

The Power of Data Sharing: Real Projects with Real Impacts

PhUSE US Connect 2019

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CEO ROUNDTABLE
ON CANCER

- Founded in **2001**
- CEOs of diverse companies
 - 38 companies, many industries
 - 18 biopharma companies
- *Mission:*
 - Reduce cancer risk
 - Enable early diagnosis
 - Facilitate access to treatment
 - Discovery of new treatments... *faster*



CEO LIFE
SCIENCES
CONSORTIUM

- Founded in **2004**
- Life sciences company executives
- *Mission:*
 - Collaborate and catalyze
 - Accomplish together what no single company might consider alone
 - Provide safe and effective new medicines... *faster*



Project Data
Sphere

- Launched in **2014**
- Not-for-profit cancer research platform
- *Mission:*
 - Broadly share cancer clinical trial datasets
 - Enable new scientific insights
 - Support drug development... *faster*

An Open-Access Cancer Research Platform Powered by Shared Data

> 135,000

Patients

> 150

Datasets

> 17,000

Downloads

> 2,000

Users

19

Data Providers

> 9,000

Logins

What if we could share, integrate, and analyze our collective historical cancer research data in a single location?

Cancer researchers are working tirelessly and remarkable discoveries have been made, yet every year, 8.2 million lives are lost to cancer around the world.

Sadly, we're losing nearly the same number of people today as we were 40 years ago. With researchers working independently and with fewer resources, we're simply not finding solutions quickly enough.

The true power of this platform will come from an ever increasing volume of data and the continuing engagement of a diverse global community focused on finding solutions for cancer patients. Imagine what will happen when the entire cancer community joins efforts.

- Launched April 8, 2014
- Broadly share, integrate, and analyze cancer clinical trial data
- Powerful analytic tools free to all users
- Industry and NCI-NCTN phase II/III trials
- Comparator arm *and* experimental arm data
- De-identified patient data, data dictionary, protocol, and CRFs

Current Data Sharing Status: New Era, New Expectations

- When clinical trial data has been shared in the past, it has been directly requested by researchers from the study sponsor
- Recently, data sharing platforms have been developed to more broadly share research data



Data sharing of cancer trial data is moving to center stage

New England Journal of Medicine
(23-March-2017)



The NEW ENGLAND
JOURNAL of MEDICINE

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Advantages of a Truly Open-Access Data-Sharing Model

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sponsible and meaningful way. The cancer research community, encouraged by recommendations from the Beau Biden Cancer Moonshot, is finally moving data sharing forward from its traditional, largely unfunded, place at the end of the long list of clinical research responsibilities to center stage.

Thus, the PDS Prostate Cancer DREAM Challenge confirmed that an open-access model empowers global communities of scientists from diverse backgrounds and promotes crowd-sourced solutions to important clinical problems. This level of engagement is not possible with gatekeeper models.

N. Engl. J. Med. 376;12, March 23, 2017

http://bit.ly/NEJM_Open_Access

Data Sharing: A Field of Dreams



“If you build it, will they come?”

A Real Project with Real Impact

● Prostate Cancer *DREAM* Crowdsourcing Challenge (July 2015)

- ✓ >500 participants; 58 teams; 21 countries
- ✓ More participants than first 32 *DREAM* Challenges
- ✓ Led to 9 peer-accepted publications

“DREAM is an acronym that stands for **D**ialogue for **R**everse **E**ngineering **A**ssessments and **M**ethods but over the years it has evolved into the dream of collaboration, sharing data, and open science being the norm in science not the exception

[ePCR: an R-package for survival and time-to-event prediction in advanced prostate cancer, applied to real-world patient cohorts](#)

[A Patient-Level Data Meta-Analysis of Standard-of-Care Treatments from Eight Prostate Cancer Clinical Trials.](#)

[Assessment of a Prognostic Model, PSA Metrics and Toxicities in Metastatic Castrate Resistant Prostate Cancer using Data from Project Data Sphere.](#)

[Prediction of overall survival for metastatic pancreatic cancer: Development and validation of a prognostic nomogram with data from open clinical trial and real-world study](#)

[Individual Patient Data Analysis of Randomized Clinical Trials: Impact of Black Race on Castration-resistant Prostate Cancer Outcomes.](#)

[Estimation of Tumour Regression and Growth Rates During Treatment in Patients with Advanced Prostate Cancer: A Retrospective Analysis.](#)

[A DREAM Challenge to Build Prediction Models for Short-Term Discontinuation of Docetaxel in Metastatic Castration-Resistant Prostate Cancer](#)

[Comparative Effectiveness of Mitoxantrone plus Prednisone versus Prednisone alone in Metastatic Castrate-resistant Prostate Cancer after Docetaxel Failure.](#)

[Prediction of Overall Survival for Patients with Metastatic Castration-Resistant Prostate Cancer: Development of a Prognostic Model Through a Crowdsourced Challenge with Open Clinical Trial Data.](#)

Additional Peer-Accepted Publications

[Statin Treatment and Outcomes of Metastatic Pancreatic Cancer: A Pooled Analysis of Two Phase III Studies](#)

[Data Integration Innovations to Enhance Analytic Utility of Clinical Trial Content to Inform Health Disparities Research](#)

[Effect of Breast Irradiation on Cardiac Disease in Women Enrolled in BCIRG-001 at 10-Year Follow-Up](#)

[5-Fluorouracil-Related Cardiotoxicity: Findings from Five Randomized Studies of 5-Fluorouracil-based Regimens in Metastatic Colorectal Cancer](#)

[Myocarditis Associated with Immune Checkpoint Inhibitors: an Expert Consensus on Data Gaps and a Call to Action](#)

[“Threshold-crossing”: A Useful Way to Establish the Counterfactual in Clinical Trials?](#)

[Obstruction Predicts Worse Long-term Outcomes in Stage III Colon Cancer: A Secondary Analysis of the N0147 Trial](#)

[On the relationship between tumour growth rate and survival in non-small cell lung cancer](#)

[Predicting Survival of Pancreatic Cancer Patients Treated with Gemcitabine Using Longitudinal Tumour Size Data.](#)



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Advantages of a Truly Open-Access Data-Sharing Model

New Project Data Sphere-led Research Programs:

Real Projects with Real Impacts

External
Control
Arms

Rare
Tumor
Registries

Immune-
related
Adverse
Events

Images
and
Algorithms

New Project Data Sphere-led Research Programs:

External Control Arms

- Cancer clinical trials typically randomize patients to either a comparator or experimental treatment arm
- External Control Arms can serve as the comparator treatment arm, resulting in:
 - Fewer patients needing to be enrolled in a clinical trial
 - Reduced costs to execute trials, leading to the execution of more trials
 - Preservation of available patients for enrollment in other clinical trials
 - Reduced time and budget for those trials
 - Opportunities for more patients to receive experimental treatment

Status:

- Initial external control arm focused on small cell lung cancer
- 5 datasets have been aggregated from different sponsors; more are expected
- First external control arm is expected to be completed by end of 1Q2019
- Manuscripts in process
- Next external control arm will extend to additional small cell lung cancer treatments
- Research program expected to include glioblastoma later in 2019

New Project Data Sphere-led Research Programs: Rare Tumor Registries

- The small number of patients with rare tumors limits research opportunities to understand these diseases
- Real-world data captured at the point-of-care, and shared across health care organizations, can be integrated with conventional clinical trial data to create new research opportunities

Status:

- Registry for Merkel Cell Carcinoma expected to launch in mid-2019
- Data capture instrument under development
- Process being developed to periodically transfer ongoing registry data to Project Data Sphere cancer research platform

New Project Data Sphere-led Research Programs:

Immune-related Adverse Events

- Seven new immune checkpoint inhibitors have been approved by FDA to treat various cancers in the past several years, and the patient outcomes can be remarkable
- These treatments can cause rare but serious (or fatal) adverse events
- Because these events are so rare, and the treatments are so new, there has been limited research regarding these safety concerns
- The goal of this research program is to develop techniques to understand, detect, predict and treat these events so that patient risk is minimized

Status:

- Research at individual health care centers is beginning, but the scarcity of patient data is limiting analysis
- Symposium scheduled for April 2019 to discuss how to share relevant data across healthcare sources, and align on research goals

New Project Data Sphere-led Research Programs:

Images and Algorithms

- Focus: Develop machine-learning algorithms through crowd-sourced challenges to enhance the performance of imaging in clinical trials thru greater reliability, automation, and outcomes of response assessment metrics
- Value: Implementation of these algorithms will reduce the time and cost and improve the performance for imaging in clinical trials, shortening the time from discovery to implementation, improving the accuracy of the reviews, and, ultimately, improving patient lives

Status:

- “Challenge Question” and “Data Requirements” working groups are active
- Imaging data sources being investigated
- Symposium scheduled for Fall 2019

The Power of Data Sharing:

Real Projects with Real Impacts

- Prostate Cancer DREAM Challenge: Data from multiple prostate cancer trials, provided by multiple sponsors, pooled and investigated to develop new prognostic and treatment models for patients
- External Control Arm Program: Data from multiple small cell lung cancer trials (to start), provided by multiple sponsors, pooled and investigated to develop external control arms to reduce the number of patients needed for individual trials and to enable more patients to receive experimental treatments
- Rare Tumor Registries Program: Data from multiple treatment centers, and multiple clinical trials, pooled and investigated to bring sufficient data together to better understand these rare cancers
- Immune-Related Adverse Events Program: Data from multiple treatment centers, and multiple clinical trials, pooled and investigated to bring sufficient data together to better understand the risk associated with this remarkable new treatment class
- Images and Algorithms Program: Imaging data from multiple cancer trials, provided by multiple sponsors, pooled and investigated to develop machine learning algorithms that will improve clinical trial execution

What's next for Project Data Sphere, LLC?

- Adding value to existing (and new) data through data curation and enhancement
- Investigating new approaches (like linked data) to bring more value to researchers
- Federated strategies for data sharing
- More data and more data types – images, genomics, ...
- More users



Register at
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