CROs' Use of eTMF Apps Increases: VEEVA SURVEY

Trending Now: A majority of CROs cite speeding study start-up as top driver for eTMF technology adoption.

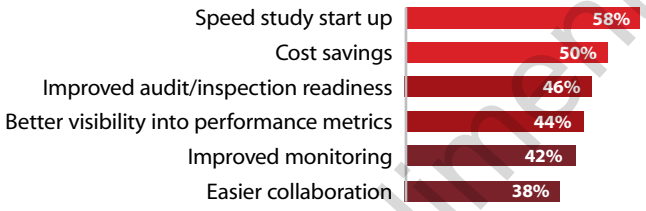

Mike Burton

A **SIGNIFICANT NUMBER** of contract research organizations (CROs) are increasingly using electronic trial master file (eTMF) applications, according to a new survey by Veeva. The global study of TMF owners found that 38% of CROs surveyed now use eTMF applications versus just 21% in 2014. A number of benefits are prompting CROs' adoption of eTMF technology. More than half (58%) say faster study start-up is a key driver, while 50% cite cost savings.

CROs that have implemented an eTMF solution report a broad range of benefits impacting all aspects of the TMF. When it comes to inspection-readiness, particularly, most CROs see improvements in the number of missing documents (92%); misfiled documents (89%); duplicate documents (86%); incomplete documents and/or missing signatures (84%); and expired documents (81%). Additionally, more than half (57%) report improved audit- and inspection-readiness as a result of eTMF adoption.

"Indeed, eTMF applications are the key to fully capitalizing on the wealth of information available to today's clinical leaders," says Mike Burton, Veeva's director of CRO alliances. "There is tremendous opportunity for improvement across clinical processes, but it's often difficult to spot weak points without metrics. Advanced eTMF solutions, in contrast, can quickly reveal common bottlenecks and process inefficiencies to help speed study start-up and, ultimately, improve study quality."

Top Drivers of eTMF Adoption



* Note: total respondents: 50

Reimbursement Biggest Challenge for Cancer Patients

Lack of reimbursement for supportive care services topped the list of challenges facing cancer programs today, with 65% of programs naming this as their biggest challenge, despite the increase in communication with payers on the value of these services, according to the Association of Community Cancer Centers' (ACCC) sixth annual Trends in Cancer Programs survey.

The number of patient-centered services provided has continued to grow, but the reimbursement necessary to provide these services is lagging. The majority of cancer programs now offer nurse navigation (89%), psychological counseling (88%) survivorship care (87%), and palliative care (87%). This expansion of services may have contributed to the 61% of respondents who cited budget restrictions as their second biggest challenge.

"America's cancer programs are increasingly being asked to do more with less, a trend we are seeing across healthcare," says ACCC President Steven D'Amato. "As these programs strive to provide more patient-centered services, knowing the positive effect these services have on improving patient health outcomes, reimbursement has become a bigger challenge."

Managed Markets Groups Manage Government Payers


Jacob Presson

In the life-sciences industry, managed markets groups at the majority of surveyed companies are the primary function responsible for communicating with government payers. According to pharmaceutical intelligence firm Cutting Edge Information, these groups are typically trained in discussing health economics data or have the flexibility to engage a medical science liaison (MSL) or health outcomes liaison (HOL).

Managed markets groups at 57% of companies are tasked with communicating with government payers. MSLs are the primary means of communication at 14% of companies. Meanwhile, 29% of survey respondents indicated dedicated reimbursement or market access-related groups that have similar responsibilities to a managed markets group.

"An important aspect of government payer relationship management is frequent contact," says Jacob Presson, senior research analyst at Cutting Edge Information. "While managed markets teams typically lead this charge, other groups are often involved with getting products onto formularies."

Americans Want to Know What's in Their DNA


Ramji Srinivasan

More than half (53%) of U.S. consumers want to know what's in their DNA, according to a new survey by health technology company Counsyl. Yet only 7% of respondents say their doctor has discussed genetic screening with them.

"The survey findings speak to the public's appetite to know what's in their DNA — something we're encouraged to see, since early awareness of risk can make a big difference in health outcomes," says Ramji Srinivasan, co-founder and CEO of Counsyl. "There is still much to be done, though, in helping patients and physicians understand how advancements have made genetic screening cost-effective and results delivery easy to navigate, so that potentially life-changing information can be within everyone's reach."

The survey, conducted by independent research company ORC International of 1,020 adults, explored knowledge of and attitudes toward genetic testing among adult consumers. The strong interest in genetic screening may point to an interest among consumers in using genetic screening to be more proactive about their healthcare. PV

Therapeutic trax

Biologics

The global biosimilars/follow-on biologics market is projected to grow at a CAGR of 49.1% from 2015 to 2020. Europe will continue to dominate the market while Asia Pacific will emerge as fastest growing region over the forecast period. Recent approval of Zarxio (filgrastim-sndz) as first biosimilar by U.S. FDA has opened new opportunities for biosimilar manufactures. Patents for number of blockbuster bio-pharmaceuticals have either expired or are on the verge of expiration, which is majorly driving the growth of biosimilars industry.

Source: Allied Market Research

Cancer

Advanced targeted therapies are dominating the colorectal cancer pipeline, accounting for 60% of the drugs under development. This trend remains in line with the broader oncology market's shift away from standard cytotoxic regimens toward tumor-specific, personalized modalities.

Source: Frost & Sullivan

Despite few products having so far reached the market and capturing strong revenue, the gene therapy pipeline remains large, with 906 products in active development. However, the majority of these remain in early steps of development, with 76% at either the discovery or preclinical stage. Oncology is the predominant area for gene therapy developments.

Source: GBI Research

The global market value for non-small cell lung cancer (NSCLC) treatment will rise from $6.9 billion in 2014 to $10.9 billion by 2021, representing a CAGR of 8.5%. This increase will occur across the eight major markets of the US, Canada, UK, Germany, France, Italy, Spain, and Japan, driven by the introduction of immune-checkpoint inhibitors, such as Opdivo and Keytruda.

Source: GBI Research

The immune checkpoint inhibitors market will grow at more than 25% annually. The market is currently characterized by the presence of three marketed drugs and 34 drugs in clinical development. BMS is the leading player followed by other giants including AstraZeneca, Merck, Pfizer, Roche, GSK, Novartis and Amgen.

Source: Roots Analysis

Cardiovascular

The global acute ischemic stroke diagnosis and treatment market was valued at $1.2 billion in 2013 and is estimated to hit $1.9 billion by 2020. The North America acute ischemic stroke diagnosis and treatment market accounted for the highest market share in 2013.

Source: Transparency Market Research

Infections

The value of the global hepatitis B virus (HBV) therapeutics market will increase modestly over the next six years, from almost $3 billion in 2014 to $3.5 billion by 2021, representing a CAGR of 2.3%. This rise will occur across the eight major markets of the US, Canada, the UK, France, Germany, Italy, Spain and Japan, and will be primarily driven by increasing immigration from medium and high-prevalence countries.

Source: GBI Research

Muscular Dystrophy

The Duchenne muscular dystrophy market will experience intense growth between 2014 and 2019, with estimates for the 2014 sales reaching about $8.2 million across the six major markets, primarily driven by the sale of generic corticosteroids. By 2019, there will be a staggering growth in sales at a CAGR of 160.5% across these markets over period.

Source: GlobalData

Respiratory

Personalized treatment for severe asthma will drive market growth despite patent expirations. Over the forecast period, the asthma therapeutics market will be strongly characterized by the loss of patent protection for several leading brands: Advair, Singulair, Symbicort, and Xolair. Significant unmet need remains for safer therapies with improved dosing regimens, and, among the severe, inadequately controlled patient population, for therapies that can improve asthma control.

Source: GlobalData

The increased use and higher cost of combination therapy for pulmonary arterial hypertension (PAH) will enhance treatment outcomes and bolster market growth. Combination treatments could become the standard of care for PAH patients sooner than expected, as the adoption of initial combinations could be rapid in future clinical practice. The only deterrent to altering the standard course of treatment could be financial pressures from healthcare insurers, as the average annual cost of therapy for PAH treatment is already around $130,000.

Source: GlobalData

Vaccines

The global vaccines market is expected to reach $57.88 billion by 2019 from $33.14 billion in 2014, at a CAGR of 11.8% from 2014 to 2019. The vaccines market is fragmented due to the presence of a few big players and several small players. Prominent players in this market include Bavarian Nordic, CSL, Emergent BioSolutions, GlaxoSmithKline, Johnson & Johnson, MedImmune, Merck, Novartis, Pfizer, and Sanofi Pasteur.

Source: MarketsandMarkets

Vaccine products in the R&D pipeline have more than tripled since 2005 and annual worldwide sales are on track to reach $40 billion by 2020. The number of vaccine products in clinical trials worldwide has grown dramatically, ranging from 223 to 298 annually since 2008, up from 77 in 1998. In addition, worldwide vaccine sales grew at an average annual rate of 11.5% between 2005 and 2014.

Source: Tufts Center for the Study of Drug Development.