

Global Clinical Research Trials

As clinical trials are conducted across the globe—and increasingly in emerging markets—pharmaceutical, life sciences, and biotech companies face many challenges. But the industry can't ignore the potential of having ready access to more patients and the possibilities of growing markets.



An Exclusive Research Report

By Jennifer Zaino

As clinical trials increasingly are conducted across the globe, pharmaceuticals, life sciences, and biotech sector companies face both opportunity and challenge—especially in emerging markets. Everything from maintaining supply chain stability to accommodating data from a growing array of sources into what often are still siloed systems is at issue. This exclusive UBM TechWeb and Wipro research explores the key trends and challenges of conducting clinical trials in emerging markets.

Change is afoot in the pharmaceuticals, life sciences, and biotech sector. It's a world of intense competition and expanding opportunity, as small-molecule blockbuster drug patents expire; start-ups challenge established entrants with the development of biologics solutions – before, perhaps, being acquired by those same industry heavyweights; and emerging markets present as potential research and development sites as much as potential sales targets. Branded drugs have a longer lifecycle in those markets, as well, even after patent protections end. That's thanks to the greater importance consumers there, at least those with rising household incomes, often place on buying drugs from well-known multinationals with reputations for manufacturing quality and drug safety.

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In fact, a look at some numbers cited in Ernst & Young's Beyond Borders: Global Biotechnology Report 2011 adds some perspective. U.S. drug sales by volume have gone from a 53 percent prescription and 47 percent generic sales split in 2003 to 22 percent prescription and 78 percent generic sales in 2010. The China drug market, valued at \$33 billion in U.S. dollars in 2007, trends up to \$61 billion in 2011, and by 2015, that is expected to spike to \$126 billion. The prevalence of chronic disease-related deaths projected as of 2020 is largely tilted to occur in developing countries – 71 percent from heart disease, 75 percent from stroke, and 70 percent from diabetes. Within those shifting demographics lie many opportunities. An Axendia study, Achieving Global Supply Chain Visibility, Control & Collaboration in Life Sciences, found that 94 percent of surveyed executives from pharmaceuticals, biotechnology and other industries affiliated with the life sciences product supply network say that global sales of life sciences products outside of the U.S. will be increasing in the next few years. At the same time, these new markets often present fast recruitment and high per-site-enrollment level opportunities.

Meanwhile, biologic drugs – expensive to manufacture but also capable of returning high margins because of their great effectiveness – are booming. It's been noted that over a half dozen biomolecular drugs have been approved per year in the U.S. since 1997, and business intelligence firm La Merie S.L. reports that 2010 sales of biologic drugs – mainly recombinant therapeutic proteins and antibodies – totaled \$108 billion, up from \$92 billion the previous year. Forecasting firm Evaluate Pharma also has predicted that biotechnology products will make up about 48 percent of the top 100 drugs in 2016.

Yet drug companies that hope to participate in this boom by way of “follow-on” or “subsequent-entry” biologics won't enjoy the same opportunity afforded to generic chemical drug manufacturers, where the usual requirement is only to verify that the active ingredient is the same as in the brand-name drug and that it has comparable pharmacological properties once taken by the patient. Instead, they likely will

face conducting clinical trials to gain regulatory approval. At the same time, there also is the prospect in the U.S. of legislation mandating additional “comparative effectiveness” clinical trials for the FDA drug review program for any new drugs in order to prove its superiority to existing therapies.

The drug industry already spends tens of billions of dollars each year on discovering and developing new medicines. The cost of developing and winning approval for a single new drug in the U.S. and Europe is over \$1 billion. Years-long clinical trials account for much of that expenditure. Now, the cost issue clearly is coming to a head, with the year 2010 marking a drop in R&D expenditures to an estimated three-year low of \$68 billion, according to the 2011 Pharmaceutical R&D Factbook compiled by CMR International, a Thomson Reuters business. The same report shows declining trends in drug success, pointing to 55 phase III drug terminations during 2008-2010 (more than double the number of terminations during 2005-2007), and a 55 percent fall last year in the number of drugs entering phase III clinical trials. With most of the money spent on Phase I or Phase II clinical trials, failure at this point has a particularly nasty sting.

In such an environment, chock full of as much pressure as it is of potential, it is not surprising that the pharmaceuticals, life sciences, and biotech sector is eager to tap into ways to lower costs during the R&D phase, for small-molecule and biologic drugs, and to reach into new and less saturated markets, both for patient trial supply and to serve those population's needs. Conducting clinical trials in those emerging markets themselves is one way to potentially help achieve those goals. But moving in that direction is not without its own challenges, from the partnerships that may be required to enable the venture, to the supply chain challenges of supporting it, to the data gathering and analysis requirements it entails to ensure compliance with more mature markets' safety and regulatory mandates.

A research survey conducted by UBM TechWeb and Wipro sheds light both on the desire the industry has to embrace this opportunity, and the issues it must sort out as

Methodology:

In May and June 2011, UBM TechWeb conducted a study The State of Clinical Trials, on behalf of Wipro. The survey was conducted online via our survey host partner, SurveyGizmo. Invitations were emailed to UBM TechWeb's qualified database of technology decision-makers. The survey included 116 biopharmaceuticals professionals who have begun or plan to begin conducting clinical trials in emerging markets.

Sector Profiles: A View into Each Drug Industry Segment

The respondents to the UBM TechWeb and Wipro research comprised various sectors of the drug industry, and in some cases there were noticeable differences among the answers they provided on questions ranging from where most trials are based, to the cloud’s role in these activities. The following information should be viewed primarily as directional in nature, given the small base of respondents from each industry – pharmaceuticals, life sciences, and biotech/biopharmaceutical.

Among the insights:

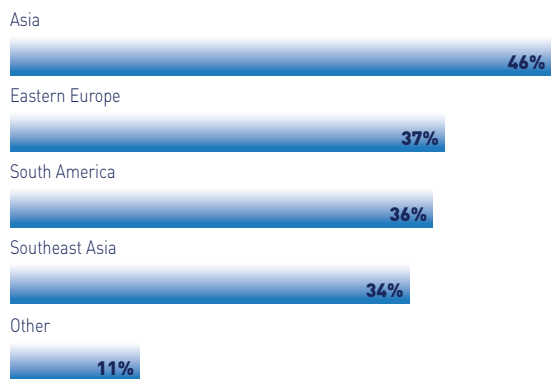
- Pharmaceutical companies are more likely to have already begun to conduct clinical trials in emerging markets (70 percent) compared to life sciences or biotech/biopharmaceutical organizations.
- Pharmaceutical companies still are more likely to conduct most of their clinical trials in mature markets (62 percent), compared to life sciences and biotech/biopharmaceutical businesses (56 percent and 50 percent, respectively).
- Pharma companies are more likely to build local infrastructure for clinical trial activities in emerging markets, while acquiring local infrastructure or using a contract research organization (CRO) are both likely options for nearly one-third of biotech/biopharmaceutical participants in each case. Life sciences companies are as likely to build local infrastructure as acquire it (each cited by 24 percent of respondents).
- Life sciences companies are more heavily influenced by the proven accuracy of patient safety data in emerging markets in their decision to offshore clinical trials compared to biotech/biopharmaceutical or pharmaceutical companies.
- Biotech/biopharmaceutical and pharmaceutical companies indicated a higher percentage of their technology spend will go towards augmenting data gathering and analysis from emerging markets compared to life sciences companies.
- When it comes to the cloud, pharmaceuticals companies are noteworthy for their embrace. Just five percent indicated they don’t leverage the cloud and have no plans to do so. Thirty-seven percent expect to use both public and private clouds, compared to 14 percent in biotech/biopharmaceutical businesses and 16 percent in life sciences. Forty-two percent of those in the life sciences sector expect to use a private cloud inside their own data centers; this is significantly higher than 16 percent for pharmaceuticals and 25 percent for biotech/biopharmaceuticals.

it does so. Respondents to the survey, which was conducted in May and June 2011, were 116 biopharmaceuticals professionals who have begun or are planning to conduct clinical trials in emerging markets. Respondents’ primary industries included life sciences (37 percent); pharmaceuticals (22 percent); biotech (19 percent); biopharmaceuticals (16 percent); and biologics (5 percent).

Trends in Clinical Trials in Emerging Markets

The momentum clearly is accelerating when it comes to conducting clinical trials outside the boundaries of the United States or Western EMEA. Fifty-nine percent of respondents to the UBM TechWeb and Wipro research indicated they already have begun conducting clinical trials in emerging markets, and the remaining 41 percent had plans to begin doing so in the next 12 to 24 months. Asia is a main target for 46 percent of the UBM TechWeb survey

Figure 1. What emerging market regions are or will be involved in these trials?



Data: 116 biopharmaceuticals professionals who have begun or plan to begin conducting clinical trials in emerging markets

respondents; it was cited by ten percent more respondents than South America, and by nine percent more than Eastern

More than one-quarter said that more clinical trials are conducted in emerging markets than mature markets.

Europe (see Figure 1). Still, the fact that more than one-third has clinical trials underway in those areas, as well as in the Southeast Asia region, indicates that those markets are not insignificant to the industry, either. More than half the respondents said that they are somewhat to heavily influenced by subject availability in nascent markets; competition for patients in these regions is much less fierce than in Western Europe and North America.

The results showing pickup in the use of emerging markets for clinical trials likely will not come as a surprise. ClinicalTrials.gov, a registry and results database of federally and privately supported clinical trials conducted in the United States and around the world, currently reports close to 110,000 trials listed with locations in 174 countries. As of this writing in July 2011, more than 2,200 studies are hosted in China; about another 2,200 are taking place in Taiwan; and just over 2,500 are underway in the Republic of Korea. India also is another emerging market with a significant representation of clinical trials, with 1,628 studies listed in the registry. In South America, Brazil and Argentina are pack-leaders, with 2,339 and 1,176 studies in progress, respectively. In Europe, formerly Eastern Bloc countries such as Poland, the Czech Republic, Hungary and Romania are emerging as host sites, though nowhere near the numbers of trials taking place in some countries west of the old Iron Curtain. Poland, with some 2,300 studies, while a tad ahead of Sweden and Switzerland, for instance, significantly trails sites such as France, with its 6,571 studies or the U.K., with 5,623 studies underway.

On its own, the United States accounts for 55,146 studies, according to ClinicalTrials.gov – a figure that adds context to the survey’s finding that the majority of respondents (55 percent) say that 60 percent or more of their clinical trials continue to be conducted in mature markets, such as the U.S. and western EMEA. Only 7 percent can say the same of emerging markets. That said, the growing interest in emerging markets is borne out by others’ answers to the same question: Taken together, more than one-quarter of respondents say that clinical trials are either evenly split between mature and emerging markets, or that slightly more clinical trials are conducted in

emerging markets than mature markets.

The industry is taking various routes to enable a more global clinical trial infrastructure. In each case, for example, 26 percent of UBM TechWeb survey respondents say that they either are acquiring local infrastructure, building it up using their own resources, or using a third-party contract research organization (CRO) to deliver services for site monitoring, data management and other clinical activities. Just 15 percent are relying on a functional service provider hub-and-spoke model, where CROs on-site – aka, the spokes – are managed by hub teams from major city sites. The hub teams themselves control operations through collaboration with the CRO spokes.

The 41 percent of UBM TechWeb survey respondents that are harnessing CROs as service providers in one capacity or another – as well as the 7 percent who suggest that systems integrators’ cloud-based services can help with these tasks – make it clear that outsourcing is an increasingly attractive option for pharmaceuticals manufacturers when it comes to the drug development process (see Figure 2).

Figure 2. What is the estimated split between clinical trials conducted in the U.S. or Western Europe, as compared to emerging markets?

A substantial portion (60% or more) of our clinical trials are conducted in mature markets (U.S./Western EMEA)



Clinical trials are evenly split (50/50) between mature markets and emerging markets



Slightly more of our clinical trials (50-60%) are conducted in mature markets than in emerging markets



Slightly more of our clinical trials are conducted in emerging markets than mature markets



A substantial portion (60% or more) of our clinical trials are conducted in emerging markets



Data: 116 biopharmaceuticals professionals who have begun or plan to begin conducting clinical trials in emerging markets

Indeed, it is expected that off-shoring clinical trials to emerging markets, particularly India and China, will create revenue growth for global CROs, according to business information provider Visiongain in its report, *Pharma Clinical Trial Services: World Market 2011-2021*. Indian and Chinese markets, its analysis shows, will experience compound annual growth rates (CAGR) over 20 percent.

It says that revenues for CROs will reach \$32.73 billion in 2015, with the industry pursuing this route thanks to its ability to drive cost advantages and offer regional expertise by way of its research service providers.

From Shore to Shore

One of the issues the industry must grapple with as it moves to increase near-shore or off-shore clinical trials is ensuring that supplies for these efforts are at hand by first-patient-in date and that supply stock-outs don't occur during the course of the trial. Otherwise, the trial could be subject to delays and even be in jeopardy altogether, with the possible loss or disqualification of patients that may result from such disruptions. Then, too, there is the potential financial impact to the sponsoring organization if serious delays lead to a competitor getting the edge in a new and lucrative drug market.

Of course, these issues also can threaten studies that take

place in mature markets. But survey respondents recognize that more global supply chains that extend to emerging markets up the ante when it comes to potential logistics pitfalls. Everything sponsors want to accomplish is just a little more fraught with problems, from speeding customs clearance to deliver materials to certain countries, to fast-forwarding their importation on the receiving end, to enabling cold-chain services for supplies subject to temperature control requirements, to assuring appropriate packaging and labeling for outgoing specimens, to securing depot facilities in-country for just-in-time delivery. Some emerging markets, it must be recognized, may be in the midst of social or economic challenges, or beset with difficult-to-negotiate bureaucratic infrastructures, that increase security or other handling demands. Additionally, it may be difficult to find comparator drug products in some locales, without sourcing expertise that takes into account product availability,

The Cloud Comes to Clinical Trials

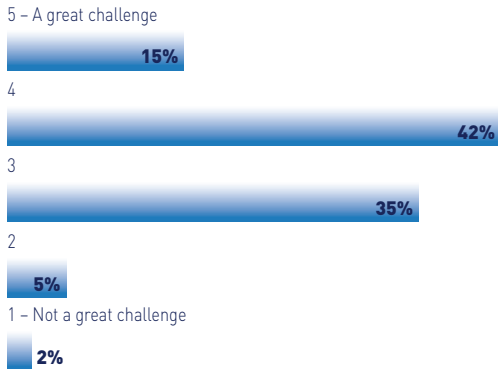
With clinical trials now crisscrossing not just one country but the entire globe – including far-off sites in emerging markets – the time has come for the cloud to take on a leading role, from enhancing data collection to improving collaboration among sponsors, partners, and others involved in multi-country drug development.

Services provider Wipro Technologies is moving the cloud into that spotlight, with its Rapid Trials platform. Rapid Trials is based on the Oracle Life Sciences software suite of products, an open standards-based platform for business process integration across the drug development life cycle. The platform enables a more efficient and cost-effective way to get trial data from disparate sites and sources, including CROs, without compromising data standards or data collection procedures. And it does it with the highest data security in place. When delays in data collection – and their costs – are avoided, and information can be assessed in real-time, sponsors will be on the road to accelerating the regulatory submission process.

The platform can be implemented in weeks and can cut the total cost of ownership by 30 to 40 percent, because cloud resources can be shared across trials. Indeed, the use of a centralized database located in the cloud simplifies the process of dropping sites or adding them to speed up recruitment efforts. The platform is used by customers including six pharmaceutical and CRO companies in the Asia Pacific region, including a successfully delivered clinical data management solution for a complex multi-site, multi-country oncology trial for a biotech company based in Singapore. The platform also is being used for a study underway by a U.K.-based CRO; implementation for that project took only ten weeks, including platform set-up and study database design. Organizations can couple their use of the platform with Wipro's business process outsourcing services. Its clinical operations support ranges from basic services, such as database design and setup to statistical services including statistical analysis plan design, to programming services for edit checks, database cleanup, and more.

Wipro also has launched its Clinical Collaboration Portal as a secure cloud service, as a means of speeding communications and document exchanges among all the stakeholders in globally extended clinical trial chains – to the tune of a 20 to 30 percent improvement in clinical trial cycle time. The platform provides a central location to manage trial financing, schedule sessions, and support patient recruitment and reporting of trial results; standardizes reports relating to trial progress across regions; and maintains adherence to regulations by following U.S. FDA rules on electronic data capture and signatures. The portal is built on Microsoft SharePoint 2010 and SQL Server 2008 and works with Oracle clinical data management software.

Figure 3. How great of a challenge are the shipping/logistics of supporting a more global clinical trial supply chain?



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discontinuation and formulation change concerns, and cost.

Fifty-seven percent of the UBM TechWeb survey respondents rated the logistics challenges around supporting clinical trials around the world as significant, assigning a 4 or 5 rating to the question (on a 5-point scale, where 5 was “a great challenge”). Thirty-five percent more see it as somewhat of a challenge. Just seven percent don’t see the issue registering as a major concern (see Figure 3).

The challenges of maintaining a global clinical trial supply chain may exist regardless of the approach an organization takes, whether it’s using a CRO or trying to build up its own local resources to accommodate test phases conducted near- or off-shore. In either case, the clinical trial supply chain manager role in support of emerging markets may still be immature, and one with more devils in the details, such as assessing the risks of working with unfamiliar clinical supply vendors in foreign sites; coordinating shipments to arrive when customs offices are open to process them; adopting regional supply models so that one main distribution hub is responsible for delivering supplies to most trial sites in each country in that wider region; or, alternately, perhaps having to adhere to state regulatory requirements that demand the use of local depots. Therefore, it’s imperative for the industry to consult with service providers whose pharmaceuticals practice includes expertise in and solutions for issues including regulatory compliance as well as e-pedigree to assure chain of custody of medications used in clinical trials, as well as to consider whether to contract for additional logistics services in support of local resources or CROs.

Demand planning, supply chain planning and capacity

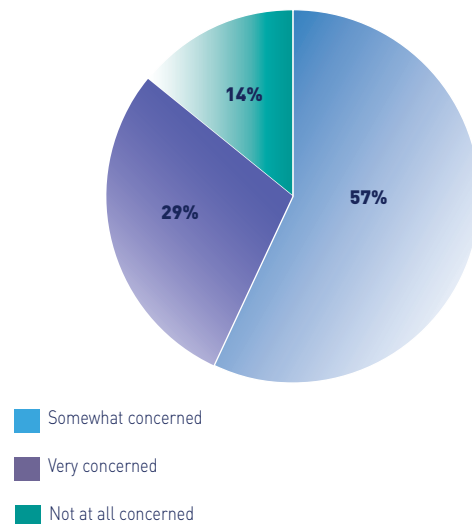
planning – with the optimization of advanced planning and scheduling systems that create forecasts and ERP systems that manage the manufacturing and distribution of clinical trial materials – is, of course, table stakes for conducting effective clinical trials where study supplies are provided to sites at the appropriate times so that drugs can be administered to patients as required.

Follow the Rules

Managing a global supply chain isn’t the only instance where pharmaceutical and life sciences companies come up against regulatory requirements. These infuse many other aspects of running clinical trials anywhere, including in emerging markets, as do international compliance issues including adherence to Good Clinical Practice (GCP) standards. This often comes down to a matter of data — to document date, quantities, batch/serial numbers, expiration dates, and protocol-specified doses; subject identification code lists; clinical study reports; reporting of serious and unexpected events for sponsors to evaluate in aggregate (a recent FDA safety-reporting paradigm for drugs being studied under investigational new drug applications), and so on.

For trial sponsors, data collection and management in the emerging market space can be a concern. The proven accuracy of patient safety data, for instance, heavily or

Figure 4. How concerned are you about regulatory agencies in the U.S. and Western Europe accepting data from clinical trials conducted in emerging markets?



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significantly influences the decision to outsource clinical trials to emerging markets for 55 percent of respondents. In particular, the majority of respondents to the UBM TechWeb survey – 86 percent – say that they are somewhat or very concerned about how regulatory agencies in the U.S. and Western Europe react to data from emerging market trials (see Figure 4).

Fresh in their minds may be the recent case of AstraZeneca's blood thinner Brilinta, for which clinical trials were conducted in 43 countries, Russia, Georgia, Poland, Turkey and Hungary among them. It did not win approval late last year from U.S. regulators pending additional data analysis to understand the differences in outcomes between North American patients and those in other parts of the world. Such delays of potentially blockbuster drugs in major markets, of course, aren't good for revenue growth, and certainly not at a time when a company's existing best-selling drugs are facing the pain of generics competition.

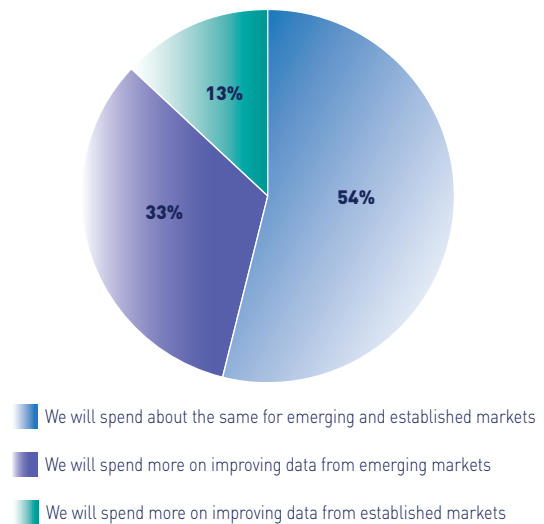
Reports at the time included commentary that the FDA is carefully scrutinizing trials that include remote sites, because officials have been critical of the quality of data coming from trials conducted outside the U.S. Questions over reliability and whether results are able to be extrapolated to North American audiences with different genetic backgrounds and lifestyles have been cited as general concerns about clinical trials conducted over more wide-ranging global locales.

On the positive side, most survey respondents said they are impressed by the timeliness of data results returned from clinical trials conducted in emerging markets. Fifty-five percent said the timing of data availability was as good in emerging markets as in mature markets, and 13 percent said it was better. That doesn't mean there isn't any room for improvement, however, as nearly one-third thought data was not available in as timely a fashion.

In seeming acknowledgment of these points of some tension, one-third of survey respondents say they will spend more of their technology budgets on augmenting data gathering and analysis from emerging markets compared to improving efficiency for data gathering/analysis from established markets (see Figure 5).

That said, UBM TechWeb survey respondents do seem to have fewer reservations about clinical practices in emerging markets from which the data is being created. More than a third of them consider the investigators to be very or highly

Figure 5. How does this amount compare to the budget devoted to improving efficiency for data gathering/analysis from established markets?



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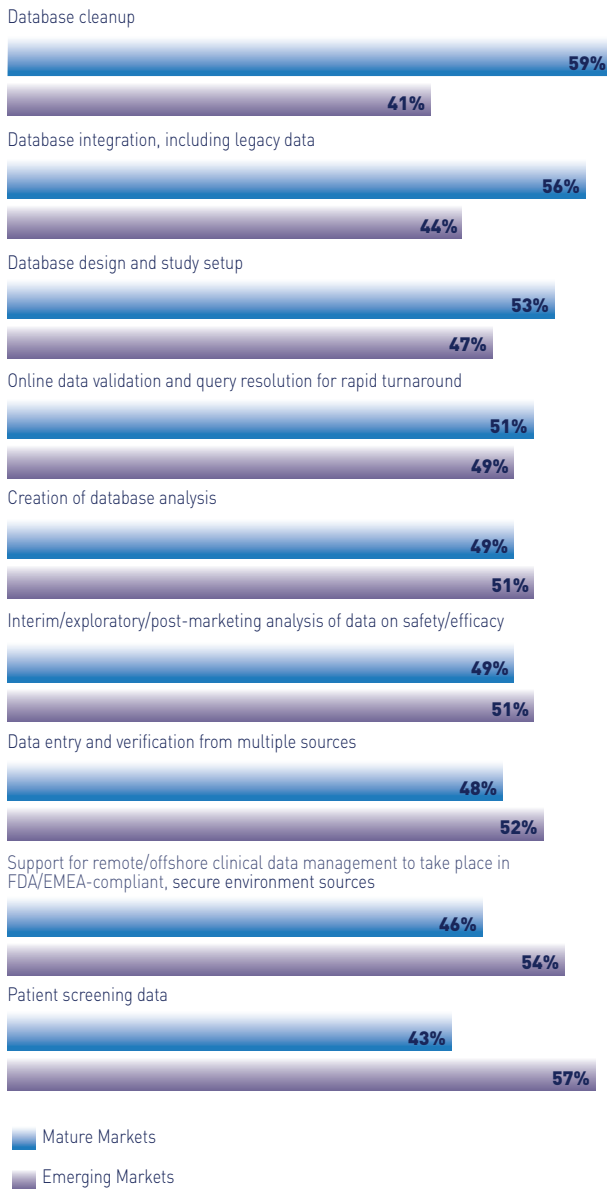
advanced, and about half seem at least to be satisfied with their capabilities. Only 13 percent have serious reservations on this point. There's reason for optimism, according to sources representing companies whose focus is clinical research. The Association of Clinical Research Organizations, for example, cites that its members invest millions of dollars annually to recruit and train high-quality investigators in more than 60 countries. The Association also has noted that between 2004 and 2007, while the number of FDA-regulated clinical investigators decreased 5.2 percent in North America, it actually increased 10.2 percent in Asia.

Technology and Data Strategies

For those already invested in, or planning soon to invest in, using emerging markets as part of their global clinical trial research, 63 percent of the UBM TechWeb survey respondents say it is important or very important to have a central database to allow access to shared data and processes, and 58 percent claim to have very or significantly mature clinical integration strategies.

Survey participants don't necessarily discriminate between mature markets and emerging ones when it comes to casting a critical eye on clinical trial data management processes they would like to enhance (see Figure 6). There's a close correlation, for example, between the respondents who want to improve:

Figure 6. Which areas of clinical trial data management would you like to see improved?



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- Data entry and verification from multiple sources (48 percent mature markets vs. 52 percent emerging markets);
- Online data validation and query resolution for rapid turnaround (51 percent vs. 49 percent);
- Database analysis (49 percent vs. 51 percent); and
- Interim/exploratory/post-marketing analysis of data on safety/efficacy (49 percent vs. 51 percent).

In some other areas, they are considerably more concerned with improving data-affiliated processes in emerging

markets. These include such processes related to patient screening data and support for remote/offshore clinical data management. As it happens, there are some aspects of clinical trial data management that the industry actually seems more focused on when it comes to mature markets, including database design and study setup (53 percent mature markets, vs. 47 percent in emerging markets); database integration (56 percent vs. 44 percent); and database cleanup (59 percent vs. 41 percent).

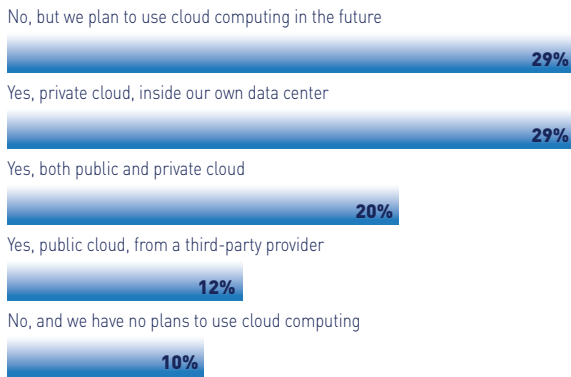
Some of this may be explained by the fact that gaps have had more time to develop in studies undertaken in mature markets, where difficulties integrating the flow of information – from sources as varied as investigators at trial sites to pharmacist or physician reports about adverse events to the subjects themselves through remote data capture – stem from the fact that the data in each case often is maintained in its own database and requires custom interface development to reconcile it all with the clinical data management system. That encompasses electronic data capture systems, clinical trials management systems, clinical investigator portals, project management, and the list goes on. That takes time and money and brings with it the risk of falling behind schedule – or even behind the pace of technology.

Many of the issues faced both in emerging and mature markets around clinical trial data management could be addressed with the deployment of an integrated suite of applications for clinical development, designed with integration in mind and supported by capabilities such as consistent data coding against the same dictionaries, storage of data entered either manually from case report forms or through remote data capture into the same tables, and a validated data warehouse that brings data together in one central location to facilitate analysis and reporting. Accessing clinical operations support and consulting services from third parties also can help companies make headway in areas that they feel are lacking, such as study database design.

Business process integration across the drug development lifecycle – including standardized electronic data management and data capture processes spanning multiple geographies – can be further facilitated, thanks to the cloud computing model. When pharmaceuticals and life sciences organizations can conduct global trials without concern for IT infrastructure challenges – especially in emerging markets, where those challenges may be greater – clinical testing

can advance more rapidly, and total costs of ownership can drop, as well, thanks to resource-sharing across trial phases. At this point, most companies rely on in-house resources for running applications ranging from electronic data capture to clinical trial management to data warehouses on internal infrastructure, rather than an on-demand model, according to the survey results. On the other hand, just 10 percent of the surveyed group say they have no plans to use cloud

Figure 7. Will your organization embrace cloud computing for hosting clinical trial data?



Data: 116 biopharmaceuticals professionals who have begun or plan to begin conducting clinical trials in emerging markets

computing. Most are comfortable with it to one degree or another, including over 30 percent of respondents who say they already use a public cloud from a third-party provider to host clinical trial data or make use of both private and public clouds (see Figure 7).

Cloud services also can be harnessed to improve collaboration efforts among sponsors, CROs, clinical sites and regulators when clinical trials encompass multiple regions. Such collaboration can address information centralization around clinical data capture and electronic data management following regulatory requirements, as well as consolidate finance management, enable reporting accuracy, deliver automated scheduling and simplify patient recruitment. Consider the efficiencies a cloud collaboration platform enables just at the level of document exchange, reducing the cycle time for submission and review of documents collected during the clinical trials process to just a day or two, vs. the multiple days required when mail or courier services perform the job. Notices of protocol violations or deviations, adverse drug reactions, or other communications can be submitted, acknowledged and tracked electronically – representing a considerable decrease in overhead costs.

Analytics in the Forefront

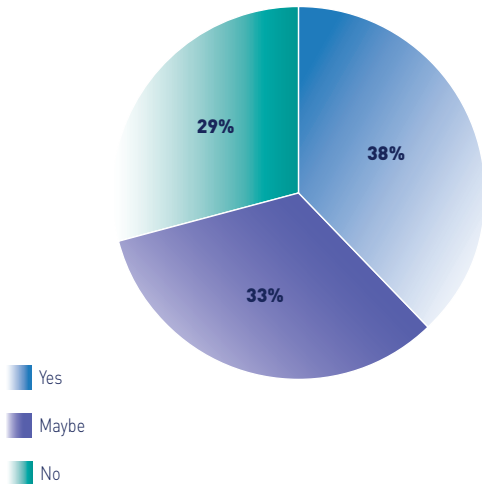
As the survey respondents' answers noted above show, there is great interest – both for at-home trials and those in emerging markets – in continuing to drive better understanding of data accumulated during testing phases. How successful much of this will be depends on efforts directed to database analysis planning and the design of analysis data sets, statistics, and efficient data displays, as well as the creation and validation of analysis databases, and statistical support services that all aid in interpreting raw data accurately and reliably.

What, for example, might analysis of that data reveal about drug safety and efficacy, including on an interim basis? Might having a better handle on that help, for instance, in a policy board's determining whether there is enough evidence that a trial should be stopped at a time other than designated in the protocol? Or, with the increasing spotlight on patient safety in emerging markets, better business intelligence affords an opportunity to assess in real-time key performance metrics across sites to assure they are performing up to par. Clinical trial efficiency also can get a lift if sponsors can use self-service business reports to get more insight into patient screening, recruitment and retention, and where bottlenecks may exist at various sites, including slowdowns in investigator sign-offs of Electronic Case Report forms.

The next stage where analytics may play a role in the clinical trials realm may have to do with the onrush of social media. The first steps of this have been seen by organizations using social media as a means to recruit patients for clinical trials. But clearly drug companies are eager to further explore how they can leverage the Web to improve the clinical trial process, and lower its costs. Pfizer, for example, is launching a virtual drug trial using smart phones and web-based technology to collect data on the safety and efficacy of overactive bladder drug Detrol LA. Patients can enroll online, have materials delivered to their homes, and manage their own trial activity at a secure website, reporting results to a trial investigator by those means.

So it's not surprising that the industry would want to further plumb the social media depths. According to the UBM TechWeb survey, 38 percent of respondents say they are already using social media networks or online patient communities to help provide real-time information and monitor the effectiveness of drugs in use. Another third

Figure 8. Are you using (or foresee using) social media networks or online patient communities to help provide real-time information and monitor the effectiveness of drugs in use?



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have plans to do so (see Figure 8).

But questions remain over the details of effectively accomplishing this: Sixty-seven percent of those who are doing this, or who have plans to do so, say that establishing an analytics approach and data capture methodology presents a challenge. Sixty-four percent say they are concerned with how to integrate self-reported or observational data with controlled trial data. A lesser number, 40 percent, expect that accounting for missing data (such as when a patient drops out of a social-media enhanced virtual trial) could be an issue.

Stepping Into the Future

In order to successfully navigate the changing nature of drug discovery on all its levels – how it’s done, the categories of therapies to be explored, and where that research takes place – pharma, life sciences, and biotech companies must take a proactive approach on many different fronts. They will have to reconsider supply management in the far-reaching global sphere; they will need to more quickly shore up weaknesses in database design and more quickly close the gaps that stubbornly persist around clinical trial data integration; and they will need to become more agile in analyzing data returns, to avoid safety concerns, better harness opportunities to lower costs, and more easily pinpoint issues not just in

patient data but also in data regarding the conduct of the trials themselves.

And, at the same time that they are negotiating the parameters around creating footprints in emerging markets, they need to explore how new technologies, such as the cloud, may help them solve not just application issues across the globe but specifically speed implementations in remote regions.

Get it right, and the future is brighter not just for drug industry companies, but also for people around the world who will benefit from new discoveries and better treatments. ♦

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