

Access to Peers
Access to Knowledge

D·S·E·C

Drug Safety Executive Council

The leading membership of pharmaceutical drug safety executives and scientists

Increase adoption and sales of your platform by:

- Gaining input into from multiple pharma companies on product design and business model
- Accessing a "pre-approved by industry" process for scientific validation
- Leveraging an accessible set of real world compounds with data
- Utilizing the aggregated data set for more powerful validation
- Building credibility and trust with multiple pharma companies by working collaborative with them to integrate your platform into their decision making process

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Collaborative Technology Evaluation (CTE) Case Study: The Impact of Collaborative Evaluation, Optimization and Validation of Novel Technologies

Introduction

Is partnering with multiple technology experts from large pharma valuable in creating a market for your new technology? And if so, in what ways is the value manifested; increased sales, better customer definition, application validation? The following is a quick example of the many areas of potential value derived from a recent collaborative technology evaluation which brought together experts from multiple pharma companies with those of a new technology vendor.

Vendor Situation

Typical new technology company situation, i.e. innovative science, limited resources, finite runway, struggling to get industry's attention, and the need for large scale validation (qualification) with 'real world' examples.

The vendor's novel *in vitro* test system was designed to quickly screen new molecular entities for toxic liabilities:

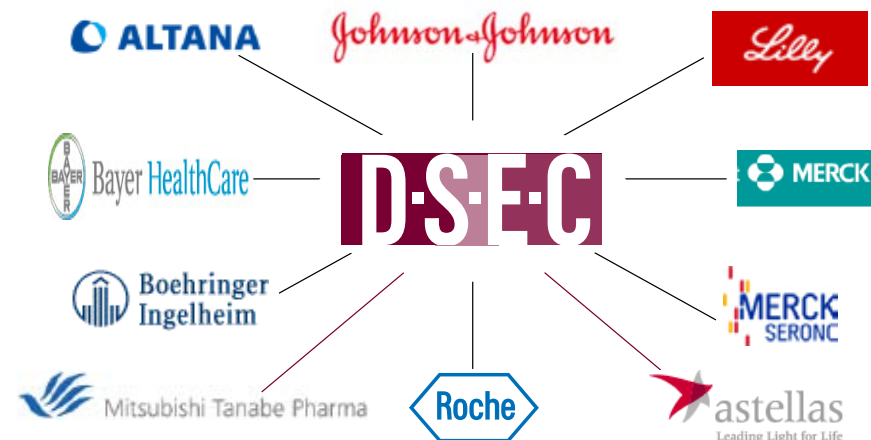
- Promising cell based assay developed, but with no clear vision of how to best apply the technology or leverage the results
- The new test system had the potential for discovering 'bad actors' very early on before the time and expense of *in vivo* animal studies.
- The test system was designed to provide insights into mechanistic pathways and similar patterns of toxicity to known toxic compounds
- Both applications required extensive scientific validation for full utility
- In addition, there needed to be better definition of who were the customers (high throughput screeners, safety scientists, chemists, etc.) and was the system optimized to meet those customer's needs

CHA's collaborative approach to technology evaluation is a proven method to generate high-quality leads that convert into paying clients.

– Dr. Lans Taylor, CEO, Cellumen (CTE sponsor)

Collaborative Technology Evaluation

Bringing 10 companies to work together in a facilitated and non-competitive forum to evaluate a novel, cell-based assay



The Process:

- Collecting 107 drug candidate NMEs from participating companies (~ ten from each partner, all samples blinded before forwarding to vendor)
- In addition, *in vivo* toxicology results for 102 of the compounds (based on 143 rat tox studies) were submitted by the partners to be used in the correlation analysis against the cell-based assay results

DSEC Project Team

Ernie Bush, Ph.D., Vice President, Collaborative Projects, The Drug Safety Executive Council



Ernie has over 23 years experience in biomedical R&D, including 1992 to 2005 he worked at Hoffmann-La Roche, Inc. and for the last 5 years of that time he led their Non-Clinical Drug Safety Department. Ernie has been asked to lead several global initiatives on safety information management practices, including a global safety LIMS system at Roche and a global information repository for toxicogenomics data for the International Life Sciences Institute (ILSI). His in-depth knowledge and broad experience in both the informatics and safety assessment fields has made him a unique leader in today's complex drug development landscape.

Eric Glazer, MBA, Managing Director, Drug Safety Executive Council



Eric Glazer has been a leading organizer and manager of collaborative initiatives within the biopharmaceutical industry for over thirteen years, and is one of the visionaries behind the Drug Safety Executive Council (DSEC). Eric manages day-to-day operations of DSEC including project management, member relations, member recruitment, DSEC events and client services.

- Screening the compounds at the vendor facility
- Analyzing the results both utilizing the vendors software tools and independently by Cambridge Healthtech Associates (CHA), the organizers of DSEC
- Conducting a summit to reach consensus on the areas of strength, weakness and ways to optimize the value to the customer

Timeline

- March 30, 2007 all compounds received for analysis
- June 10, 2007 all lab analysis completed
- July 17, 2007 member summit to review results and reach consensus
- September 20, 2007 final report completed

Results

- A first generation classifier was developed by the vendor
 - 100% accurate at identifying compounds with high *in vivo* toxicity
 - 85% accurate at identifying compounds with moderate *in vivo* toxicity.
- The overall conclusion was that the system has very strong potential to produce an effective safety ranking system, especially those that show very toxic behaviors
- Vendor learned of needs of customers and defined proper customer target
- ROI > 300 % in first year when four pharma companies converted to clients
- Project generated over \$1M in new funding
- Renewals (retention) resulting in a an even greater multi-year ROI

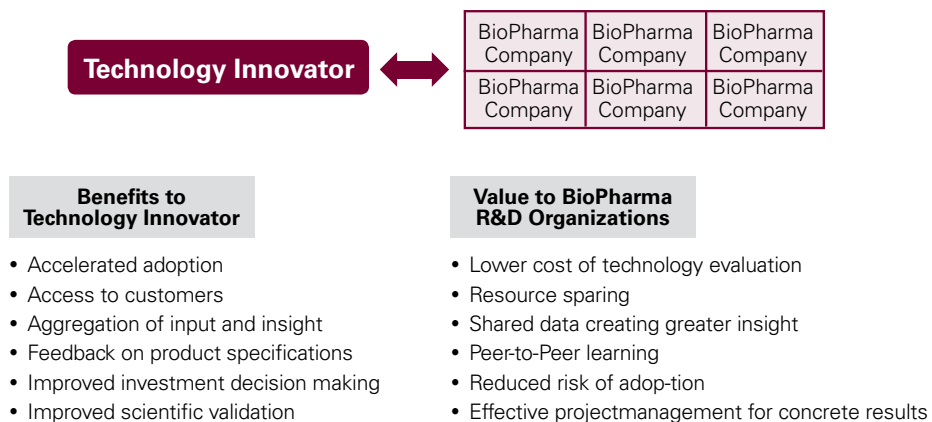
Intangibles

CHA has conducted many collaborative evaluation projects and consistently one of the most positive areas of feedback has been the value of meeting at the table with a group of peers from across the industry. Both from a vendor perspective and the user/customer perspective, this opportunity to interact as a group in defining the optimal experimental protocols, conducting the testing and evaluating the results is often rated as the most valued outcome of the project. The quality of the outcomes clearly benefits from the wisdom of the combined expertise. In addition, the relationships generated with pharma companies, even the ones who do not immediately convert to clients, become qualified leads (aka prospects) who may have long term value to the vendor.

Summary

The impact of a well executed CTE can not only **increase a life science technology or service provider's customer base** and market exposure, but also help **define the optimal marketing strategy and product definition**. It helps validate the utility of the technology while simultaneously building strong relationships with the experts in the industry. There are few, if any, other tools available to new technology vendors that can offer such high returns for your investment so early in the product sales cycle.

CTE = A Win-Win Value Proposition



The consortium approach is a very powerful model to evaluate new technologies.

– Dr. Stefan Mueller, Senior Toxicologist, Merck Serono Research