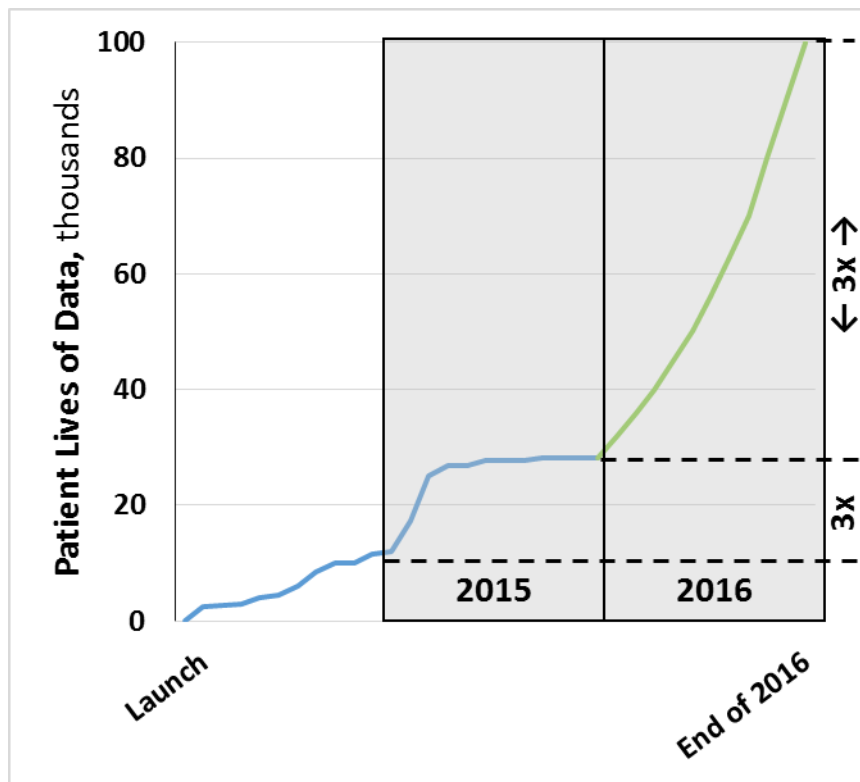
Key Metrics: 2 Years of Operation

- Commitment from industry and NCI-NCTN
 - ✓ ~30,000 patient lives of data from 14 data providers
- Sustained use by researchers
 - ✓ >1,200 researchers have accessed data ~4,000 times
- **Prostate Cancer DREAM Challenge** ended July 27, 2015
 - ✓ >500 participants; 58 teams; 21 countries
 - ✓ More participants than any of 32 DREAM Challenges
 - ✓ Peer-reviewed publications, submitted
- Prostate Cancer: Proof of Principle for Project Data Sphere®
 - ✓ Pace-setting publications, using mathematical modeling, predict prostate cancer tumor burden over time; other hormone-driven tumors to be explored

PDS: Timeline since Conception



2016 Goal: 100,000 patient lives of data



The Power of Access to Patient-Level Data



“The ***Project Data Sphere*** platform has allowed the development of new models to predict prostate cancer tumor burden over time – research that will have **real implications for the drug development process** and that can be repeated for many other tumor types if the right volume of data is made available.”

- **Tito Fojo, M.D., Ph.D.**

Director, Neuroendocrine Cancers, *Columbia University*

“Data sharing through efforts such as the ***Project Data Sphere*** initiative allows **new research and new discoveries** that no single trial could provide on its own. The Alliance for Clinical Trials in Oncology is **proud to cooperate** with *Project Data Sphere, LLC* to make our data available in a responsible manner.”

- **Daniel J. Sargent, Ph.D.**

Group Statistician, *Alliance for Clinical Trials in Oncology*



A Patient-Level Data Meta-Analysis of Standard-of-Care Treatments from Eight Prostate Cancer Clinical Trials

Nophar Geifman, Atul Butte

“Open clinical trial data offer many opportunities for the scientific community to independently verify published results, evaluate new hypotheses and conduct meta-analyses... **This study illustrates how the use of patient-level clinical trial data enables meta-analyses that can provide new insights into clinical outcomes of standard of care treatments and thus, once validated, has the potential to help optimize healthcare delivery.**”

Full Manuscript:

bit.ly/PDSNatureProstate

SCIENTIFIC DATA

a nature research journal

Peer Reviewed Manuscripts

	Publication	Author	Pub. Date
1	Comparative Effectiveness of Mitoxantrone plus Prednisone versus Prednisone alone in Metastatic Castrate-Resistant Prostate Cancer after Docetaxel Failure. <i>The Oncologist</i>	Angela K. Green, <i>et al.</i>	May 2015
2	Individual Patient Data Analysis of Randomized Clinical Trials: Impact of Black Race on Castration-resistant Prostate Cancer Outcomes. <i>European Urology</i>	Daniel E. Spratt, <i>et al.</i>	April 2016
3	A Patient-Level Data Meta-Analysis of Standard-of-Care Treatments from Eight Prostate Cancer Clinical Trials. <i>Nature Scientific Data</i>	N. Geifman & A. J. Butte	May 2016
4	Predicting Survival of Pancreatic Cancer Patients Treated with Gemcitabine Using Longitudinal Tumour Size Data. <i>Cancer Chemotherapy and Pharmacology</i>	Theirry Wendling, <i>et al.</i>	May 2016
5	Assessment of Prognostic Models, PSA Metrics, and Toxicities in Metastatic Castrate Resistant Prostate Cancer using PDS Data. <i>PLOS One</i>	Anthony Joshua, <i>et al.</i>	In Press
6	A Community Challenge to Improve Prognostic Models in Patients with Metastatic Castrate Resistant Prostate Cancer. <i>Lancet Oncology</i>	James Costello, <i>et al.</i>	Submitted
7	Estimating Rates of Tumor Regression and Growth During Treatment in 3054 Patients with Advanced Prostate Cancer: A Data Mining Project. <i>Lancet Oncology</i>	Tito Fojo, <i>et al.</i>	In Preparation

Peer Reviewed Posters and Abstracts

Publication		Author	Date
1	Review of Metformin and Statin Therapy in Prostate Cancer. Prostate Cancer Foundation Scientific Retreat	Anthony Joshua	Oct. 2014
2	Project Data Sphere in Prostate Cancer: A First Look Including Concomitant Medication Use. ASCO GU #204	Anthony Joshua	Feb. 2015
3	Association Between RECIST Changes and Survival in Patients with Metastatic Castration-Resistant Prostate Cancer Receiving Docetaxel. European Urology	Guru P. Sonpavde, <i>et al.</i>	May 2015
4	The Prostate Cancer DREAM Challenge: A Community-Wide Effort to Use Open Clinical Trial Data for the Quantitative Prediction of Outcomes in Metastatic Prostate Cancer. <i>Commentary, The Oncologist</i>	Kald Abdallah, <i>et al.</i>	May 2015
5	Results from First 6 Months of Broad Access to Oncology Trials Data. ASCO #17691	Kald Abdallah, <i>et al.</i>	May 2015
6	A First Look at Prostate Cancer Including Concomitant Medication Use, Prognosis, and Toxicity. ASCO #5022	Anthony Joshua	May 2015
7	Use of Crowdsourced Research to Develop a Prognostic Model for First-Line Metastatic Castrate Resistant Prostate Cancer. ASCO GU #180	Fang (Liz) Zhou	Jan. 2016
8	Impact of Single Agent Daily Prednisone on Survival and Toxicities in Post-Docetaxel Men with Metastatic Castration-Resistant Prostate Cancer (mCRPC): An Analysis of 2 Phase III Trials. ASCO GU #213	Guru P. Sonpavde	Jan. 2016



Martin J. Murphy, DMedSc, PhD
Chief Executive Officer
Project Data Sphere, LLC
O: +1-919.402.8750
M: +1-919.641-5304
Martin.Murphy@ProjectDataSphere.org



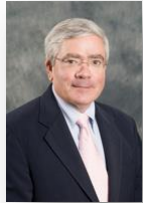
John N. Dornan, Jr.
Chief Operating Officer
Project Data Sphere, LLC
O: +1-919.531.0966
M: +1-919.357.0659
John.Dornan@ProjectDataSphere.org



Joseph K. Morrell
Program Management Office
Project Data Sphere, LLC
M: +1-202.746.0219
Joe.Morrell@ProjectDataSphere.org



Liz Zhou, MD, MS
Director, Scientific Analytics
Project Data Sphere, LLC
Sanofi Oncology
O: +1-908.981.5329
Liz.Zhou@ProjectDataSphere.org



Gregory A. Curt, MD
Co-Chairman
Life Sciences Consortium Task Force
AstraZeneca Oncology
M: +1-301.792.2804
Gregory.Curt@astrazeneca.com



Mace L. Rothenberg, MD
Co-Chairman
Life Sciences Consortium Task Force
Pfizer Oncology
O: +1-212.733.5080
Mace.Rothenberg@pfizer.com

THANK YOU!

www.ProjectDataSphere.org