CLINICAL LEADER

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Can We Improve On ClinicalTrials.gov?

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Today, patients and pharma professionals looking for information on clinical trials generally visit ClinicalTrials.gov, a website run by the National Institutes of Health (NIH). On the site, users can search by condition/disease, country, and other keywords. Patients can find studies in which to participate, and researchers are able to find information on more than 250,000 studies being conducted in the U.S. and 200 other countries.

But is it time for a new database that better meets the needs of pharma executives and researchers? Beau Bush thinks so. Bush is an industry veteran, having spent over eight years identifying and forecasting growth opportunities for Johnson & Johnson. Today, he is president of Ozmosi, a consulting services company specializing in forecasting and predicting trends for pharma and biotech clients. More recently, the company has been moving into the area of data services and launched GlobalClinicalTrialsData.com

"The database really came about from a need that my team identified internally," says Bush. "We spend a lot of time cleaning up messy data for clients and helping them make strategic decisions about their trial development. What we hope to impact and influence with this new database is more robust clinical trial development throughout the industry."

To get to a more robust level of clinical development, Bush believes the industry requires greater transparency. If for no other reason, greater transparency would reduce the amount of redundancy that exists in drug development. That desire for greater transparency was the overall impetus for GlobalClinicalTrialsData.com.

More Data Is Needed

"Clinical research has changed dramatically," says Bush. "We no longer simply treat breast cancer. We take a deep look at the cancer to see how we can apply the best treatment for it. When researchers look at what other companies are doing, they might want to know the enrollment criteria, number and detail of study arms, patient groups being targeted, inclusion and exclusion criteria, biomarkers are being used, and primary and secondary endpoint details. Although it could be added at some point in the future, that type of information is currently not available on ClinicalTrials.gov – even if you perform a full download. Having that information will also help researchers better understand the results of trials."

When talking to Bush, you find he never speaks poorly of ClinicalTrials.gov. He will tell you that stems from his understanding of how hard it is gather this type of data. He also notes there are many people making use of ClinicalTrials.gov, and most are satisfied with the information it provides. For each person complaining about the site, he says there are many more benefitting from the information. Still, when looking at trends across the entire drug development industry, he notes there is "juicy," text-heavy data that is missing from the site's downloads for analysis.

The missing data Bush refers to is detailed descriptions about trials as well as the different arms of trials. Bush uses algorithms to extract keywords from trial descriptions in order to categorize and segment trials. Once Bush developed the tools he needed to extract the data, he needed a database to store the information. With his website, clients are now able to filter data, dig into trials, and produce answers to their business questions.

"ClinicalTrials.gov is clearly the industry leader for trial information," notes Bush. "In crowded disease spaces where combination trials that use biomarkers are fighting to attract patients, clinical-stage companies are able to see where competing trials are located and what companies are conducting them. While some information is not very different from ClinicalTrials.gov, users will have access to analyzing additional information that previously only existed in private databases, if at all, and does not appear in the ClinicalTrials.gov downloads.

Trial Design Insights Are Possible

Bush performs a lot of work in the area of trial design and believes this is an area where companies require additional insight. Competitive intelligence is critical to allowing companies to strategically develop their pipelines. The insights companies can get from GlobalClinicalTrialsData.com include the best endpoints to explore, what patients groups to include, what biomarkers should be included, and what diagnostic tests are needed. In short, if companies know what their competitors are doing, they will be able to make better trial decisions.

There is no cost to use the site, which carries the tagline, “Free Data Should Be Free.” “We aggregated the free data for our databases and felt it should remain free,” says Bush. “This is why we enable anyone to use the information contained in the database.”

Bush notes GlobalClinicalTrialsData.com also features a simple interface which has been streamlined to include only one search box. That could be both a good and a bad feature, as some users who are comfortable using ClinicalTrials.gov might feel the new database is too simplistic.

My search on the topic “prostate” returned a list of over 5,300 studies with trial name, condition, interventions, Phase, and GCT ID. Clicking on the trial name brings up additional information such as start and completion data, trial location, trial description, and source URL. One simple download puts all available information into one Excel spreadsheet.

“You can never make everyone happy,” adds Bush. “We attempted to find a middle ground. Users will use one simple search box but will have the ability to filter results by a few different elements, such as relevance, first received, last updated, and an advanced search option. Additional elements will likely be added at a later date. We are hoping to hear feedback from users on how we can improve the database going forward. Our goal was for this to feel no different than performing a Google search.”

Patients are free to use the site as well, although Bush notes the database is not currently pulling main contact information or a list of clinical sites conducting the trial. That is another feature he hopes to add in the near future.