The Upside of CLINICAL SOLUTIONS

Even as pharmaceutical companies and their development partners continue to grapple with bringing safe products to market on time and on budget, new technologies, models, and analytics are driving improvements to counter the industry's challenges.

According to R&D leaders who recently participated in a roundtable discussion convened by the Tufts Center for the Study of Drug Development, drug companies and their development partners who are seeking to increase clinical success rates of new drug candidates are developing tools to help them predict the likelihood of marketing approval and incorporating business planning earlier in clinical development.

"The research-based drug industry is racing to boost its research pipelines, as existing patents expire and development times continue to lengthen," says Tufts CSDD Director Kenneth Kaitin. "Drug companies are exploring new approaches to product development that focus on increasing the probability of clinical success and speeding time to market."

One tactic, Mr. Kaitin cites, focuses on statistical models that help predict clinical success. For example, his team, working with a pharmaceutical company, created a simple algorithmic model called the Approved New Drug Index (ANDI) — modeled on the five-factor APGAR score widely used in delivery rooms to evaluate the health of newborns — that reliably predicts which oncology products emerging from Phase II testing are likely to receive marketing approval.

The team concluded that, compared with the prevailing industry metric, the data support assigning a much higher probability of success to oncology drugs with top ANDI scores of 7 and 8, and much lower probabilities of success to those with scores of 0 to 4.

Other points discussed in the roundtable included:

- A shift in approach to decision-making that favors data-driven models over intuition and what is already known can improve drug development success.
- More rigorous use of risk-adjusted net present value calculations earlier in clinical development can improve decision making on how to structure clinical trials.
- Advances in development of personal genomic information, increased voluntary sharing of patient data, and an explosion in data on cell metabolism have significant potential to transform clinical trials, but effectively mining the data these advances create presents a major challenge for research centers.

KENNETH KAITIN
Director, Tufts CSDD

Drug companies are exploring new approaches to product development that focus on increasing the probability of clinical success and speeding time to market.

Breaking Down the eClinical Market

The global eClinical solutions market, which is estimated to grow at a CAGR of 13.5% from 2013 to 2018, is broadly categorized into two segments, namely, products and professional services.

According to MarketsandMarkets, a global market research and consulting company, the products segment is further classified into clinical data management system/electronic data capture (CDMS/EDC), clinical trial management systems (CTMS), electronic clinical outcome assessment (eCOA), randomization and trial supply management (RTSM), safety solutions, and others. The professional services segment is classified into implementation services, training, support services, and consulting.

The CDMS/EDC solutions segment accounted for the largest share of the global market, by product at an estimated $899.1 million in 2013; while the eCOA solutions market is expected to grow at the highest CAGR of 21.2% from 2013 to 2018. The professional services market includes implementation services, training, support services, and consulting.

Moreover, analysts at MarketsandMarkets say the global market also has been classified on the basis of type of buyer and delivery mode. On the basis of type of buyer, the market is classified into pharmaceutical/biopharmaceutical/medical device companies, clinical research organizations (CROs), and healthcare providers. Based on the type of delivery mode, the global market has been categorized into Web-hosted, licensed enterprise, and cloud-based eClinical solutions. Based on geography, the market is divided into North America, Europe, Asia-Pacific, and rest of the world (RoW).

A number of factors such as the increasing pressure for reducing the cost and time con-

sumed in the clinical trial process, growing need for improved data standardization to meet regulatory requirements, government funding for conducting clinical research, and high expenditure on clinical R&D by pharmaceutical and biopharmaceutical companies are driving the growth of the global eClinical solutions market. But factors such as, scarcity of a skilled labor force and high cost of eClinical systems are restraining the growth of the global market.

According to MarketsandMarkets, in 2013, North America held the largest share of the global market, followed by Europe, Asia-Pacific, and ROW. The Asia-Pacific region is estimated to grow at the highest CAGR in the forecast period. Factors such as the presence of a large patient population, low operating cost of conducting clinical trials in developing Asian countries, emerging Asia-Pacific pharmaceutical industry, and shortage of trial volunteers in European and North American countries are stimulating the growth of the eClinical solutions market in the Asia-Pacific region.

Trends for 2014

The Drug Information Association (DIA) released its second annual "What Lies Ahead?" report, providing experts' insights into the year ahead for pharmaceuticals, biotechnology, and medical devices.

Thought leaders from industry, academia, government, and patient organizations were asked to choose the trends they foresee shaping the world of medical product development and access during the coming year. These diverse respondents were closely aligned in their selections of the year's most influential trends, despite sometimes unique perspectives on medical product issues.

"The concurrence of multiple stakeholders on the trends that will be most important in 2014 lends credibility to their feedback," says Susan Cantrell, director, DIA Americas.

For 2014, thought leaders once again placed a focus on collaboration in the top 10 trends but dropped it from the 2013 top spot. Three different trends tied for the 2014 top position: the evolution of patient/consumer engagement, regulatory agency support of innovation, and learning how to use big data.

The importance of both patient/consumer engagement and big data were among the Top 10 trends of 2013, and on 2014's list, they share the top spot. The shift in focus for both issues attests to progress in engaging all stakeholders in the discussion about the development of effective, safe, and patient-focused therapies.

For 2014, thought leaders once again placed a focus on collaboration in the top 10 trends but dropped it from the 2013 top spot. Three different trends tied for the 2014 top position: the evolution of patient/consumer engagement, regulatory agency support of innovation, and learning how to use big data.

Regulatory agency support of innovation was a surprise top trend, acknowledging the increasingly critical role regulatory agencies play in balancing safety with innovation to meet the needs of patients.

Based on experts' responses, personalized medicine and companion diagnostics will continue to be among the top priorities in 2014, as will the push for clinical trial data transparency, according to Ms. Cantrell. The implementation of risk-based monitoring in clinical trials appears for the first time in the top 10 list and underscores a commitment to patient protection and data integrity despite pressure to conserve resources when conducting trials.

"Our thought leaders' insights were quite accurate last year, and we believe these projections of the future landscape can be valuable to companies as they strategize to successfully meet the ever-changing needs of the marketplace," Ms. Cantrell says.

In 2014, the top trends include the following (there was a three-way tie for No. 1):

1. Evolution of Patient/Consumer Engagement (tied)

The goal of therapies is to improve patient health and healthcare outcomes, and the patient/consumer has been recognized as an important stakeholder in their development. Industry at large, beyond the early adopters of patient engagement, is evolving in its understanding of the full potential of patient input. Moving beyond the informed patient's treatment choice at the point of care, industry is acknowledging that patient input can accelerate the development of therapies for the disease community as a whole. Patient input can inform the design of clinical trials, the endpoints/outcomes sought, the weighing of benefit vs. risk,

SUSAN CANTRELL
Director, DIA Americas

the products that will be developed, and those that will stay on the market. The industry continues to look for the best ways to engage patients in meaningful dialogue and to optimize their input.

1. Learning How to Use Big Data (tied)

In an incredibly short period of time, industry has recognized the power of big data for purposes ranging from innovation and discovery to the assessment of real-world outcomes of treatments. Industry and its partners have learned what constitutes big data, how to access it, and what to use it for. But, even veterans of real-world data analysis have been humbled by the task of leveraging these large data sets to their full potential. Traditional analytical approaches are not adequate to go deep into the data to understand patients in the complex dimensions made possible by the integration of multiple data sets. A new field of analytics is emerging that will take full advantage of these big data sets, even to answer evidence questions. Also important is that there are many types of companies in the biopharmaceutical and device industry, with different questions and different abilities to work with the data. New skill development for industry professionals of all disciplines is needed, from those who will work with the data to those who will conceptualize what they want from it.

1. Regulatory Agency Support of Innovation (tied)

As science drives innovation, it is important that regulatory agencies balance their efforts to ensure safety of new types of products, such as live biotherapies and oligonucleotide

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inVentiv Health clinical

VIEWPOINTS

BRANNON CASHION
Global President
Addison Whitney,
part of inVentiv Health

Therapeutic Innovation

A great way to incentivize true therapeutic innovation is to extend marketing exclusivity. Not only should the innovator be able to receive fair market price for his/her drug, but extending exclusivity further rewards manufacturers for innovating/developing truly disease-altering, and in some cases, curative drugs that may not have otherwise been developed under the current framework.

MICHELLE FOUST
Director of Supply Chain Strategy
Almac

The Chain Continuum

We've seen instances where companies have saved millions of dollars simply through better trial supply management. Too often, sponsors and CROs focus on individual elements of the overall process vs. looking at the entire continuum. A best-practice approach would encompass a globally consistent supply plan that accommodates country-specific requirements, adequate forecasting information, and clear channels of communication that support on-time study start-up and ongoing management. Trial managers also should consider packaging and design requirements, including their downstream impact. And they'll need a robust distribution system that offers real-time supply and demand metrics across the supply chain.

MARC SIROCKMAN
Executive VP and General Manager
Artcraft Health

Removing the Risk

To resist innovation is to welcome extinction. The biggest barriers to innovative solutions and practices is the perceived risk associated with innovation, including the changes it brings, the cost of developing new products, and the lack of awareness of the benefits gained from innovative clinical practices.

Connected Health

By far the greatest clinical innovation has been in connected health. In particular, mobile health (mHealth) solutions have transformed and will continue to drive the adoption of a patient-centric and outcomes-based model for healthcare. mHealth offers the opportunity to improve efficiency, from patient-reported analytics to remote monitoring. This approach leads to a new way of interacting with and providing healthcare to improve health outcomes from the clinical to the commercial market.

KEVIN WILLIAMS
VP Corporate Development & Marketing
CFS Clinical

Collaborative Tools

The industry has had "traditional" CTMS systems for many years with certain levels of core functionality that serve their purpose, but the advent of cloud-based technologies and new innovations has opened the door to transforming long-standing approaches. With the critical need for the industry to become more efficient, collaborative tools that involve the investigator sites is of paramount importance. The key is now harmonizing breakthrough tools to drive standardized processes that can truly take work out of the system and reduce the burden for the sites and all key stakeholders.

JEANMARIE MARKHAM
Founder and CEO
Clinlogix

Breaking the Rules

Today's life-science ecosystem requires more to consider: Products that meet unmet medical needs are cost-efficient and demonstrate effectiveness. Innovation requires risks, perseverance, and tenacity to continue to move ideas forward despite challenges. "There are no rules here; we're trying to accomplish something." — Thomas Edison

HUGO STEPHENSON
Executive Chairman
DrugDev

Closing the Clinical Need Gap

The biggest challenge to biopharma today is the disconnect between the therapeutic candidates being put forward and the clinical need. We see this most palpably through the increasing difficulty we all experience finding investigators, and, ultimately, patients to help develop these less than exciting candidates. A new first-line therapy for Alzheimer's disease with excellent science and Phase II data would be knocking investigators and patients back from day one. To drive therapeutic innovation that aligns with social needs, we need to involve investigators and patients earlier in the therapeutic candidate selection. This will guarantee manufacturers a base of motivated researchers for the candidates that get selected, thereby reducing development costs and timelines and will avoid the industry spinning cycles on drugs that nobody wants to study let alone prescribe.

RAJ INDUPURI
Executive VP, Principal Partner
eClinical Solutions

Driving Innovation Through Technology

Innovation is critical for the future and an overarching solution is the use of technology to enable collaboration, data sharing, and gaining insights from research data. There are several primary barriers to innovation: lack of collaboration between different business units and lack of a shared vision inhibits forward-thinking; outdated technology and data

architecture make it difficult to enhance processes and implement best practices; and limited collaboration in pre-competitive phases between industry, academia, and service providers to share knowledge and address R&D challenges.

The DNA of R&D

The Human Genome Project is the most significant innovation. The life-sciences industry is in the early stages of leveraging and benefiting from this to enhance R&D. DNA testing and sequencing enable us to design and develop highly effective new treatments based on genetic factors and achieve personalized medicine goals. DNA analysis also provides insights into risk factors for susceptible illnesses thus allowing us to maximize preventive medicine efforts. R&D based on genetic research will fuel innovation in the immediate future.

KEVIN BURGES
Technical Business & Standards Director
Formedix

Maintaining Standards Across Studies

There are several approaches using individual "common to all" and "therapeutic area" (TA) libraries that define the core standards for a company, or creating one library with all the metadata, regardless of project or TA requirements.

In data acquisition libraries a lot more granularity is possible. Design features of CDISC mean multiple sections can be created in a library. Study teams just pick the appropriate section for the study.

RAMITA TANDON
Senior VP and General Manager
inVentiv Clinical Trial Recruitment Solutions

Datamining Databases

There are global databases of patients, investigators, sites, and trials that can be mined to learn where patients can be found, which sites are in their proximity, and which sites have the best track record. We also recommend using primary research to understand the patient journey and what drives patient and caregiver behavior. It all mirrors the type of work done on the commercial side of the business to understand the landscape and the patient population.

Patient Recruitment: A Constellation of Activities

The processes used in recruitment planning must leverage data and analytics, for a start. Outcomes-based pricing is only feasible if you can introduce a new level of predictability into the process such that everyone knows what is really achievable in a given timeframe. And just as important, sponsors must start to think of the recruitment process more holistically — as a constellation of activities that work together to achieve the end goal of launching new products faster.

JAMIE STACEY
VP, Americas Science Product Leader
Kelly Services Inc.

Innovative Science

The pharma industry conducts extensive analysis to determine the number of drugs that need to enter the pipeline in order to get a viable product to market. Regardless what the data illustrate, the success of the pipeline depends on the results. Today, organizations do not offer the freedom to researchers who work diligently to create and manage drug innovation as much as they did in the past. The company that truly encourages its scientists to take risks and reward those efforts, regardless of outcome, will be the company prolifically filling the pipelines with innovative drugs.

CHRISTOPHER JOCK
VP, Global Managed Solutions – STEM Group
Kelly Outsourcing and Consulting Group

Three Confluence Trends

It's not one single innovation, but rather the combination of three independently developed inventions and methodologies that collectively have had the biggest impact in the past half-century: Internet tools such as WebMD and social media have empowered patients with knowledge; advancements in companion diagnostics coupled with insight gained through the use of integrated (human) systems biology design schema; and mapping the human genome to isolate the hows and whys of diseases to direct patient-specific clinical solutions.

JEFF MEEHAN
Chief Commercial Officer
MD On-Line (MDOL)

iPads Transforming Interactions

Marketers have resoundingly adopted technology: from iPads in the hands of the reps tracking core data on the time and quality of the rep-doctor interaction to using EMRs to deliver co-pay cards. One interesting innovative channel is Instinctive Data (ID). ID is connected to the economics of a physicians practice and works by leveraging MDOL's real-time electronic-claims database to help HCPs identify patients who can benefit from testing, and treatment options. Because these messages are in the doctors non-clinical workflow and are accessed at a time when the physician can spend time understanding the data and tools offered, the success that ID is having in delivering value has been remarkable.

ROB ROBERTSON
President and CEO
MedNet Solutions

eClinical Vendor Considerations

Cloud-based eClinical solutions have proven instrumental in increasing clinical research efficiency and lowering associated costs. Providing sponsors and CROs with intuitive, flexible, and affordable technology platforms ▶

▶ lead to decreased study timelines, increased data quality, and satisfied research personnel. But while the capabilities of the clinical trial solution are important considerations, the characteristics of the company behind the solution are equally important. Make sure to look closely at the eClinical vendor's experience, size, stability, quality systems, audit track record, training services, support philosophy and more.

SHEILA ROCCHIO
VP, Marketing
PHT Corp.

Patient-centric Research

Patient-centric research will transform clinical development into a more productive, efficient process. There's a greater focus on developing products to meet medical needs or outperform existing care standards. Developing drugs that greatly affect smaller populations requires more collaboration among sponsors, patients and advocacy groups. Technology makes it easier for patients and physicians to find suitable trials. Smartphones can be convenient data collection hubs for providing data streams to track safety, symptoms and compliance between visits.

PAUL TANPIENGCO
VP, Marketing and Business Development
Projecis

Project Management Excellence

In the pursuit of doing more, faster, cost-effectively, and flexibly the industry has turned to outsourced services. The potential benefits are often espoused; however there is a growing need for integrated tools to manage this new team paradigm. We are not talking about CTMS or EDC, but tools that aid in the management of projects holistically; documents, assignments, activity status, discussions, events, etc.

Integrated tools allow teams, at a low cost, to work efficiently; providing a common platform to manage project workflows, share current information, and lessen the activity burden on the project manager. Such tools further increase the management opportunity when integrated across different systems; such as EDC, CTNs, IxR, ePRO, etc.

SANDRA LOTTES, PHARM.D.
VP, Global Clinical Development
UBC

Disruptive Innovation

Disruptive innovation is the key phrase for R&D. In clinical research this can be exemplified with development programs that take the investigative molecule from translational medicine to Phase II, especially in oncology. The patient is his/her own control based on an individual genomic profile, which may minimize Phase III development.

Building an Ideal Partnership

The ideal relationship is one built on the framework of a partnership. A collaborative mindset and scientifically rigorous, but flexible, processes will ensure high-quality results and a successful outcome. Innovative technology platforms and solutions driven by an expert team with enough flexibility to manage unforeseen developments in the process are also essential.

SAM DRANOFF
Clinical Practice Leader
UL EduNeering

Applied Technology

Applied technology in clinical development is the greatest innovation for mitigating the constraints of protocol complexity, regulatory and ethical requirements, and business realities. From initial GCP training to TMF submission, applied technology facilitates and maintains continuous quality, compliance, and communication. Managing the diversity and magnitude of the dispersed global clinical trial would not be possible without it. New innovations of applied technology will drive adoption of the coming generation of patient-centered trials.

therapies, with efforts to foster innovation. FDA has risen to the challenge, backed by FDASIA provisions and user fee commitments, by expediting regulatory pathways and working collaboratively with sponsors throughout the drug development process. The agency's commitment to regulatory science and participation as a stakeholder in problem-solving consortia further its understanding of how innovation can be fostered. There are new areas that require guidance from the agency, such as nanotechnology, biosimilars, regenerative medicine, and cellular therapies.

4. Importance of Collaboration

Collaboration as an avenue for innovation was identified as the top trend for 2013 by DIA thought leaders and appears again on this year's list. The perception of collaboration is moving from that of a "novel approach" to a necessary tool for progress in today's environment. Collaboration among the stakeholders in the "healthcare ecosystem" is considered key in fulfilling the "triple aim" of healthcare reform: providing high quality care, with better health outcomes for patients, while reducing cost. A recent survey of biopharmaceutical, payer, and provider executives indicated that there is strong agreement on the need to collaborate with other stakeholders; fewer than 20%, however, said they have made progress in this area.

Biopharma has an important role to play in collaborations for innovation and improved care and outcomes but must form relationships with diverse stakeholders to be fully effective. Positioning itself as an effective collaborator will be a focus for the biopharma industry this year.

5. Personalized Medicine/Tailored Therapies and Companion Diagnostics

The focus on personalized medicine moved up slightly from the sixth most important trend in 2013 to the fifth in 2014. Scientific advances are improving our understanding of disease states, mechanisms of action of new and existing treatments, and reasons for variable responses to therapies among individuals. Industry has recognized that there is potential for success of therapies in smaller, more appropriately identified patient groups. Companies, with the cooperation of regulatory agencies, are optimizing processes for developing companion diagnostics for new and existing therapeutic products. Within the past year, the Supreme Court ruled that naturally occurring DNA is not patentable, opening the field for new companies to compete in the develop-

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ment of genetic testing options, and a number of gene patents are soon to expire, broadening the impact of the Court's decision. Lower cost testing may pave the way to payer coverage of genetic testing, opening access to precision diagnostics for many more patients. At the same time, questions of affordability of precision medicine are being pondered. Personalized medicine is becoming a reality and is moving along a continuum where both benefits and limitations are being identified.

6. Clinical Trial Data Transparency

Although clinical trial data transparency will continue in 2014 to be an area of debate, many changes have occurred in 2013, paving the way for a system in which data sharing is the norm. The EMA put forth for comment its plan for the release of clinical trial data and received more 1,000 comments, delaying the release of final documents until the agency is able to review and assimilate the feedback. GSK released its plan to share data upon request to qualified researchers, and FDA has discussed in various forums the benefits of the prudent release of clinical trial data. Supporters and opponents both have rational points to make, and 2014 will be a year of debate and working through challenges as we move toward consensus or compromise on the question of sharing of detailed data from clinical research.

7. Implementation of Risk-Based Monitoring in Clinical Trials

The FDA, through its risk-based monitoring guidance, has acknowledged that verification of all source documents is not always an effective monitoring approach for clinical trials. It recommends instead the design of a tailored plan to address patient protection and data integrity risks specific to the study.

Translating this concept into clinical practice presents a number of challenges to sponsors, and though TransCelerate Pharma has initiated a project to establish a standard framework to help in this regard, sponsors will be tasked with strategizing how to best allocate their study resources based on risk.

8. Focus on Unmet Medical Needs

In 2014, this issue has moved up in the top 10 trends. In both mature and developing markets, the search for innovation is focusing on unmet medical needs. Products that duplicate available treatments are no longer valued unless they are meaningfully superior or lower in cost. In developing markets, products must fill country-specific needs at competitive prices in order to be successful. In mature markets, there is unmet medical need in diseases such as Alzheimer's and Parkinson's as well as certain cancers. Rare diseases also represent a large collective disease burden and will continue to be a focus of therapeutic development.

It's expected that public discussion of endpoint development and selection, use of surrogate endpoints and accelerated approval, reasonable safety exposures, and other complex issues will be needed to address the needs of rare disease populations.

9. Data Standardization and Interoperability

This was an "honorable mention" trend in 2013 and is gaining importance for a number of reasons.

Standardized, fully electronic data and analysis sets will be required for all submissions to FDA by the year 2018. This has driven the adoption of data standards such as CDISC. Beyond individual clinical trial data sets, the ability to easily combine multiple data sets for big data analysis is greatly enhanced by the application of data standards, and the interoperability of data systems relies on the application of data standards to allow seamless exchange of accurate data. As an example, the goal of extracting clinical research data from electronic health records relies on the adoption of data and operational standards by both enterprises. Industry will be focusing on the adoption of data standards and on interoperability of data systems in the coming year.

10. (Tied) Continued Importance of Global Markets

It is important for companies to work in global markets, especially in developing markets such as China, pan-Asia, Russia and Eastern Europe, India, and Brazil, Argentina, Venezuela, and other Latin American countries, because this is where the majority of future growth will be. But the approach to developing markets is maturing; from previous learnings, the challenges of these regions are better understood. The economics, culture, regulatory and healthcare infrastructures are unique to each country and must be strategically assessed. Successful companies conduct early stage analysis and planning to account for varying global factors when selecting countries for expansion. They also create partnerships to address these varying needs and to build infrastructure, including training of the workforce.

A Top 10 trend in 2013, the topic of global markets just managed to remain above the cut for 2014. It is not really less important this year; it is, as one thought leader expressed, "almost an established fact of life and no longer a trend."

10. (Tied) An Explosion of Mobile Health Applications

In 2013, this was trend No. 7 according to DIA thought leaders, who agreed that regulatory agencies will need to establish rules and guidelines for the appropriate utilization of this new technology. As 2014 begins, FDA has issued its guidance providing clarity on the types of mobile applications it will regulate, and many believe that this will facilitate innovation among developers. As mobile technologies become more reliable, sophisticated, and interoperable, the potential for development is limitless. Companies are utilizing the technology for patient-reported data, monitoring, and simple communication. Context-based applications can collect data about the patient's environment and prompt reminders or medical team alerts. The promise of enhanced patient-provider relationships resulting in higher quality care is discussed, but some warn that this ability to exchange information is only a tool and that trust and attention to the relationship must be a priority.

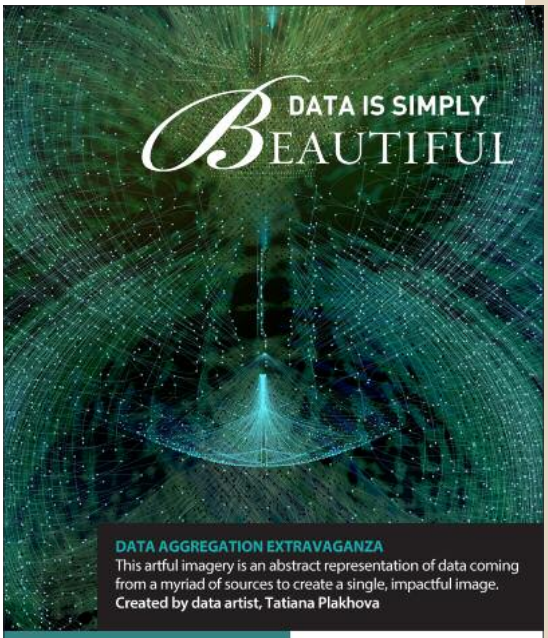
One important trend from the 2013 Top 10 that almost made it to the 2014 list deserves an honorable mention:

11. Meaningful Benefit-Risk Assessments Still in Development

From numerous frameworks for assessing the balance of therapeutic product benefit versus the patient safety risk, a set of common elements has emerged that is integral to meaningful benefit-risk analysis. The industry and regulatory agencies are also growing in their understanding of the variable importance of different risk elements at different stages of the product development and regulatory review. The FDA continues to work out the details of its more qualitative benefit-risk assessment framework, with input from industry and other stakeholders. The methods and best practices for successful communication of the assessment to the patient and the healthcare provider will continue to evolve.

There is no doubt that determining how to best assess benefit-risk will be a priority in 2014, with a shifting focus to the meaningful communication of benefit-risk to patients and practitioners. One can envision the day that these concepts will become so fundamental to the development and use of medical therapies that they are no longer considered trends.

For more information about the 2014 trends impacting the drug industry, visit diahome.org. PV



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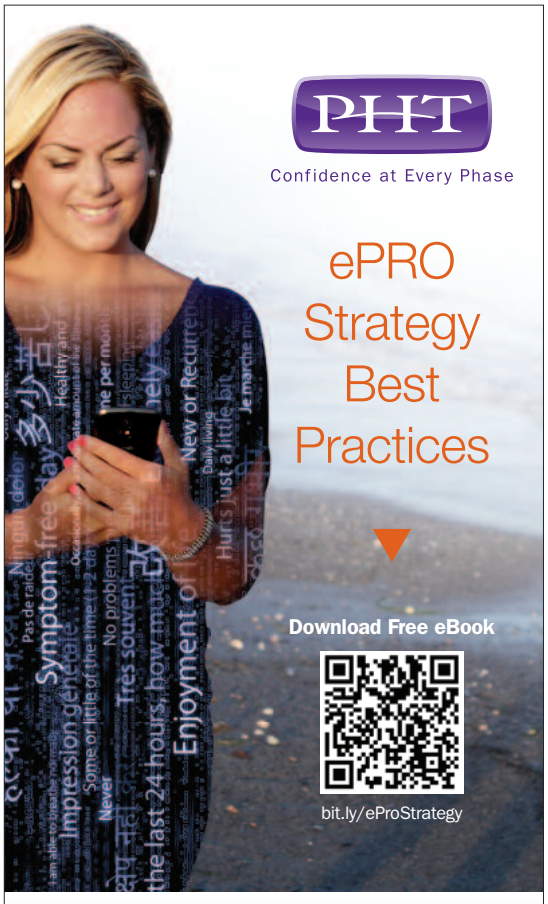

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