

The Evolution of Computing in Clinical Research: Past, Present and Future

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ABSTRACT

If you are new to the biopharmaceutical industry, you probably wonder how some of the technologies you use each day became so widely adopted across the industry. You may also wonder what the future might hold for clinical research technologies and how future technology directions will impact your career.

This paper will help you understand the history and evolution of computing in clinical research at one large pharmaceutical company from both a computer software and hardware perspective. Similar technology evolutions occurred at other companies in the industry. This paper will not attempt to justify or defend the technology decisions that have been made in clinical research, but instead present the relevant facts from the history of their adoption.

Armed with this understanding of history, you will be better prepared to help shape the future clinical research technology decisions within your company, and quickly adjust to these technology transitions.

INTRODUCTION

History can teach valuable lessons. Looking back over my career in the biopharmaceutical industry, it's shocking to think how much valuable company time and resource was expended debating about the proper technologies to use for a particular business purpose.

A relevant example today is the purchase of a smartphone - whether to buy the latest Apple iPhone or the latest Android device. When making a purchase decision, some people spend countless hours studying the features and benefits of these products. For the most part, both devices provide excellent user experience in terms of functionality, application availability and ease-of-use. Of course, some differences in functionality do exist and each individual in the market for a smartphone needs to understand which device they prefer.

Whether the debate involved Prime Computer versus Digital Equipment Corporation, Unix versus Windows or other key technology decisions, these discussions have consumed a lot of company resources both during evaluation and after implementation. Over time, both company business processes and technologies evolve and improve. Today's cool new technology or business tool will most likely be a relic of the past at some point in the future. And even if you make what turns out to be the "wrong" or "incorrect" technology decision, you always have the opportunity to evaluate that decision when the next wave of technology transformation occurs.

In my experience, the best approach for a professional new to the industry is to remain **flexible** to new technologies and new approaches to accomplish a particular business goal. After all, most of us are paid to accomplish a specific business goal for the company that employs us.

A GREAT INDUSTRY FOR YOUR CAREER

Having been associated with the biopharmaceutical industry for almost 90% of my career – either as a direct employee in the industry or as a vendor to the industry, I highly recommend the industry for your future career satisfaction and prospects.

First, you can take pride and satisfaction in the fact that your daily efforts to develop new treatments for disease helps society through better health, longer lives and increased wellness. Second, innovation powers growth in this industry and your role involves helping innovative new products to obtain market approval. And third, business prospects are strong for those biopharmaceutical companies and CROs that foster innovation.

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The rewards of innovation are clearly visualized in Figure 1. This figure graphs the stocks in the NASDAQ Biotechnology Index versus the overall NASDAQ composite index from 1995 to 2015. We are all fortunate to spend our careers in an industry where innovation benefits society and carries potentially significant financial rewards. Clearly, investor interest is high in the innovation taking place in the biotechnology industry.



FIGURE 1. BIOTECHNOLOGY STOCK INDEX SHOWS THE VALUE OF INNOVATION

Positive demographics are another positive trend for the future of the life sciences and health care industries. The rise in the population over 65 years of age represents a strong opportunity for the life sciences industry since prescription drug use per person tends to increase significantly as individuals age. Certainly, there will be companies that succeed and companies that do not succeed in the marketplace, but overall the life sciences industry should be an excellent industry for your career for the foreseeable future.

THE R&D COMPUTING JOURNEY AT ONE LARGE PHARMA

The year is 1987. That is the year my pharmaceutical career started in the Information Technology (IT) department at a major, rapidly expanding pharmaceutical company. My role was to establish a completely new R&D computing environment on the Digital Equipment Corporation VAX hardware running the VMS operating system.

The company's R&D executives decided to migrate from the Prime Computer environment running the Primos operating system to the Digital Equipment platform because of the availability of most common R&D software applications on the VMS operating system. That strategic decision opened the door for my career in the pharmaceutical industry since I had prior experience with these technologies. Figures 2 and 3 show photographs of these computer technologies which were much less powerful than the server and storage technologies you currently use in your job each day.



FIGURE 2. DIGITAL EQUIPMENT CORPORATION VAX-11 780 (VMS OPERATING SYSTEM)



FIGURE 3. PRIME COMPUTER (PRIMOS OPERATING SYSTEM)

LESSON 1 – BE FLEXIBLE

Not everyone in the organization agreed with the decision to migrate all Research and Development computing to a new platform. Some individuals were even openly hostile to the new platform. Just think how negative it can be to your overall career when you let a technological decision affect your attitude about your work for months or even years. It's best to accept the decision, stay focused and remain dedicated to accomplishing the company's business goals.

The key point is that the pharmaceutical company wanted to use technology to accomplish a key business objective – discover and develop innovative new medicines. Whether an individual agrees with the strategic direction or not, in order to advance their career in the industry – they need to support the business in meeting the business goals.

SAS AND ORACLE

One of my first tasks involved installing SAS and the Oracle relational database management system in the Research and Development (R&D) computing environment. Although multiple statistical packages were installed on the R&D systems for use by researchers or other personnel, the clinical trials programming group used SAS.

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I also installed Oracle's relational database management system. Believe it or not, there was some uncertainty at the time over whether the company should standardize their R&D data on Oracle or a competing hierarchical data base management system. Ultimately, my company made what technology history now shows was the right technology decision and chose Oracle as our R&D standard database management system.

This is one good example of a strategic technology choice that did have future consequences. If the competitor had been selected, the company would need to migrate to the relational model in the future due to the evolution of the database technology and the eventual later market withdrawal of the competitor product. Even if the company had initially selected the wrong strategy, it is important to support that strategy in order to keep your career on track.

During this timeframe, Oracle began to build vertical industry applications specifically for the pharmaceutical industry such as Oracle Clinical.

TECHNOLOGY ADVANCES AND THE MIGRATION COMPLEXITY BEGINS

Over time, the UNIX operating system gained significant popularity with pharmaceutical industry software developers and UNIX systems begin to appear to support applications in research. Microsoft Windows was also gaining popularity as a desktop and server operating system during this time. Eventually, the pace of migration to UNIX and Microsoft Windows accelerated and the decline of VAX/VMS and Digital Equipment Corporation began. Digital Equipment Corporation was acquired by Compaq in 1998 and then Compaq was acquired by Hewlett-Packard in 2002.

Over time, most of the company's R&D applications computing services migrated to the UNIX operating system. The clinical trials programming and job execution environment was migrated to Sun Microsystems computers running the Solaris operating system. Sun was eventually acquired by Oracle in 2010.



FIGURE 4. SUN MICROSYSTEMS LOGO

Of course, this was not the final technology migration. Over time, many R&D applications and services were moved to commodity servers running the Linux operating system. And the pace of change in technology continues to accelerate today.

LESSON 2

Once again, not everyone in the organization agreed with the decision to migrate R&D computing to a new platform – and once again, some individuals were even openly hostile to the new platform. Fortunately, at this point in my career I had gained a good deal of experience and perspective on business and technology. By this time, I understood that my job was to support the business initiatives without regard to the technologies.

Eventually, I was given the opportunity to manage all personnel and budget supporting these pharmaceutical Research and Development systems. This was a tremendous responsibility and it was also an excellent career opportunity for me. Without a doubt, acceptance of rapid technological change helped to advance my career.

THE FUTURE

Figure 5 summarizes the computing technology evolution in one company's clinical research environment from 1987 to the present and attempts to predict the future. While future technology trends are VERY difficult to predict, adoption of Cloud based services and applications are definitely one rapidly evolving technology trend. Many of today's enterprise software vendors are transforming their company cultures and products to remain relevant in the Cloud.

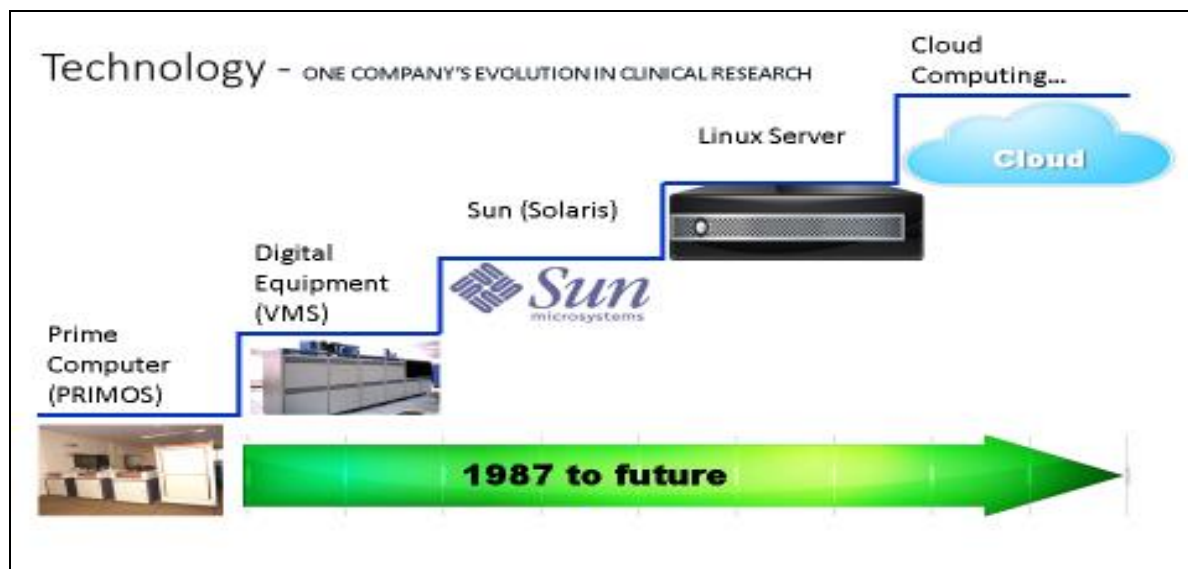


Figure 5. An Example Clinical Research Technology Evolution – 1987 to Future

History teaches us that the technological advances will continue. In order to maximize our career opportunities, it will be important for each of us to remember that our goal is to leverage technology as a tool to accomplish a task or initiative for the business. To achieve success in the pharmaceutical industry, we must be open to new approaches and technologies to accomplish our business goals.

CONCLUSION

If you choose to continue your pursuit of a career in the life sciences industry, you will find the industry can be an excellent choice for your ultimate career success and career satisfaction.

In order to succeed in the biopharmaceutical industry, be as FLEXIBLE and ADAPTABLE to new ideas and technologies as you possibly can. Always keep in mind that the role of technology is to help the business efficiently accomplish its business goals. For instance, if the goal is to accomplish a business task such as complete a regulatory submission, you should remain focused on achieving the business goal – and not overly focused on what technologies the company uses to accomplish those business goals. This you help you to have a successful career in the biopharmaceutical industry.

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