Project Data Sphere
Data Sharing in Cancer Research

Joel Beetsch, PhD
Faster Cures, November 4th, 2013
• The opinions expressed in this presentation are my own, and not that of either Celgene Corporation nor Project Data Sphere, LLC. The presentation is for informational purposes only. There are no representations or warranties expressed or implied, with respect to the usefulness or sufficiency of the information for the purposes of clinical trial sharing.
CEO Roundtable on Cancer

- To expedite cancer research
- What no single company might consider alone
- *Project Data Sphere, LLC* is a not-for-profit independent initiative
  - Transversal broad-access cancer data sharing
  - Unrelated to current PhRMA / EFPIA initiatives
GoldCorp Challenge
Challenge of Cancer

What would happen if we liberated cancer data?
Data Sharing: What can we achieve?

- **Transparency and….**
- Faster, more efficient research
  - Improved trial design and statistical methodology
  - Secondary hypotheses & epidemiology
  - Disease model development
  - Smaller trials sizing
- Reduced duplication
- Real World corroboration with Trial Data
- Data Standards & Meta-analysis
- Newly available analytics and insights
- **Unknowns**

1: Vickers 2006
FDA sees huge opportunities in opening up drug data

LONDON | Mon Dec 5, 2011 9:23pm IST

(Reuters) - Regulators and drugmakers need to find ways to make more clinical data openly available, since vital knowledge about fighting disease is often locked away in confidential databases, the head of the U.S. drugs watchdog said on Monday. Food and Drug Administration (FDA) Commissioner Margaret Hamburg said opening up data to public scrutiny needed to be done selectively, given legitimate concerns among companies over commercial confidentiality, but more could still be done.

How do we do it?

Access Models: One size doesn’t fit all..

1. **Black Box, or Database Query model:**
   - May be suitable for some types of very sensitive health information

2. **Gatekeeper Model:**
   - PhRMA / EFPIA principles
   - Independent review board
   - Limited access, and broad data

3. **Broad Access Model:**
   - Immune Tolerance Network, Sage Bionetworks, and *Project Data Sphere*
   - No applicant review panel and responsible-use attestation
   - Broader access, but less data. Data integration. Crowd.
Project Data Sphere’s choices over the past 2 years

Broad access, voluntary transversal NFP platform

- Academia & Commercial
- Cancer, Comparator Arm Data - feasible
- Unified provider / user agreements
- Open IP to drive innovation
- Integration, Analytics & Competitions
- What about Privacy...?
Expert Determination: Suppression & Generalization

Figure 2. Re-identification rates for various countries and distribution of ethnicities.

1: Malin B, PhD. data on file
Introducing the Project Data Sphere Initiative

Brilliant minds and valuable data together in one location.

WATCH THE VIDEO

Researchers are working tirelessly and new advances are constantly being discovered, yet every day, tens of thousands of our loved ones lose their battle with cancer. Sadly, we’re losing nearly the same number of people today as we were 40 years ago. With researchers working independently, we’re simply not finding solutions quickly enough.

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

The Project Data Sphere Initiative provides a universal platform built to responsibly share and analyze control arms of historical cancer trial data sets so we can learn from them and accelerate future research. It is an evolving project and we value your feedback to continue to develop the platform. The easy-to-use database is accessible to researchers affiliated with life science companies, hospitals, and institutions, as well as independent researchers.

Imagine what could happen if the cancer community joined efforts.

Get Involved

APPLY TO USE AND SHARE

APPLY FOR ACCESS

SPREAD THE WORD

SHARE THE VIDEO
Access Data

Instructions: Search fields have been provided to narrow search results, however these are optional and not required to display search results. Selecting or inputting criteria will provide matching results only. Inputting no criteria will return all results.

The Resources section of the website contains how-to guides and other information to help you provide and access data.

Search the text in the Trial and Data Summaries

Search

Additional Search Criteria

Age Range
- None
- Adult (18-65)
- Elderly (66+)

Cancer Stage
- Stage 0
- Stage I
- Stage II
- Stage III

Trial Start Year
- 2000
- 2006
- 2007
- 2008

Region
- Africa
- Asia-Pacific
- Europe
- North America

Study Type
- Clinical Study Phase III
- Clinical Study Phase IV

Trial Summary and Conditions: This was a randomized, controlled, double-blind, placebo-controlled, phase 3 clinical trial evaluating the efficacy and safety of sintilax plus prednisone (SP) versus placebo plus prednisone (PP) in subjects with CRPC whose disease failed treatment with a docetaxel-based chemotherapy regimen.

2. A Randomized, Double-Blind, Multicenter Phase II/III Study to Compare the Efficacy of Cediranib (AZD2171) in Combination With 5-Fluorouracil, Leucovorin, and Oxaliplatin (FOLFOX) to the Efficacy of Bevacizumab (Bev) in Combination With FOLFOX in Patients With Previously Untreated Metastatic Colorectal Cancer.

Trial Summary and Conditions: With the exception of patients with locally advanced or metastatic CRC that can be resected, the median survival time for patients with metastatic CRC is less than 2 years. The study evaluated the efficacy and safety of cediranib plus FOLFOX compared to bevacizumab plus FOLFOX in patients with metastatic CRC.

3. A Randomized, Open-Label, Multi-Center Study of XIP6258 at 25 mg/m² in Combination With Prednisone Every 3 Weeks Compared to Mitoxantrone in Combination With Prednisone For the Treatment of Hormone Refractory Metastatic Prostate Cancer.

Trial Summary and Conditions: Based on a very good pre-clinical activity, a favorable safety profile in addition to the early activity observed in prostate cancer and taxane resistant Metastatic Breast Cancer (MBC) patients, it was hypothesized that cabaptecan in combination with prednisone may prolong survival in prostate cancer patients who failed a docetaxel containing regimen.

4. A multicenter, phase III randomized trial comparing TAXOTERE administered either weekly or every three weeks in combination with prednisone versus mitoxantrone in combination with prednisone for metastatic hormone-refractory prostate cancer.

Trial Summary and Conditions: Promising results have been reported with Docetaxel in Hormone Refractory Prostate Cancer (HRPC) in terms of objective response in measurable lesions, ilio pelvic response (pelvis, anal/rectal, iliac nodes, symptom control), and PSA decline of more than 50%. These results, which compared favorably with data from other cytotoxic combinations reported thus far, should now be confirmed and further prospectively investigated through a multicenter randomized phase III trial.

5. A Multicenter, Randomized, Double-Blind Study Comparing the Efficacy and Safety of Axitinib Versus Placebo Administered Every 3 Weeks in Patients Treated With Docetaxel/Prednisone for Metastatic Androgen-Independent Prostate Cancer.
<table>
<thead>
<tr>
<th>Outcome Measures (Maximum number of characters: 1000)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Overall survival, progression-free survival, response rate, adverse events.</td>
</tr>
<tr>
<td>Total Study Enrolled Patients</td>
</tr>
<tr>
<td>Randomization</td>
</tr>
<tr>
<td>Blinding Method</td>
</tr>
<tr>
<td>Intervention Type</td>
</tr>
<tr>
<td>Data Set Type</td>
</tr>
<tr>
<td>Cancer Stage</td>
</tr>
<tr>
<td>Study Phase</td>
</tr>
<tr>
<td>Tumor Type</td>
</tr>
<tr>
<td>Region</td>
</tr>
<tr>
<td>Age Range</td>
</tr>
<tr>
<td>Study Start Year</td>
</tr>
<tr>
<td>ClinicalTrials.gov ID</td>
</tr>
</tbody>
</table>

**ClinicalTrials.gov URL**


**Uploaded By**

First Name: Ronit  
Last Name: Simantov  
Email: Ronit.simantov@pfizer.com

**Available Downloads:**

*PDF, ZIP, All Data, Protocol, CRF, Individual Files*
Analysis Tools

As part of the Project Data Sphere initiative, researchers will have available at time of launch SAS® analytical tools to help them explore and analyze the available data. Access the tools using the links below.

- SAS® Visual Analytics
- SAS® Drug Development
- SAS® Clinical Data Integration

5 Data Sets Available
Help us achieve our goal of 50 data sets in the next 12 months

The 2014 Project Data Sphere Prostate Cancer Challenge webinar
Where are we?

1. **Build the Platform**
   - How / Legal / IT / Analytics / Governance NFP
   - Value of the framework, not only data
   - [Green checkmark]

2. **Provide Initial Data – De-id**
   - Critique – only comparator arm, non genomic Initial heterogeneity.
   - But it's feasible, we have a vehicle
   - [Green checkmark]

3. **Access Large Amount of Data**
   - How do we do it?

4. **Use the Data**
   - Competitions?
   - [In parallel?]
Are 50 open access datasets useful?

- Both failed and positive trials - CROs
- Disease models
  - Patient sub-groups
  - Disease data standards
  - Improved trial design and operations
- Cross study comparisons
  - Assessment of FDA submissions
  - Reduced duplication
  - RWD v clinical trial data
- Quasi-comparator arms – reduced trial sizes?
- Unknowns
Can we get the data? PoC in place

Tumor Type - TBD

- **Prostate**: 6
  - Org 1: 1
  - Org 2: 1
  - Org 3: 1
  - Org 4: 1
  - Org 5: 1
- **Breast**: 2
  - Org 1: 1
  - Org 2: 1
- **Colorectal**: 1
  - Org 3: 1
  - Org 4: 1
- **NSCL**: 1
  - Org 5: 1
- **Renal Cell**: 1
  - Org 6: 1
  - Org 7: 1
  - Org 8: 1

**Tumor Types**
- Prostate
- Breast
- Colorectal
- NSCL
- Renal Cell

**Organizations**
- Org 1
- Org 2
- Org 3
- Org 4
- Org 5
- Org 6
- Org 7
- Org 8
Competitions?

- *Project Data Sphere, LLC* platform
- Sage Bionetworks computational
- Prostate Cancer Foundation data & expertise
Summary

Project Data Sphere, LLC

- Broad access not-for-profit transversal research repository
  - Share, integrate & analyze historic cancer data: academia / industry
  - Addresses privacy and intellectual property challenges
  - Uniform legal agreements covering sharing and use
  - State of the art analytics with simple infra-structure

- Benefits may include:
  - Leveraging past learnings for future trial design
  - Disease model development
  - Development of novel methodologies and secondary hypotheses
  - Disease area standards
Free Data, Fast Competitions, and Plagiarism...

Sources:
4: Sage---DREAM Breast Cancer Prognosis Challenge. 154 participants, 27 countries
Project Management Office:

info@projectdatasphere.org

www.projectdatasphere.org - coming soon