

# CROs are Leading Drive to Improve THE EFFICIENCY OF CLINICAL TRIALS

► *Trending now:* Survey reveals significant improvements in inspection readiness among CROs.

**A GLOBAL INDUSTRY** survey by Veeva of trial master file (TMF) owners shows growing use of electronic trial master file (eTMF) solutions among clinical research organizations (CROs) as a result of benefits in audit and inspection readiness. In addition, findings reveal that CROs are leading the drive toward active TMF management and making strides in the use of performance metrics and data to improve the efficiency and speed of clinical trials.

eTMFs are helping CROs to maintain complete and accessible trial master files to reduce the number of inspection findings. CROs who use eTMF applications are achieving significant improvements across major inspection finding categories such as fewer duplicate documents (61%), misfiled documents (53%), and incomplete documents (51%).

Given these benefits, one of the top drivers of eTMF adoption among a majority of CROs (65%) is improved audit and inspection readiness. At the same time, CROs are now less reliant on document exchange methods that are more difficult to track and provide little to no audit trail. For example, the use of email for document exchange is down significantly from 80% in 2014 to 61% today, while almost a third (31%) are using an eTMF application to share TMF documents with sponsors (up from 24% in 2014).

“Over the past several years CROs have played a pivotal role in moving the life sciences industry toward more efficient clinical trial processes,” says Jill Johnston, VP of Veeva Vault Clinical. “As clinical trials become increasingly outsourced, we’ll see that trend continue especially as demand grows for unifying systems, processes, and stakeholders across clinical operations.”



Jill Johnston

gressive specialty drug contracting terms that maximize client and patient value.”

The study found that health plan cost trends have gone down compared with 2016, but continue to significantly outpace inflation and average wage increases. While prescription drug cost trend is projected to rise 11.3% in 2017 and the popular open access PPO/POS plan cost trend by 7.8%, wages are projected to increase by just 2.5%.

## Pharma Companies Are Targeting Western Markets for New Drug Launches

A recent study by Cutting Edge Information found that 74% of surveyed drug companies market new products in the United States during their first launch wave. During this same wave, only 20% of surveyed companies launch in all five major ex-U.S. markets; a small portion (10%) launch in both the U.S. and those ex-U.S. countries.

However, during the second launch wave, 87% of surveyed drug manufacturers release products in the United States, while 90% launch in all five major ex-US markets, and 80% of firms launch in the major Western markets.

“Getting approval in major Western markets early and at high price points provides a solid base for subsequent launches in the process,” says Adam Bianchi, senior director of research at Cutting Edge Information. “In addition, successful launches in high-price, high-population markets can provide an important boost in product revenue to support ongoing operations as later launch waves continue.” <sup>PV</sup>

## Prescription Drug Benefit Cost to Outpace Inflation and Wage Increases

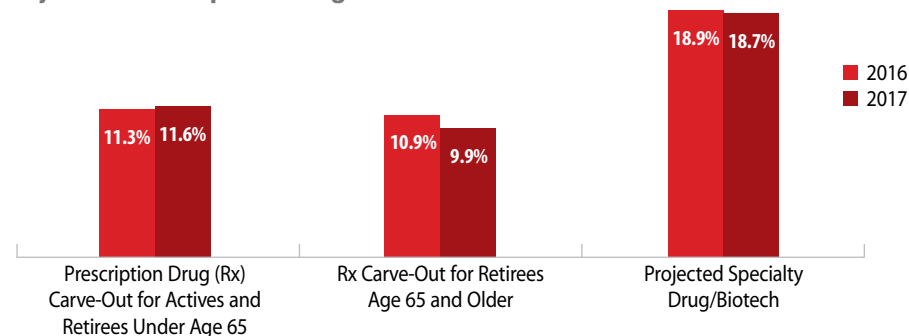
Prescription drug benefit cost trends for active populations continue to increase at double-digit rates, according to forecasts in Segal’s 2017 Health Plan Cost Trend Survey.

The prescription drug cost trend for active employees and early retirees is projected to be 11.6% in 2017, up from 11.3% in 2016. For Medicare-eligible retirees, prescription drug trend is also projected to be high (9.9%), but lower than the 2016 projection (10.9%). However, the projected specialty drug/biotech trend rate for 2017 is an exceptionally high 18.7%, and while typically less than 1% of all medications are specialty drugs, survey respondents indicated those drugs now account for 35% of total projected prescription drug cost trends for 2017.

“Given the increasing number of pharmaceutical products now available for conditions that require the use of specialty medications, plan

sponsors should consider implementing strategies that manage patients who use these drugs and target their costs,” says Edward Kaplan, national health practice leader. “This can include utilization-management controls, formulary or preferred step-therapy; tiered copayment structure and ag-

### Projected Prescription Drug Trends: 2016 and 2017



Source: 2017 Segal Health Plan Cost Trend Survey

## Therapeutic trax

### Arthritis

The osteoarthritis market across the seven major markets of the U.S., France, Germany, Italy, Spain, the UK, and Japan is forecast to grow from \$3.25 billion in 2014 to \$10.49 billion by 2024, representing a CAGR of 17.8%. This growth can be attributed to the launch of new biologic therapies priced at a substantial premium to small-molecule therapies, the launch of drugs with novel mechanisms of action (MOAs) and disease-modifying effects, the growth of the osteoarthritis population, and recent improvements in imaging techniques to facilitate the development of disease-modifying osteoarthritis drugs.

Source: GlobalData

### Autoimmune Diseases

America's biopharmaceutical research companies have 311 medicines and vaccines in clinical trials or pending review by the FDA for patients with autoimmune diseases. Today, more than 80 autoimmune diseases have been identified, including psoriasis, lupus, and celiac disease. Lupus, for example, affects about 1.5 million Americans, and it is estimated that more than 16,000 new cases of lupus are reported each year. There are 39 medicines in development for lupus.

Source: PhRMA and Lupus Foundation of America

### Cardiovascular

Sales of venous thromboembolism therapeutics were about \$2.8 billion across the seven major markets in 2015, which includes the U.S., the five major European markets (France, Germany, Italy, Spain, and UK), and Japan. By 2025, the VTE market is expected to grow at a CAGR of 2.89%. Over

this forecast period, the most prominent wave of sales increases comes from the novel oral anticoagulants class, which is expected to peak in global sales by 2023, reflecting a 10-year CAGR of 5.79% by 2025, despite the generic erosion of several key players.

Source: GlobalData

The heart failure market is set to rise from around \$3.2 billion in 2015 to \$11.8 billion by 2025, a CAGR of 13.7%. The major drivers of this growth, which will occur across the seven major markets of the U.S., France, Germany, Italy, Spain, the UK, and Japan, will be the launch of Novartis' first-in-class drug, Entresto, and several acute heart failure add-on therapies, as well as an increase in the global prevalence of chronic heart failure.

Source: GlobalData

### CNS Disorders

The market for attention deficit hyperactivity disorder (ADHD) across the seven major markets of the U.S., France, Germany, Italy, Spain, the UK, and Japan, is set to experience an increase from about \$6.1 billion in 2014 to \$13.9 billion by 2024, at a CAGR of 8.5%. This growth can be attributed to the launch of efficacious pipeline products with convenient oral formulations or less frequent dosing than currently available products, an increase in treatment rates, and the continued awareness and recognition of ADHD in the adult age group.

Source: GlobalData

The global Alzheimer's therapeutics market is expected to reach \$6.4 billion in 2024. Some primary factors driving the market growth include rising government initiatives to raise awareness levels among people. Growing knowledge about the Alzheimer's disease (AD)

and its high prevalence and incidence in developing economies are few of the major drivers supporting the market growth.

Source: Grand View Research

### Dermatology

The global dermatology market was valued at \$20.0 billion in 2015, and is projected to grow at a CAGR of 7.73%, reaching \$33.7 billion in 2022. Key drivers of this growth will be the uptake of recently approved premium biologics, as well as promising late-stage products that are expected to be highly valuable.

Source: GBI Research

### Diabetes

The global market for diabetes mellitus and obesity is set to rise from \$70.8 billion in 2015 to \$163.2 billion by 2022, at a strong CAGR of 12.7%. This market increase is driven by the success of a number of T2DM pipeline products, and a rapidly expanding global patient population. However, obesity pipeline activity is set to remain markedly low, despite a patient population of epidemic proportions.

Source: GBI Research

### Women's Health

The global osteoporosis drugs market was valued at \$8.86 billion in 2015 and it is expected to grow at a CAGR of 3.8% during 2016-2022. Among the various classes of osteoporosis drugs, the rank ligand inhibitor segment is expected to witness the fastest growth, a CAGR of 4.3% during the forecast period. This growth is due to growing geriatric population, increasing awareness of osteoporosis, and increasing healthcare expenditure.