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April 2014



BioMarketing Insight Newsletter

Creating Markets and Marketing
Strategies

Dear Regina,

Welcome to BioMarketing Insight's monthly newsletter.

Last month I discussed Today's Definition of Genomics and It's Translation into Medicine. If you missed last month's article, click [here](#) to read it. So now you've sequenced the whole genome and generated this Big Data, how can you use this data to your advantage? Find out how companies are using Big Data to their advantage in this month's newsletter.

Read on to learn more about this topic and other current news. On the right are quick links to the topics covered in this month's newsletter. The next newsletter will be published on May 15th.

We encourage you to share this newsletter with your colleagues by using the social media icons at the top left, or by simply forwarding the newsletter via email.

Please email [me](#), Regina Au, if you have any questions, comments, or suggestions.

Sincerely,
Regina Au
Principal, Strategic Marketing Consultant
[BioMarketing Insight](#)

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Save the Date: April 28th - 29th, 2014 - Medical Informatics World Conference

Second Annual
**Medical
Informatics
World Conference**
2014

April 28 - 29, 2014
Seaport World Trade Center | Boston, MA

Transforming Care Delivery Models with IT Innovation
Presented by Cambridge Healthtech Institute and Bio-IT World

The healthcare industry goal, particularly for those classified as Accountable Care Organizations (ACOs), is to deliver quality healthcare and reduce its cost. It is believed that the goal will be achieved through the coordinated efforts of all stakeholders: providers, payers, patients, and pharma by way of electronic medical records used to analyze and stratify patients into various risk management groups. Risk group information will be used to tailor specific treatment programs that both ensure quality care and control costs. This meeting will focus on innovative solutions that include biomedical sciences, health informatics, and IT.

I will chair the session on "Patients and Consumers Managing Their Own Data," on Monday, April 28th at 1:55 pm under the Coordinated Patient Care, Engagement and Empowerment Program track. The Program is designed to show healthcare providers how to engage patients and encourage them to be more proactive in their healthcare and will include remote healthcare monitoring for early detection, health care portals for patients to access their medical records and information via automated communication and feedback to for specific diseases, all customized for patient involvement.

I look forward to seeing everyone at the end of the month!

Click [here](#) for more details.

For full information on the conference, click [here](#).

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How You Can Use Big Data to Your Advantage in the Life Science Industry

Other industries have been using Big Data for data mining and making predictions for the stock market, the auto market, the retail market, the election and the box office. So how can the life science industry use big data to its advantage and speed up development of drugs, recruiting patients for clinical trials, targeting patients with specific disease more effectively and other uses?

[McKinsey & Co.](#), predicts that Pharma using Big Data, could reduce R&D costs by \$40 billion to \$70 billion. "An era of open information in healthcare is now under way," McKinsey said in a research about the big data revolution."

There are now thousands of patient communities online and grouped by various diseases. PatientsLikeMe.com connects more than 220,000 patients in more than 2,000 condition groups. The Association of Cancer Online Resources links more than 200 cancer support groups.

Big pharma/biotech has already started partnering with health care data companies to explore ways in achieving efficiency in the following areas in bring drugs/biologics to market faster:

1. Targeting patients more effectively when treating diseases

[AstraZeneca](#) is partnering with HealthCore, the health outcomes research subsidiary of WellPoint, Inc., to conduct real-world studies designed to determine how to most effectively and economically treat disease. "We are seeking to answer a fundamental question with this research: How can we improve overall patient health while lowering the total cost of care - especially in the treatment of chronic diseases?" said James W. Blasetto, M.D., AstraZeneca vice president of U.S. strategic development. "In doing so, the research will help drive the development and delivery of medicines with clear value to patients and payers, creating an opportunity to change the focus of the healthcare conversation from cost to value."

2. Access to Clinical Trial Data

In 2013, [GlaxoSmithKline](#) partnered with SAS Institute Inc., a health analytic company to provide a secure online data and analysis environment that allows researchers to gain access to patient-level clinical trial data in accordance with the idea of pharmaceutical data transparency in hopes of speeding up the development of drugs and biologics.

[Project Data Sphere](#) (PDS), a new Big Pharma consortium comprised of AstraZeneca, Bayer, Celgene, Johnson & Johnson, Pfizer, Sanofi and Memorial Sloan Kettering Cancer Center formed to make available raw clinical trial data to researchers.

The PDS initiative, was born out of the CEO Roundtable on Cancer's Life Science Consortium designed to be a single place where the cancer research community can share and analyze de-identified, patient-level data from late-stage comparative studies.

The goal in providing access to historical clinical trial data is to help other researchers better understand disease progression, accelerate drug development or design more efficient clinical trials. The site was launched April 8, 2014 and includes nine data sets from the founding companies.

3) Recruiting patients for clinical trials more efficiently

[Pfizer Inc.](#), Eli Lilly & Co. and Novartis AG are partnering to improve the clinicaltrials.gov website by making it more effective at matching patients to studies. Identifying a suitable clinical trial for a patient is currently a manual process, but with electronic health records (EHRs) this process can be automated. The plan is to include a machine-readable "target health profile" for each clinical trial so



that software can find patients with EHRs that fit the basic inclusion criteria.

[BioClinica](#) announced a partnership with NNIT, a Life Science IT solutions company to implement and integrate BioClinica OnPoint CTMS (Clinical Trial Management System) and Microsoft® SharePoint for international clinical trial sponsors. CTMS applications address the management of business and operational processes for clinical trials which include: clinical site management; personnel, patient and clinical supplies administration; scheduling, tracking and performance monitoring; site payments, study document management; and more.

"Our goal (is to) bringing the science of managing clinical trials into the 21st century," said Peter Benton, eClinical President for BioClinica. "The unprecedented pressures on clinical research require accurate, flexible and reliable tools to manage cost and risk. This necessitates better technology."

4) **Decreasing R&D time and cost, bringing drugs to market faster**

Now that we can sequence the whole genome, Pharma and Biotech have turned to bioinformatics as the key to speeding up R&D. [Jay Flatley](#), CEO of Illumina, explains why in an interview in the tech publication *Re/code. The New England Journal of Medicine* April 2014 issue looked at "results generated by sequencers from Illumina and Complete Genomics--now part of BGI--and found several weaknesses. For the authors, these flaws--which include incomplete coverage of inherited genes and low reproducibility of detection of genetic variation--suggest sequencing must improve before it is clinical grade."

Flatley acknowledged that there needs to be improvement. "What's hard is to determine whether there's a base inserted or deleted. That's a bioinformatics problem, not a sequencing problem. That's a software issue that we and others and the whole world is trying to work on," Flatley said.

Pfizer has teamed with the Broad Institute, outside experts in identifying targets or target validation.

[GlaxoSmithKline](#) partnered with the European Bioinformatics Institute (EMBL-EBI) and the Wellcome Trust Sanger Institute to establish the Center for Therapeutic Target Validation (CTTV). The basic goal is for EMBL-EBI to mine through the combined data of genomics, proteomics, chemistry and disease biology data to find new therapeutic targets.

CCTV will share its sequencing data publicly, potentially providing a platform for drug development at GSK and its competitors. "If you can double the base knowledge then you've de-risked things enormously, though you've still got to make your judgment in your invention. It is not going to give you all the answers but it is going to increase the chance of getting it right," GSK's pharma R&D head Patrick Vallance told Reuters.

Discussions of collaborating in early stage drug discovery, base knowledge, or pre-competitive space have been well-received by a number of Big Pharma companies and various initiatives have been formed for this purpose. The Wellcome Trust and GSK are also involved with the Structural Genomics Consortium, and all of the European health care system is contributing to the Innovative Medicines Initiative. Eli Lilly, Johnson & Johnson and Merck applied these same principles to their clinical trial investigator database and this grew into a Big Pharma consortium called TransCelerate BioPharma.

GSK established CCTV and took the lead in bringing more drug makers and academic institutes together. "I fully expect others to join. But it seemed sensible to get started right away rather than spend two or three years trying to get lots of other people involved," Vallance said.

[Berg Pharma](#), a Framingham, MA start-up co-founded by Silicon Valley real estate billionaire Carl Berg, is taking it one step further. Berg claims his company is capable of "revolutionizing" healthcare. President and chief technology officer Niven Narain says that Berg Pharma can cut the time, and expense, of drug development "in half." With three divisions, an in-house diagnostics unit and about 200 employees, the six-year-old company looks like an established biotech player. The company has a drug discovery platform with development programs in cancer, diabetes, and Parkinson's disease.

"We see ourselves as fertilizing the Big Pharma community with great, validated clinical assets that can be marketed that are much more safe and effective," Narain says.

Berg Pharma claims to have the secret sauce methodology by combining elements of biological models, Big Data analytics, artificial intelligence, genomics, proteomics, lipidomics, and metabolomics.

"There are companies that do genomics, companies that do systems biology, who do computational modeling, and who do AI [artificial intelligence], but there's not one company that's taken all the elements at play in one complete concentric platform that's using it as robustly in medicine as we are," Narain says.

4) Other areas of efficiency

The Office of Science and Technology Policy (OSTP) revealed it is using Big Data to predict pandemics. The OSTP project will combine outputs from sensors with existing data and develop tools to analyze the information.

The Centers for Disease Control ([CDC](#)) launched the "Predict the Influenza Season Challenge," a competition designed to foster innovation in flu activity modeling and prediction in late 2013. The goal of this challenge is to "encourage exploration into how social media data can be used to predict flu activity and supplement CDC's routine systems for monitoring flu." One local [Massachusetts group](#) demonstrated that using social media such as Twitter could predict flu trends and try to intervene before there is a flu epidemic.

Government and other organizations initiatives

Helping to drive these partnerships to use Big Data and find more efficient ways to bring treatments to market is the White House's "Big Data Research and Development Initiative," a \$200 million effort that seeks to greatly improve techniques used to extract insights from large and complex collections of digital data.

With the idea of "open source", The National Institutes of Health has made the world's largest set of data on human genetic variation, the 1,000 Genomes Project available on the Amazon Web Services cloud for free. Other organizations, such as the [Allen Institute for Brain Science](#), are building an open, online, interactive atlas of the human brain to find cures for neurological disease faster.

The amount of data being generated today is exploding and will continue to rise exponentially, but the challenge that pharma/biotech faces is their ability to weave the many threads into useful and accurate information that will result in decreasing the time and money required to market better drugs/biologics. At the end of the day, can we count on Big Data to decrease health care costs?

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Closing Thoughts

I believe our industry is almost at a "tipping point," where drug/biologic development is going to take off and usher in better treatments for patients and bring us a step closer to phenotype personalized medicine. I emphasize that we are only approaching this tipping point, because the industry is just beginning to understand what we need to get there.

- We know we need to understand diseases better and that collaborations and partnerships to conduct basic research will continue to form between academic institutions and



"Human genetics is not just a tool for understanding biology," said David Altshuler, deputy director and chief academic officer at the Broad Institute and a professor at Harvard Medical School. "It can also powerfully inform drug discovery by addressing one of the most challenging and important questions - knowing which targets to go after."

To read the full article in *Bloomberg*, click [here](#).

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About BioMarketing Insight

We help companies de-risk their product development process by conducting the business due diligence to ensure that it is the right product for the right market and the market opportunity for the product meets the business goals of the company. We can then develop marketing strategies to drive adoption for the product.

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