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## Offshoring Clinical Trials and Clinical Data Management – Are You Running?

*EDC Today is an independent publication on current information and issues in Electronic Clinical Systems (ECS) strategies and technologies for the Biotechnology and Pharmaceutical (Biopharma) industry. Each month we examine topics related to ECS theory, technology, practice, or implementation.*

*EDC Management has been a service provider for several years in the eClinical Research arena, and is intimately familiar with the global nature of the biopharmaceutical industry. Having recently read Thomas L. Friedman's book *The World is Flat*,<sup>1</sup> and having experienced the offshore movement of IT jobs, EDC Management has decided there is a need to discuss this book, and the potential ramifications of a world that has been flattened (or in which the playing field has been leveled) on eClinical professionals.*

*In this issue, we summarize Friedman's main points, highlight some of the developments in the biopharmaceutical industry that show Friedman's discussion in action, and describe some of the pros and cons of the flattening movement. In the end, what develops can be an opportunity for those who can adapt and capitalize on the movement. However, it is clear that complacent eClinical professionals will encounter stiff competition for their jobs soon if they have not already.*

### Introduction

It is clear that many jobs that were once the mainstay of the United States economy have migrated to other countries. Many, if not most, of the manufacturing jobs are being done elsewhere, and the U.S. manufacturing community has dwindled. One needs only to look at the steel industry to see a prime example of such a migration. Other jobs, including many professional jobs such as science and engineering have also seen a steady move to other parts of the world.

Thomas Friedman, in his book *The World is Flat*, says information-related jobs are moving to areas where the labor pool is less expensive. Friedman elaborates on ten forces that he believes have contributed to the flattening. These forces include: the fall of the Berlin Wall; the rise of Netscape and the dotcom boom that led to a trillion dollar investment in fiber optic cable; the

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*EDC Management is the leader in Clinical and Data Management and Electronic Data Capture (EDC) consulting services for the biopharmaceutical industry. EDC Management publishes well-researched and timely information about Electronic Data Capture technologies and processes through EDC Today<sup>®</sup> and EDC In Depth. We do not sell or endorse any specific EDC software application or vendor. Improve process today; position for tomorrow.*

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emergence of common software platforms and open source code enabling global collaboration; and the rise of outsourcing, offshoring, supply chaining and insourcing. The result of the flattening is that anyone that has a good data connection to the internet can perform information based jobs anywhere in the world, even where there are no roads or no office buildings.

There are two current examples of large pharmaceutical companies offshoring major portions of clinical data management, Wyeth and Pfizer. Wyeth has a long term arrangement with Accenture to perform data management in India. Pfizer has an arrangement with Cognizant to do similar services.

What does this mean for the U.S. eClinical professional? As Friedman puts it, they have to work harder and faster to remain employed. As companies find they can get the same work performed more inexpensively elsewhere, it will be up to the clinical data professionals to prove they can do better work and are worth their salaries. Otherwise, a decrease in the number of U.S. based jobs and a reduction in compensation awarded for those jobs will happen. Essentially, competition for U.S. clinical data professional jobs has increased from tens of thousands to hundreds of millions.

This issue will describe the major points of Friedman's book followed by some examples from a recent Business Week article of offshoring in general. It will examine examples of the globalization of clinical data professional's jobs as well as describe the potential impact on U.S. based jobs in general. Finally, EDC Management wants to stress that even though the future is not predictable, it is in U.S. eClinical professionals' best interest to expand their skills or move into areas where they can capitalize on the shift in the labor force.

## **Friedman's *The World is Flat***

*The World is Flat* is a testimony to the rapid change of events in our world. Many Americans know that a large number of U.S. companies have moved major portions of their operations out of the U.S. However, the "service economy" mindset of many Americans has probably kept them from seeing these jobs becoming global at the rate they have. Friedman entitles the first chapter of his book "While I was Sleeping." Perhaps others have been sleeping through these changes too.

Friedman presents a number of examples of the globalization affecting professional jobs. One such example is in the accounting industry. Friedman speaks of Jaithirth Rao of the India firm MphasiS, which has been working with a number of American accounting firms doing tax returns. Rao says:

We are doing several thousand returns. Your CPA in America need not even be in their office. They can be sitting on a beach in California and email us and say, "Jerry, you are really good at doing New York State returns. So you do Tom's returns. And Sonia, you and your team in Delhi do the Washington and Florida returns." Sonia, by the way, is working out of her house in India, with no overhead [for the company to pay]. And these others, they are really complicated, so I will do them myself.<sup>2</sup>

Friedman states the following statistics:

In 2003, some 25,000 U.S. tax returns were done in India. In 2004, the number was 100,000. In 2005, it is expected to be 400,000. In a decade, you will assume that your accountant has outsourced the basic preparation of your tax returns – if not more.<sup>3</sup>

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Hard to imagine something so American as personal U.S. tax returns being done offshore. But it underscores the point that Friedman is making – if the information needed can be put in electronic form, the work can be done anywhere internet connectivity is available.

In addition to giving examples of work that is being done globally, Friedman describes what he believes are the catalysts behind the “flattening” of the world. These forces were mentioned in the introduction and it is sufficient to say that the combined effect of each of these forces has been to make global collaboration possible. One of the earlier forces he lists is when Netscape went public. He says this opened the internet to public accessibility. He also credits workflow software for allowing people to work together, and the general movement of open sourcing, where diverse people can collaborate to build better software (e.g. Linux).

However, these forces would not be sufficient if businesses had not started outsourcing in the first place. Many firms in America, witness Ford Motor Company as an example, spent many years trying to incorporate all aspects of the production of their products within their own company, even to the point of producing their own steel. The currently hot concept of shedding tasks not central to “core” business is a somewhat recent innovation. Once certain functional tasks have been outsourced, the door was open to sending the work further away, and eventually offshore.

Insourcing is an extension of outsourcing. Friedman describes insourcing as giving small companies the ability to act like large companies. He describes how United Parcel Services (UPS) can provide logistics services to small companies that allow them to operate “big” business that deliver good and services world wide. Companies that provide insourcing are large companies that can leverage economies of scale, but act as extensions of their clients businesses.

Finally, Friedman concludes with the technologic inventions that make it all possible. One of the technologies he stresses is wireless technology. Wireless gives us the possibilities of going almost anywhere and being connected almost all the time.

The second half of Friedman’s book is devoted to exhorting people and governments to embrace the flattening of the world and find ways of using it to one’s advantage. We will discuss some ideas on how to do this in the clinical data management arena shortly.

## **Business Week**

In a Business Week article entitled “The Future Of Outsourcing,” Pete Engardio describes a number of more current examples of offshoring<sup>4</sup>. While the somewhat controversial thrust of the article is that offshoring can help business grow and create more jobs, it is clear that the main message is businesses have to find ways to reduce costs to remain competitive with firms that can and do leverage inexpensive offshore labor forces. Engardio says:

Ever since the offshore shift of skilled work sparked widespread debate and a political firestorm three years ago, it has been portrayed as the killer of good-paying American jobs. "Benedict Arnold CEOs" hire software engineers, computer help staff, and credit-card bill collectors to exploit the low wages of poor nations. U.S. workers suddenly face a grave new threat, with even highly educated tech and service professionals having to compete against legions of hungry college grads in India, China, and the Philippines willing to work twice as hard for one-fifth the pay.

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Workers' fears have some grounding in fact. The prime motive of most corporate bean counters jumping on the offshoring bandwagon has been to take advantage of such "labor arbitrage" -- the huge wage gap between industrialized and developing nations. And without doubt, big layoffs often accompany big outsourcing deals.

The changes can be harsh and deep. But a more enlightened, strategic view of global sourcing is starting to emerge as managers get a better fix on its potential. The new buzzword is "transformational outsourcing." Many executives are discovering offshoring is really about corporate growth, making better use of skilled U.S. staff, and even job creation in the U.S., not just cheap wages abroad. True, the labor savings from global sourcing can still be substantial. But it's peanuts compared to the enormous gains in efficiency, productivity, quality, and revenues that can be achieved by fully leveraging offshore talent.<sup>5</sup>

However, it is clear from the numerous reader comments on this article that not everyone agrees that offshoring is good for the American economy. One comment from a person nicknamed Praying Mantice (sic) states:

The real unemployment rate in the USA is 40%. The numbers by the government are fudged at 5% so the stock market doesn't crash. The truth to the matter is that due to taxes, social security, and federal taxes taken out of paychecks totaling 23% and then health benefits U.S. companies are moving overseas. Soon no cars will be built in the USA due directly to union wages and health care costs. When a job is posted here in the USA more than a 1,000 people apply with degrees and plenty of experience and obvious smarts. The simple truth is that there now are no jobs in America. It won't be long till Americans migrate out of America and it will be the "Reverse Ellis Island."<sup>6</sup>

However, some people think that American workers have it coming to them. One comment by Juan Valdez states:

That's the way the ball bounces. When a society develops its people become lazy and spend their time getting fat while glued to the TV remote control. Then the foreigners must take over and clean trash cans. The next generation will become lazy, and so on and so forth. Congratulations America. You got fat.<sup>7</sup>

No matter what one's opinion of the article, it does make one think. Could this be a good thing? Is it all necessarily bad? In the controversial article, Engardio says that offshoring is helping small companies as well as large companies. Engardio states:

Crimson Consulting Group is a good example. The Los Altos (Calif.) firm, which performs global market research on everything from routers to software for clients including Cisco, HP, and Microsoft (MSFT), has only 14 full-time employees. But it farms out research to India's Evalueserve and some 5,000 other independent experts from Silicon Valley to China, the Czech Republic, and South Africa. "This allows a small firm like us to compete with McKinsey and Bain on a very global basis with very low costs," says CEO Glenn Gow.<sup>8</sup>

To some extent, this is reminiscent of Friedman "insourcing" where a small company can look like a much larger company.

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## Biopharmaceutical Examples

There are two major examples of offshoring on a large scale that have taken place in the biopharmaceutical industry. The first example is Wyeth. The second example is Pfizer.

Wyeth has outsourced its clinical data management department to Accenture, who is utilizing personnel in India to perform the work. According to Scott Lundstrom of Contract Pharma:

In April 2003, Wyeth tapped Accenture again for an even more ambitious project. This time the companies entered into a 10-year risk/reward-sharing contract that many in the pharmaceutical and outsourcing industries deemed precarious and unattainable. The engagement marked a dramatic turning point in the clinical outsourcing market because, instead of keeping data management in-house or contracting with a CRO with data management expertise, Wyeth chose a specialist in business transformation to reengineer and manage global clinical data management (CDM) operations.

Specifically, the goal of the Wyeth-Accenture engagement is to improve clinical trial productivity in Wyeth's Phase II and III trials. Central to the engagement is a contractual commitment to delivering key metrics such as reducing the cycle time between last patient, last visit, and database lock by 80% and reducing contracted costs by more than 30%. To accomplish this goal, Accenture acquired Wyeth's clinical data management staff, put in visible metrics via monthly reports, and established strong, visible leadership for the life cycle of the project.

Despite the skepticism with which the Wyeth-Accenture deal was originally met, Wyeth's Clinical Operations group has again reported positive results. In April 2005, Wyeth announced that the number of IND applications has increased, cycle times have been reduced, and both Wyeth and Accenture are benefiting financially from performance metrics being on or close to plan.<sup>9</sup>

But what exactly is Accenture doing? According to Patrick McGee, Senior Editor of Drug Discovery and Development, they are offshoring the work:

[Wyeth and Accenture responded to the quandary of increased clinical data management needs by forming] the Alliance for Clinical Excellence (ACE), a separate entity created by Accenture to manage Wyeth's data, says John Shelton, assistant vice president of global clinical data management at Wyeth. For ACE, about 200 people from Wyeth joined Accenture and now work in centers in the United States, Europe, and other parts of the world. "We transferred a lot of knowledge and capability and relied on Accenture's ability to build the entry and validation capacity in Bangalore, which they have done." There are 400 employees in Bangalore, India, who handle data entry and editing. "We were either faced with the choice of making a significant internal investment in upgrading capability," says Shelton, "or finding another way of doing it. What we saw in Accenture was the ability to manage IT and transactional processing."<sup>10</sup>

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Similarly, Pfizer has contracted Cognizant in a smaller but still large deal. According to John Ribeiro of Bio-IT World:

Pfizer Inc. is outsourcing high-end business processes in clinical data management and biometrics to Cognizant Technology Solutions Corp., an offshore outsourcing company based in Teaneck, New Jersey, with operations in India.

Pfizer Global Research and Development, through its Indian affiliate, announced the multiyear business process outsourcing relationship on Monday. Cognizant will provide database design, data management, programming and clinical communication or medical writing as part of the deal.

Cognizant is initially committing 90 people to the Pfizer project, the bulk of whom will be staff holding bachelor's and master's degrees in pharmacy, statistics and analytics, according to a company spokesman. The staff will initially work out of Pfizer's facility in Mumbai[, India], though in about six months they will be moved to Cognizant's facility being set up in the city, the spokesman added.<sup>11</sup>

## Impact on eClinical Jobs

It is clear that biopharmaceutical companies are taking outsourcing and offshoring seriously. It is also clear that while there may be some setbacks along the way, offshoring will be here to stay. The real question is what the impact on eClinical jobs in the U.S. is.

One thing is clear. At minimum, more clinical research professionals will have to interact with workers from other countries in a collaborative fashion. Since clinical data management in the biopharmaceutical industry is a regulated industry, clinical professionals should be intimately acquainted with producing specifications. However, going forward, these specifications and other documents may have to be strengthened to allow someone from another part of the world to understand what is needed and to implement it.

EDC Today® Issue 33 on “Improving Communications” contains a number of tips for helping eClinical professionals. One of the more relevant sections of “Improving Communications” is the section on email. Email will become the predominate form of communication if only because of time zone differences. The time when Americans and people in India are at work simultaneously is minimal. Thus email will have increased importance. It is worth recalling the following from “Improving Communications”:

When using e-mail to communicate, always provide a complete context for your communication - please remember, e-mail is not a dialog and the recipient is not fully involved in your frame of mind. Also, some time will pass while an email is being delivered, read, answered, and returned. Do not assume you can simply resume an interrupted “give and take” session using e-mail without re-establishing context and a communicational goal.<sup>12</sup>

Thus in the short term the impact will be learning to work with more people who are not physically nearby. This will not only provide a communication hurdle for co-workers, but getting used to the concept of managing people remotely will be a challenge for management.

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Another short term impact will be on clinical data management system programmers. These people will have to contend with the distinct possibility that their jobs may be taken away from them. In this case, they may need to start positioning themselves to do other forms of work that cannot be outsourced, or find jobs with biopharmaceutical companies that will not be offshoring in the immediate future.

However, this is only part of the picture. The larger part of the picture is when will all of the functions of the clinical departments get sent overseas? There may soon come a day when protocols are not written in the U.S. Even before that will come the day when many data management documents are prepared overseas, including data entry systems and edit check specifications. In which case, everyone in the clinical arena should be aware that they may need to adapt their skills to other areas in the company.

## **Adapting to a Changing World**

These impacts point to an even bigger issue. As the U.S. economy trends in the direction of a global workforce, what can be done? What should be done? Who should be doing what?

The first thing an eClinical professional can do is to keep abreast of regulatory requirements and continue to learn new skills to keep his or her value to their company high. To some, this may be a scary thought. But as it is aptly stated in Friedman's book, there is no time to rest. Friedman quotes an African proverb that was posted in an American auto parts manufacturer's division in China:

Every morning in Africa, a gazelle wakes up.

It knows it must run faster than the fastest lion or it will be killed.

Every morning a lion wakes up.

It knows it must outrun the slowest gazelle or it will starve to death.

It does not matter whether you are a lion or a gazelle.

When the sun comes up, you better start running.<sup>13</sup>

Are you running? This may not be a comforting thought. Unfortunately, it is the way of capitalism. We have always had to deal with competition. The competition has become thousands of times more intense. And the hardest part for people in America is that it costs more to live here than it does in many other places of the world.

What else can be done? Improving communications skills are a must. It may even be in the best interest of an eClinical professional to learn a language other than English. It would certainly be useful to learn about the culture of countries where offshore work is being performed. In any case, EDC Management believes that Americans must learn to interact better with people from other countries.

*(continued on page 8)*



## Conclusion

The world is becoming flatter because of many forces, but most notably it is due to new technology. The flattening of the world is bringing many people together that can do similar kinds of work, and therefore are competing with one another for jobs. The competition provided by offshore personnel has an undisputable leg up on salary requirements given that the cost of living and likewise salaries are still very low in other parts of the world compared to the U.S.

EDC Management cannot predict the future. However, given that manufacturing has steadily moved out of this country, and that many of its college and university students are from other countries, professional and service based jobs will eventually follow the manufacturing jobs.

Currently there are factors that slow the shift of this work offshore. Some of these factors are legal issues such as Intellectual Property rights. Other factors are communication issues where offshore workers whose primary language is not English do not always understand what is being communicated. However, as Friedman points out, this will change because nations such as India and China see the enormous benefit to their economies to make American offshoring work well.

American businesses see the need for offshoring business functions that can be performed cheaper elsewhere. However, it remains to be seen if American workers can adapt to the increased competition or change to jobs that are harder to offshore. In general, jobs that are tied to a specific location are the most difficult to offshore. But even then, the competition may come from people that want to work and will work for less money immigrating to the U.S. An example of this is someone who cuts your grass. You cannot send your lawn overseas, but you can find people willing to come to your property to cut it fairly inexpensively.

The U.S. biopharmaceutical industry has already started moving to a global workforce. The American clinical professional will have to keep ahead of the movement. There will be no chance to rest. Are you running yet?

### Resources

<sup>1</sup> Thomas L. Friedman, *The World is Flat*, Farrar, Straus and Giroux, New York, 2005.

<sup>2</sup> *Ibid.*, p. 13.

<sup>3</sup> *Ibid.*, p. 13.

<sup>4</sup> [http://www.businessweek.com/magazine/content/06\\_05/b3969401.htm](http://www.businessweek.com/magazine/content/06_05/b3969401.htm)

<sup>5</sup> *Ibid.*

<sup>6</sup> *Ibid.*

<sup>7</sup> *Ibid.*

<sup>8</sup> *Ibid.*

<sup>9</sup> <http://www.contractpharma.com/articles/2005/11/clinical-industry-developments.php>

<sup>10</sup> <http://www.ddmag.com/ShowPR.aspx?PUBCODE=016&ACCT=1600000100&ISSUE=0602&RELTYPE=pr&origreltype=&cho&PRODCODE=00000000&PRODLETT=Ap&CALLFROM=NEWSLETTER&CommonCount=0>

<sup>11</sup> [http://www.bio-itworld.com/newsitems/2005/01/012405\\_report7239.html.news](http://www.bio-itworld.com/newsitems/2005/01/012405_report7239.html.news)

<sup>12</sup> EDC Today™, Issue 33, “Improving Communications”.

<sup>13</sup> Friedman, p. 114.



## Who's behind the research?

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Our lead researcher, Kirk Mousley, PhD received BS and MS degrees in Electrical Engineering from MIT and a PhD in Computer Science from Lehigh University. He has been the President of Mousley Consulting, Inc. since its founding in 1993 and has directed the company's efforts in the areas of clinical database design, data editing/cleaning, document management, and submissions.

Karl Mousley received his BS in Mechanical Engineering from Rose-Hulman Institute of Technology and a MS in Computer Science from Villanova University. He has been a senior member of the technical staff at Mousley Consulting, Inc. since 1993. Among his significant accomplishments are the investigation, evaluation, and implementation of new computer technologies for clinical data management systems and developing strategic plans for integrating these technologies into current systems. He has extensive experience preparing Standard Operating Procedures (SOPs).



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