# Five Ways Technology Will Save the Pharma Industry

PHARMICA CONSULTING

ERIC LAKE AND MATT HENDRICKS

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# Introduction

Current trends and new developments in the way clinical trials are being conducted bode well for the future of the industry. The differences between next-generation and traditional clinical trial methods has great potential to a) streamline recruitment and marketing, b) generate larger quantities of useful data, c) improve safety standards through risk-based monitoring, d) evaluate data in a more person-specific manner, and e) achieve greater time and cost effectiveness via mobile technology, combination trials, and various other means.

Each of these areas of innovation will serve to enhance the effectiveness of clinical trial research in its own unique way. The net effect will be an industry that is faster, easier to manage, less expensive to engage in, and more effective at communicating its results. In some respects, these developments may end up "rescuing the industry," since more traditional trial methods already are beginning to recede in the face of a harsh and unpredictable legal environment. As lawsuits mount and health regulations pile higher, fewer and fewer trials are conducted in the interests of saving money. Next-generation clinical research, however, holds out promise to both overcome this financial dilemma and yield a superior end result.

Five of the most crucial areas in which clinical trials are changing for the better will be looked at below in more detail to help us better understand what the future of clinical research may end up looking like.

# Cutting-Edge Recruitment and Marketing Strategies

## Social Media Recruitment

Without the ability to quickly and cheaply assemble a list of candidates interested in participating in a clinical trial, efficiency is effectively curtailed. Social media based recruitment methods address this dilemma by making it faster, cheaper, and easier to collect a group of interested potential participants.

By creating online patient communities, based on common conditions like arthritis or high blood pressure, a constantly available pool of trial subjects is obtained. Groups can also be assembled around areas of interest or filtered based on age, sex, race, or any other desired demographic breakdown.

While this method has much promise for the future, it also has its challenges and glitches at present. For example, it is critical to engage in conversation with subjects in, say, Facebook or Twitter patient communities. This, of course, takes time, effort, and a salaried position. Furthermore, a recent survey by Blue Chip Patient Recruitment found that out of 179 social media health communities, only 16% had ever actually taken part in a clinical trial. Part of the reason for this low participation rate may be the 36% who were worried about the credibility of online trial information and the 88% who desired to get their information from an actual doctor.

## Online Marketing

Without the ability to successfully advertise the results of a completed trial, it may be quite difficult to convince patients or customers to risk their health and money on a product they are unsure about.

Marketing trial-results online may be as crucial to the success of a new drug, medical device, or other product as is its very development.

The latest inbound marketing strategies are outperforming outbound models and taking better advantage of the worldwide audience that the Internet provides. Some of these online ads consist of links, surveys, and audio-visual interactions interspersed within content the reader is already interested in. Others are social media driven, with easily shareable and downloadable content that "follows" specified target groups on Facebook and "is followed by" those same groups on Twitter.

## Data Production and Visualization Techniques

### Data Production

The most cutting-edge class of clinical trials going on today are far larger and far more complex than those of the past. This fact leads to enormous data-generation, which lays the foundation for an improved cost-benefit ratio.

Some data is still recorded manually and then quickly entered into a computerized record, but more and more data is being captured electronically and immediately fed to far-off processing centers. Sources of raw data include:

- Electronic health records and lab reports
- Medical images produced by digital devices
- Electronic diaries completed by participants

This data can come in any form: text, photographs, audio or video clips, and more. The individual data results can then be aggregated and arranged by highly skilled programmers using sophisticated computer software. Once duly captured, all data can be safely stored, systematically reviewed, and meticulously analyzed.

### Visual Analytics

This boon in data-production, however, is useless without accompanying methods of "mining" and effectively presenting it. First of all, the most relevant data must be selected, and this selected datum must then be "interpreted" to reach proper conclusions.

At this point, visual analytics and data integration tools can be used to make the results of the trial easier to grasp. This will include the traditional charts and graphs but go far beyond into more "interactive" territory such as 3D-video presentations, clickable slide shows, and other visual interfaces. The science behind these methods combines psychology, with complicated theories of optimal visual memory retention being involved, and computer programming skills in unique ways.

Visual analytics takes the raw results of clinical trials data and presents it in ways easier to grasp and remember. Researchers create theories that align computational data-analysis, analytic reasoning

processes, and visualized data-structures to achieve greater understanding. Meanwhile, skilled programmers develop software that excels at making abstract concepts "visually traceable" and utilizes human-computer interactions to make presentations more memorable.

## Risk-Based Monitoring (RBM) Systems

### Electronic Data-Capture (EDC)

Despite stringent efforts to keep participants safe, there are thousands of injuries and fatalities accompanying clinical research every year. This has led to a flurry of lawsuits, one recent example being Scott Scheer v. James Burke. Mr. Scheer's death allegedly stemmed from participation in a study involving hydralazine, and the Pennsylvania Superior Court's decision to allow the expert testimony of a clinical-practices auditor set new precedent.

The use of EDC techniques to facilitate closer RBM may well have prevented the above litigation, and it certainly holds promise of shrinking risks to unprecedented low levels. EDC's moment-by-moment monitoring allows quicker detection and correction of errors, as opposed to retrospective analysis that may not reveal problems until too late.

### Algorithmic Data Verification

After EDC has collected the data but before on-site monitors assess reports, an intermediate process called "algorithmic data verification" is used to minimize the need for in-person verification of source data. Since case report forms can now be submitted digitally, such data can be centralized from multiple sites and then analyzed and monitored. RBM software algorithms scan this data for specific "triggers" associated with risks and inaccuracies. Unexpected patterns and data significantly "deviating" from multi-site averages is targeted for special attention.

### Advanced Predictive Analytics

Predictive analytics is the principle on which oversight personnel determine where, when, and how to verify the safety of participants. The basic idea is to determine the probability of failure at each juncture and to focus on the high-risk areas.

One of the most common causes of error comes from monitors neglecting data, misunderstanding it, or drawing wrong conclusions from it. Some of the best practices for preventing such mishaps include:

- Continuously operative central data-collection in immediate contact with monitors
- Regular review processes that verify the veracity of EDC-sourced data
- Risk-identification schemas customized to each trial and based on scientific and historical risk assessments
- Staff role-assignment for step-by-step risk-response procedures

# The Fruits of New Data-Evaluation Capabilities

## Individualized Data

New techniques are shifting the focus from population-wide averages, and even demographics, to the unique characteristics of individuals. A combination of new scientific knowledge and high-tech data processes have yielded highly person-specific information.

One example of how individualized data has been helpful is the new understanding of breast cancer. Originally, breast cancer was assumed to be "monolithic," but person-specific data led to the discovery of different tumor-types, each requiring different treatment. Whether cancer cells originated on the lining of milk ducts, in the milk-producing lobules, or in the breast's connective tissues, for example, is the single-most important factor for determining treatment. Whether the cancer cells have hormone receptors for estrogen or progesterone and even the individual's genetic mapping can also be significant.

Thus, great progress has already come from individualized data, but challenges remain, including:

1. The costly and time-consuming process of mapping human genomes
2. The implementation of new research protocols that make each patient his own control
3. The difficulty of targeting rare diseases, given the small patient population

## Personalized Medicine

The direct offspring of individualized data is personalized medicine, a complex new field involving the close cooperation of person-specific data, advanced medical devices, pharmaceuticals, and hyper-specific disease diagnoses. This is one of the most "futuristic" aspects in clinical research, but it is already showing great promise.

One current study, for example, is examining the possibility of individualized treatment for hypertension of the arteries. The study seeks to discover how biomarkers may change the effectiveness of angiotensin receptor blockers (ARB) in different patients. ARB lowers blood pressure by preventing angiotensin from binding to muscle tissue surrounding blood vessels, which then enlarges those blood vessels and reduces pressure. A person-specific understanding of ARBs could affect which ARB and how much ARB is administered. For example, the ARBs irbesartan and candesartan have proven more effective in most patients, but a double-dose of the weaker ARB losartan is more beneficial to others. Knowing why ARB side effects hit some people harder than others and reducing their impact is another goal of the study.

# New Cost and Time Saving Developments

## Master Protocol Approach

Major late-stage trials usually require dozens of time-consuming protocol approvals and take over two years to complete. To simplify and streamline the drug-approval process, many lung cancer and other cancer-related trials are resorting to "master protocols" that allow multiple, late-stage candidate

medications to be tested under a single protocol in hundreds of clinics all over the country. This new master protocol approach offers great potential to speed up and simplify the drug-approval process, while reducing operational redundancy across several similar trials. Instead of requiring each novel treatment to run through its own separate regulatory approvals, training, and all the other work which comes with the startup of a new study, this is done once through the master protocol. The different study arms may have separate screening criteria and as has been seen with lung and breast cancer studies, different novel therapeutics approaches. Not only is this approach more efficient, it is more in line with the mandates of personalized medicine. Beyond oncology, several opportunities exist for further explorations of the master protocol approach. In particular, specialized patient groups or other groups which have historically been difficult to recruit to clinical trials, such as the pediatric population, could benefit from leveraging a master protocol approach.

## Combination Trials

Combination trials involve the testing of two distinct medical devices in a single trial. In a heavily regulated and expensive clinical trials environment, they are becoming ever more common. A case in point is the breast cancer drug Herceptin and the HER2/neu receptor, its accompanying diagnostic. Many drug-eluting stents and their emitted drugs also were developed in combination-trial manner.

According to one Tufts Center estimate, the average cost to develop a new drug is a staggering $1.3 billion, FDA regulations and malpractice suits being the main drivers of expense. It also takes, on average, 12 years for a drug to move from pre-clinical testing to actual use. The ability to test two regulated entities simultaneously greatly reduces both the cost and time involved.

## Mobile Technology

The explosion in mobile technology has impacted clinical trials by enabling the oversight of multiple, widely scattered clinics from one central processing center and by introducing health apps that monitor patients long-term while they reside at home. The ability to remotely gather patient data through on-body and in-body sensors, which monitor things like respiration, glucose level, and cardiac activity makes trials easier to participate in. Additionally, bring-your-own-device policies increase the odds of patient adherence and persistence. The end result is a process that is quicker, cheaper, and much more convenient to participants.

Some of the most recent developments in mobile-assisted trials include:

- A fully mobile data aggregation and analytics platform put out by iClinical
- A mobile pill-organizer, by iPillBox, that will aid patient-adherence to complex pill schedules and allow doctors to monitor compliance online
- A touchscreen interface, by MedUX, that surgeons can safely use to digitally access case data without scrubbing out

## Conclusion

Clinical trials are seemingly on the verge of a major transformation that will leave them faster, cheaper, and safer. They will also be easier to recruit for, manage, and advertise. They will yield more data and more person-specific data. The motivations behind these improvements include both the desire to innovate and the need to adjust to a highly regulated and litigated environment.

***Eric Lake***
Partner
**PHARMICA Consulting**
Eric.Lake@PharmicaConsulting.com
www.pharmicaconsulting.com
973-945-4482

***Matt Hendricks***
Partner
**PHARMICA Consulting**
Matt.Hendricks@PharmicaConsulting.com
http://www.pharmicaconsulting.com
215-272-0791