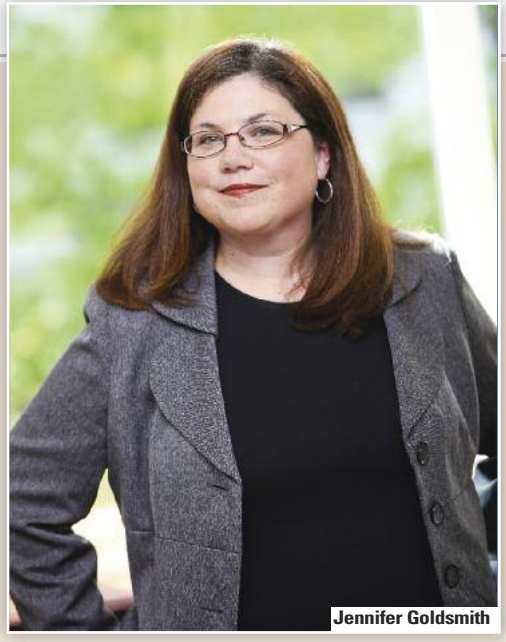
TMF Survey Reveals Lagging Technology Adoption and

Use of Manual Processes

TRENDING NOW: Although advanced eTMF technologies improve inspection readiness and compliance while reducing costs, a majority still use paper or electronic files to manage their TMF.


Jennifer Goldsmith

A majority of 260 trial master file (TMF) owners surveyed by Veeva Systems still use paper or electronic file systems to manage their TMF. The data also show that those using advanced eTMF technologies see greater inspection readiness, visibility, SOP compliance, and cost savings from their eTMF than those using local or cloud file systems.

Respondents using more mature technologies, specifically eTMF applications and content management systems, derive greater benefit from their eTMF. For example, 47% of those with an eTMF application report cost savings as compared to only 28% of those using a local file system. TMF quality is also higher, 84% of those with eTMF applications reported good or major improvement in misfiled documents, compared with 52% of local file system users. Yet, today only about 1 in 10 respondents (13%) report using an eTMF application to manage their TMF.

The survey shows that email (68%) and paper (57%) remain the predominant means of exchanging trial documents with sponsors/CROs.

"Historically, the industry has focused on the rate of eTMF adoption in broad, general terms," says Jennifer Goldsmith, VP of Veeva Vault. "With this more in-depth look at which specific eTMF technologies, processes, and metrics are used, we gain a comprehensive understanding of what is really driving improvements. Technology is a key aspect, but we now know the use of metrics to optimize trial operations is also having an impact."

For more information, visit veeva.com.

Paperless TMF Survey Highlights

Types of eTMFs

- The most common eTMF is a file share, with 25% of respondents using a local file system and 19% a cloud share.
- Content management systems accounted for 30% of eTMFs in use.
- Advanced eTMF applications were used by 13% of respondents.
- 13% of respondents were still using a paper TMF.

Benefits Attributed to eTMF Solution

- Real-time tracking and viewing of documents (68%)
- Easier to search and find documents (65%)
- Easier collaboration with CROs (50%)
- Improved audit and inspection readiness (40%)
- Easier collaboration with sites (40%)
- Cost savings (38%)
- Better visibility into key trial performance metrics (37%)

Use of Metrics

- Organizations that report extensive use of metrics to improve trial execution and design realized a greater number of eTMF benefits than those that do not collect data or utilize metrics.
- Improved document quality/reduced QC findings (64% versus 28%)
- Improved audit and inspection readiness (57% versus 25%)
- Easier collaboration with sites (55% versus 31%)

IPOs Revive Investments for PHARMA AND BIOTECH INDUSTRY

The heightened private equity and venture capital (PEVC) deal activity in the global healthcare industry during the recession years, 2008-2010, witnessed a decline post-2010. However, the fall in deals was not uniform among the constituent sectors, with the pharmaceutical, biotechnology and healthcare equipment sectors experiencing a much sharper decline in investor interest than the healthcare technology and provider segments, according to Frost & Sullivan.

"Private equity deals in the pharmaceutical sector have been relatively stable over the post-recession period whereas activity in the biotechnology segment began to decrease after reaching its peak in 2010, due to the uncertainty caused by healthcare reform in the U.S., long incubation periods, and delayed approvals," says Frost & Sullivan Financial Analyst Dr. E Saneesh. "VC deals across both these sectors also started to plummet from 2011 due to

THERAPEUTIC TRAX...

CANCER

Oncologists are optimistic that Boehringer Ingelheim's second-generation irreversible EGFR tyrosine kinase inhibitor (TKI) Gilotrif/Giotrif will offer efficacy and deliver advantages over currently available agents for the second- and subsequent-line treatment of EGFR-mutation-positive non-small cell lung cancer (NSCLC). Interviewed oncologists are also optimistic that the third-generation EGFR TKIs CO-1686 (Clovis oncology/Celgene) and AP-26113 (Ariad pharmaceuticals) will offer competitive advantages in efficacy, safety, and tolerability and delivery attributes.

Source: Decision Resources Group, NSCLC (EGFR-Mutation-Positive; Previously Treated): Are Emerging Targeted Therapies Poised to Fill the Significant Unmet Need of Patients in the Second and Subsequent Lines of Therapy?

For more information, visit DecisionResourcesGroup.com.

Fueled by the increasing global prevalence of pancreatic cancer (PC), coupled with the approval of at least three new drugs, the PC therapeutics market value will climb from $855.8 million in 2012 to about $1.21 billion by 2019, at a CAGR of 5.1%. Threshold's TH-302 and Merrimack's MM-398 will be approved during the forecast period. This will be due to these drugs demonstrating significant improvements in progression-free survival, and trends toward improved overall survival in clinical trials.

Source: GBI Research, Pancreatic Adenocarcinoma Therapeutics in Major Developed Markets to 2019 - Early Stage Pipeline Shows Diversity of Novel Targets though Commercial Impact Remains Distant

For more information, visit gbiresearch.com.

The discovery of acquired genetic alterations in the EGFR gene and rearrangements in the ALK gene has shifted the NSCLC treatment landscape away from chemotherapies toward targeted biomarker-driven therapies. The launch of AstraZeneca's Iressa, Roche's Tarceva, and Pfizer's Xalkori (crizotinib) has revolutionized the treatment options available to NSCLC patients who harbor specific EGFR mutations and ALK rearrangements. Emerging second-generation EGFR and ALK-targeting therapies from Boehringer Ingelheim (BI) and Novartis will seek to displace the established marketed therapies and capture market share by providing superior clinical efficacy in these specific patient populations.

Source: GlobalData, PharmaPoint: Non-Small Cell Lung Cancer - Global Drug Forecast and Market Analysis to 2022

For more information, visit globaldata.com.

CARDIOVASCULAR

Multiple major drug patent expiries will cause the global anti-hypertensive market value to decline from $40 billion in 2013 to $37.6 billion by 2020, at a negative CAGR of 0.9%. While the anti-hypertensive market value is first expected to increase to $44.5 billion by 2017, representing a CAGR of 2.6%, it will then fall at a negative CAGR of 5.4% through to 2020.

Source: GBI Research, Anti-Hypertensive Therapeutics in Major Developed Markets to 2020 – Increased Uptake of Combination Therapies to Offset Effects of Key Patent Expiries

For more information, visit gbiresearch.com.

CNS

The epilepsy therapeutics market value in the eight major countries — the U.S., Canada, France, Germany, Italy, Spain, the UK and Japan — will increase from $3.4 billion in 2012 to $4.5 billion by 2019, at a modest CAGR of 3.9%. The U.S. will grow at a higher CAGR of 4.8%, climbing from $1.9 billion in 2012 to $2.6 billion by 2019. Meanwhile, the five European countries and Canada will achieve a combined, smaller CAGR of 3.1% during the forecast period.

Source: GBI Research, Epilepsy Therapeutics in Major Developed Markets to 2019 - New AEDs with Novel Mechanisms of Action Signal a Shift in Treatment Patterns

For more information, visit gbiresearch.com.

GASTROINTESTINAL

Surveyed U.S. and EU5 gastroenterologists say the effect on mucosal healing and improvement in the maintenance of remission are two of the attributes that most strongly influence their prescribing decisions in moderate to severe ulcerative colitis. Emerging therapies that offer improved effect in these attributes over current therapies would be well received and poised for strong uptake. Based on thought leaders' opinions and clinical trial data, Takeda's vedolizumab (Entyvio) has great potential owing to its improved efficacy in the maintenance of remission and long-term mucosal healing.

Source: Decision Resources Group, Ulcerative Colitis (moderate to severe): Amid significant unmet need, what attributes do gastroenterologists and payers expect of a therapy with a mechanism of action different from the currently available TNF-alpha inhibitors?

For more information, visit DecisionResourcesGroup.com.

INFECTIONS

Thanks to patent expirations of several key therapies, the HIV treatment market value will increase at a slow pace in the coming years, from $14.3 billion in 2012 to $16.3 billion by 2019, at a CAGR of 1.9%. The first-line antiretroviral therapies Atripla and Truvada will lose patent protection during the forecast period, which will hurt their markets in Europe and Canada.

Source: GBI Research, HIV Therapeutics in Major Developed Market to 2019 - Limited Pipeline Efficacy Improvement, Patent Expirations and Stringent Healthcare Spending to Suppress Market Growth

For more information, visit gbiresearch.com.

VACCINES

The market for meningococcal vaccines was valued at $1.5 billion in 2012 and is expected to reach a value of $3.7 billion in 2019, growing at a CAGR of 14.9% from 2013 to 2019. The conjugate vaccines segment is likely to lead the overall meningococcal vaccines market in terms of revenue, which is estimated to reach approximately USD 2.5 billion by 2019 at a CAGR of 12.9%. Amongst the pipeline vaccines, Novartis's Bexsero is expected to grow at the fastest rate of 24.7% during the forecast period 2013 to 2019.

Source: Transparency Market Research, Meningococcal Vaccines Market (Polysaccharide, Conjugate, and Combination Vaccines, along with Pipeline Analysis) - Global Industry Analysis, Size, Share, Growth, Trends and Forecast, 2013 – 2019

For more information, visit transparencymarketresearch.com.

risks associated with regulatory uncertainty, long gestation periods, and increased cost of production."

The strong comeback of initial public offerings (IPOs) in 2013 signals a positive outlook for investment in the pharmaceutical and biotechnology industry.

The number of IPOs in the global biotechnology sector surged by 100%between 2012 and 2013, primarily on account of the 26 IPOs that took place in the U.S. IPOs in the pharmaceutical industry also rose with 11 deals in 2013, after the volume of IPOs declined to almost one-sixth of the sector's value between 2011 and 2012.

For more information, visit financialservices.frost.com.

Public Perception of Trials CONTINUES TO IMPROVE

Public perception of clinical trials has improved, according to a new study by inVentiv Clinical Trial Recruitment Solutions (iCTRS), in collaboration with The Center for Information and Study on Clinical Research Participation (CISCRP).

The percentage of people who learn of clinical research from family members is almost three times higher in Latin America than in North America. And, patients in the Asia-Pacific region are less than half as likely as patients in North America to continue participating in a clinical research study because they feel obligated to do so.

A better understanding of the patient and caregiver perspective can improve patient recruitment and retention in trials, says Jim Kremidas, senior VP of patient recruitment at iCTRS and a member of the CISCRP board of advisors.

"The basis for successfully engaging patients is understanding them," he says. "Through conducting behavioral research, we can gain insights into people's decision-making processes, motivational drivers and influencers, all of which inform the success of a study's outreach strategy and communication plan."

For more information, visit ciscrp.org.

Public Perceptions of Clinical Research

- Although overall a high proportion of respondents say that they understand what the term "Clinical Research Study" means, a relatively high percentage (26%) don't know where clinical research is conducted.
- More than 60% of the public believe that clinical research studies are conducted in university medical and government health centers; 40% in hospitals; and 33% in clinics.
- A very high percentage believe that clinical research studies are somewhat safe (58%) and very safe (36%).
- 46% of the public agreed with the statement that participants are experimental test subjects in 2005; 35% agreed with that statement in this recent study.
- A high proportion (87%) of the public says that it is somewhat willing or very willing to participate in a clinical research study.

Source: The Center for Information and Study on Clinical Research Participation

Dearth of Blockbuster Drugs Boosts DISCOVERY SERVICES MARKET

The market for outsourced drug discovery services is robust with an optimistic outlook going forward, according to Kalorama Information. The healthcare market research firm say outsourcing in drug discovery market reached $12.8 billion in 2013, which increased about 15% from $11.1 billion in 2012.

The global drug discovery outsourcing market is expected to continue a similar growth pattern in the next five years.

Global pharmaceutical sales growth has slowed due to the prevalence of lower-cost generics, the sustained impact of the global economic slowdown that began in 2008, and patent expirations, particularly of blockbuster drugs. This is a driver of discovery efforts and puts pressure on firms to move more work out of the firm.

"Drug discovery is essential right now," says Bruce Carlson, publisher of Kalorama Information. "Between 2009 and 2015, the pharmaceutical industry is facing the most abrupt revenue decline in history as 18 of the top 20 bestselling drugs will lose patent protection."

For more information, visit kaloramainformation.com.

Pharma has to Overcome PAYER MISTRUST

The majority of payers in the United States and Europe believe that drug adherence solutions and data that pharma companies possess are vital to lowering healthcare costs and improving outcomes.

But lingering mistrust of the pharma industry is likely to stymie efforts by pharma companies to engage with payers in these areas without a fundamental change from current

Building Blocks for Strategic Payer Engagement

Many pharma companies have been experimenting with services and solutions that expand beyond the pill. In considering the adoption or expansion of such approaches, companies should:

Make the right comparison. At a time of rapid change, companies should make decisions about moving beyond the pill based on comparisons to the drug business of tomorrow, not the drug business of yesteryear.

Approach payers strategically and comprehensively. To move beyond pilots, companies need to consider four key components: screening payers to identify the best targets; segmenting to customize offers to different payers; sequencing to expand solutions more broadly over time; and building sustained, enduring relationships.

- Develop data-driven insights and interventions. The big opportunity in engaging payers with big data is in building the complete picture and targeting the small percentage of patients who will drive the biggest percentage of costs.

Create customer-centric solutions. Payers are interested in solutions that look across disease franchises, span the cycle of care and are unbiased between the products of different manufacturers. Companies need to create solutions that help payers address challenges — rather than merely to sell more product.

Be transparent to rebuild trust. Without trust, pharma's data and solutions will get little traction with payers.

Source: EY

approaches. These are findings of EY's Progressions report.

The survey finds that payers are focused on cost containment and budgetary predictability over outcomes-based approaches. While prescription drugs only account for about 10% of healthcare expenditures, payers see curbing rising drug costs as a more important business challenge than non-drug costs.

Eighty-eight percent of payers strongly or somewhat agreed that drug prices are a major driver of healthcare cost increases, while only 42% of pharma respondents did the same.

Additionally, 78% of payers agree that boosting drug adherence is a critical component of lowering healthcare costs and 57% agree that pharmaceutical companies have data that is vital for measuring and improving outcomes. However, fewer than half of payers (43%) agree that pharma's data is credible for measuring and improving outcomes.

Most payers do not think that pharma companies developing "beyond-the-pill" services can be unbiased between their products and those of competitors, with only 15% of respondents even somewhat agreeing with that statement.

"More than ever, payers today need help with implementing healthcare reforms," says Patrick Flochel, EY's global pharmaceutical leader. "But while pharma companies have useful data and potential solutions in areas such as drug adherence, they are unlikely to get much traction because payers simply don't trust that they have the impartiality required."

For more information, visit ey.com.

Impact of CER on HEALTHCARE DECISION-MAKING IS STILL ON THE HORIZON

A new survey of healthcare stakeholders reveals continued optimism for the use of comparative effectiveness research (CER) as a tool for improving healthcare decision-making, but shows the impact of CER has not yet been realized, according to the fourth annual survey of CER stakeholders, conducted by the National Pharmaceutical Council (NPC).

"It's clear from this survey that while expectations around CER's promise remain strong, the impact is viewed as a future prospect rather than an immediate reality," says NPC President Dan Leonard. "However, the work of PCORI and other entities in key areas has translated into some notable shifts in perceptions among stakeholders, suggesting that the work being done in the CER field is being closely watched by those most likely to be impacted."

According to the survey, while 59% of respondents felt CER was very important, the majority of respondents (84%) felt CER had little impact on healthcare decision-making in the past 12 months. Confidence in CER's potential increases with the time horizon. Respondents felt more confident about the impact of CER on healthcare decision-making over the next three to five years, with a moderate improvement indicated by 56% and 50%, respectively, and a substantial improvement indicated by 21% and 42%, respectively.

For more information, visit npcnow.org. PV