

Biopharma SALES OPERATIONS STABILIZING

► *Trending now:* Growth in sales operations spending driven by changing biopharma challenges and priorities.

THE BIOPHARMACEUTICAL SALES OPERATIONS rollercoaster ride appears to have leveled off, according to TGaS Advisors. A recent TGaS Commercial Operations Landscape Study shows that operations teams' efforts to absorb change and new capabilities while reducing levels of overall investment have stabilized. Findings also point to the need for sales operations to evolve more rapidly than ever to stay ahead of continuing changes in the pharmaceutical landscape.

TGaS research across its network of more than 50 pharmaceutical companies shows that investment is being driven by the shifting landscape of specialty salesforces, new data sources, and the changing influence of customer types.

"Sales operations departments are not just investing in more of the same activities, they have had to adjust and will continue to do so," says Curt Staab, a management advisor at TGaS. "The rapidly evolving industry has increased the level of complexity for sales operations teams, which impacts how sales teams are resourced and incentivized as well as how data is managed and reported."



Curt Staab

Pharmaceutical Deals Offset Cost of Developing a Novel Drug

With the average cost of getting a novel drug to market at almost \$2.5 billion, and few products achieving blockbuster status, deal-making is becoming increasingly vital for pharmaceutical companies to offset rising research and development (R&D) costs, says business intelligence provider GBI Research.

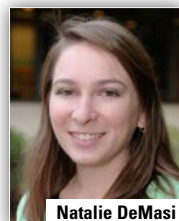
The company's latest CBR Pharma report states that pharmaceutical companies are considering various strategies to overcome the current challenges, which also include shifts in patent laws and the struggling global economy, with deal-making the foremost method of boosting short-term revenue.

GBI Research's report also states that overall pharmaceutical deal values remained between \$110 billion and \$160 billion from 2010 to 2014, but will rise markedly this year, with a total value of \$261 billion already amassed by the end of July 2015, and further increased by more recent deals.

"Deal volume and value have so far increased in 2015 compared with 2014," says Priyatham Salimadugu, analyst for GBI Research. "This creates a pyramid whereby more companies are developing drug molecules at the bottom of the pyramid, than

commercializing them at the top, as typified by Pfizer's recent \$160 billion takeover of Allergan. Partnerships were the most popular type of deal between January 2014 and July 2015, followed by licensing deals and acquisitions. Though acquisitions were fewer, the disclosed deal value for this category was the highest."

Authorized Generics Show Significant ROI



Natalie DeMasi

Implementing an authorized generics strategy produces a 5,100% return-on-investment (ROI), higher than any other lifecycle management (LCM) strategy examined in the research, according to Cutting Edge Information.

The study found that drug companies continue to invest in authorized generics strategies to maintain profits and avoid patent litigation. One of the primary goals for pharmaceutical brand teams that undertake an authorized generics strategy is to slow the pace of market share decline after market exclusivity loss, according to the study.

Cutting Edge Information researched the cost effectiveness of major pharmaceutical companies'

Therapeutic trax

Diabetes

The uptake of recently approved and pipeline premium products for Type 1 diabetes mellitus will be a key driver of market growth to 2021. The global market value for T1DM treatment will rise from \$4.2 billion in 2014 to \$7.1 billion by 2021, at a robust CAGR of 7.9%. This increase will occur across the eight major countries of the US, Canada, France, Germany, Italy, Spain, the UK, and Japan.

Source: GBI Research

The global human insulin market is expected to reach \$48.49 billion by 2020. The market is growing moderately due to an increase in prevalence of diabetic population, rise in geriatric population, rising awareness of diabetes, and rising prevalence of obesity. But, strict regulatory requirements for approval of insulin and the high cost of analogues are inhibiting growth.

Source: P&S Market Research

Gastrointestinal Disorders

The opioid-induced constipation treatment

authorized generics strategies and highlighted those findings. Although not as popular as other lifecycle management strategies, authorized generics deliver the most substantial ROI among all of the LCM tactics studied. The study found that for every dollar spent implementing an authorized generics strategy, a drug company receives \$51 back.

"Authorized generics strategies were rated as highly effective lifecycle management tactics," says Natalie DeMasi, senior research analyst at Cutting Edge Information. "Companies often turn to authorized generics deals to preserve branded drug sales and avoid lengthy court battles when generic companies file a Paragraph IV certification."

market across the six major countries of the US, Germany, France, Italy, Spain and the UK will increase from an estimated \$66.7 million in 2014 to \$652.4 million by 2019, representing a rapid CAGR of 57.8%. The introduction of novel targeted oral therapies for opioid-induced constipation, such as peripherally acting mu-opioid receptor antagonists, will be a major driver of market growth.

Source: GlobalData

Respiratory Diseases

The COPD treatment market landscape will change substantially by 2021, as patents of leading brands expire and competitors offer new alternatives. The market will rise steadily from \$9.2 billion in 2014 to \$11.2 billion in 2021, at a CAGR of 2.9%. The COPD therapeutics market landscape will be characterized by the sales erosion of leading brands. Currently, the market is dominated by three brands: Pfizer's Spiriva, GlaxoSmithKline's Advair, and AstraZeneca's Symbicort.

Source: GBI Research

Transplants

The global market for graft-versus-host disease

(GVHD) treatment will increase from \$295.7 million in 2013 to \$544.6 million by 2023, representing a robust CAGR of 12.8%. The report states that the impressive growth, which will occur across the six major markets of the US, France, Germany, Spain, Italy, and the UK, will be primarily driven by the rising number of allogeneic hematopoietic stem cell transplantations and the increasing use of marketed and off-label biologic therapies.

Source: Global Data

Vaccines

The U.S. vaccine market is expected to exhibit 4.3% CAGR between 2014 and 2020, driven by favorable government initiatives. Strict regulations drafted by the federal government mandating immunization against certain ailments has also accelerated the demand for vaccines in the country. Meanwhile, the escalating incidence of zoonotic diseases among animals and the high risk of transferring the infection to humans have fuelled the market for animal vaccines in the U.S.

Source: Transparency Market Research

The Bioprinting Market Expected to Rise

Global 3D bioprinting market is expected to reach \$1.82 billion by 2022, according to a new report by Grand View Research Inc. Rising prevalence of chronic diseases such as chronic kidney disease (CKD), which demands kidney transplantation, is expected to boost the market growth, as 3D bioprinting is a convenient and cost-effective substitute for organ transplantation.

Emerging medical applications of 3D bioprinting such as toxicity testing, drug discovery, tissue engineering, and consumer product testing are

expected to further drive the market growth positively. Increasing R&D expenditure is anticipated to be high impact rendering driver for the industry. 3D bioprinting advances in tissue engineering and allows developments to be done using biomaterials which have better biocompatibility.

Moreover, rising geriatric population is expected to assist the market growth, as this demographic is highly susceptible to age related organ deformities.

North America dominated the regional 3D bioprinting market with more than 35.0% share and is expected to grow at a CAGR of 10.0%. Supportive government initiatives to improve healthcare

infrastructure coupled with growing disposable income are vital driving factor for this region's growth.

Drug Repositioning Quickly Meeting Demand for Novel Therapeutics

Drug repurposing is a relatively new approach to the drug development process that is revolutionizing the pharmaceutical industry. The global market for drug repurposing reached nearly \$24.4 billion in 2015 and should reach \$31.3 billion in 2020, reflecting a five-year compound annual growth rate (CAGR) of 5.1%, according to BCC Research. Its new report reveals that advances in technologies such as in silico drug repositioning should especially stimulate growth in this vital and emerging market.

The U.S., which dominated the market, totaled about \$13.7 billion in 2015 and is forecasted to reach nearly \$17.9 billion by 2020, demonstrating a five-year CAGR of 5.4%. The non-U.S. market is expected to increase to nearly \$13.4 billion by 2020 from \$ 10.6 billion in 2015, with a CAGR of 4.7%.

The increased worldwide incidence of cardiovascular and autoimmune diseases and central nervous system disorders diseases has increased demand of repurposed drugs, a trend that should continue over the forecast period. Other key drivers include advancements in technologies, including computational tools such as bioinformatics, chemoinformatics, network biology and system biology. An increase in chronic diseases, a rapidly growing elderly population, and rising healthcare costs are driving the market, as well.

Drug Developers Are Working to Boost R&D Productivity

Drug developers are significantly scaling up their level of process improvements to reduce the time and cost required to bring new drugs to market, according to the Tufts Center for the Study of Drug Development.

"The core challenge is that developing new drugs has become more complex and more expensive than ever," says Tufts CSDD Director Kenneth Kaitin, noting that it takes an average of \$2.6 billion and 15 years to develop and win approval for a new drug. In addition, a typical Phase III protocol now entails an average of 167 procedures, 60% more than at the start of the millennium.



Oncology Corner...

► News and updates around cancer-related R&D, trends, services, and products.

AACR and Bayer Form Partnership on Grant Opportunities in Cancer Research

AACR
American Association
for Cancer Research



The American Association for Cancer Research (AACR) and Bayer have announced the 2016 AACR-Bayer Innovation and Discovery Grants program for meritorious projects that examine novel targets and biomarkers in oncology research.

The AACR-Bayer Innovation and Discovery Grants promote the key tenets of the Bayer Grants4Targets initiative: to provide new treatment options for cancers with high unmet medical need, to encourage innovation and translation of ideas from basic research into novel drugs, and to foster collaborations between academic groups and the pharmaceutical industry. Bayer's Grants4Targets initiative, originally introduced in 2009, translates ideas from basic research into novel drugs through grants for research into drug targets and biomarkers.

"Bayer is committed to partnering with elite organizations, and we are delighted to launch the AACR-Bayer Innovation and Discovery Grant program and support exciting early cancer research," says Karl Ziegelbauer, Ph.D., Bayer's senior VP and head of global therapeutic research groups at global drug discovery. "The goal of the AACR-Bayer partnership is to help translate innovative ideas into projects that will result in an improved understanding of the pathogenesis of cancer."

All the recipients will be offered the opportunity to work with a Bayer mentor, who will provide guidance, expertise, and/or tools to accelerate the translation of their scientific idea.

In the Developing World, Cancer is a Different Disease

In the United States the median age at which colon

cancer strikes is 69 for men and 73 for women. In Chad the average life expectancy at birth is about 50. Children who survive childbirth — and then malnutrition and diarrhea — are likely to die of pneumonia, tuberculosis, influenza, malaria, AIDS, or even traffic accidents long before their cells accumulate the mutations that cause colon cancer, according to an article in the New York Times in December.

In fact, cancers of any kind don't make the top 15 causes of death in Chad or in Somalia, the Central African Republic, and other places where the average life span peaks in the low to mid-50s. Many people do die from cancer, and their numbers are multiplied by rapidly growing populations and a

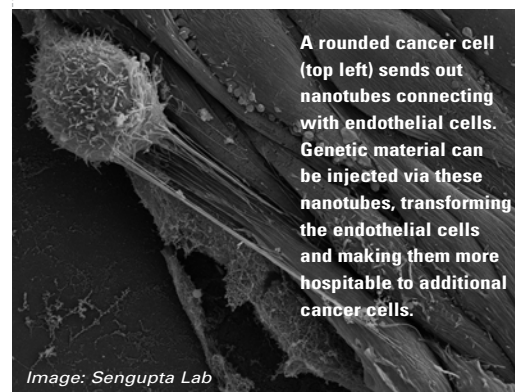
stomach, and liver cancers. Another story in NPR highlights that the majority of cancer cases — 57% — now occur in low- and middle-income countries. And 65% of cancer deaths worldwide occur in these countries, according to an analysis by the American Cancer Society.

But there's a flip side to that story: Rates of certain cancers, including cervical cancer, have gone down in high income countries, according to the research published in *Cancer Epidemiology, Biomarkers & Prevention*.

The study also highlights the lack of resources or infrastructure to fight cancers in many poor countries.

Scientists Discover How Cancer Cells Escape Blood Vessels

Scientists at MIT and Massachusetts General Hospital have discovered how cancer cells latch onto blood vessels and invade tissues to form new tumors — a finding that could help them develop drugs that inhibit this process and prevent cancers from metastasizing.



Cancer cells circulating in the bloodstream can stick to blood vessel walls and construct tiny "bridges" through which they inject genetic material that transforms the endothelial cells lining the blood vessels, making them much more hospitable to additional cancer cells, according to the new study.

"Endothelial cells line every blood vessel and are the first cells in contact with any blood-borne element," says Elazer Edelman, the Thomas D. and Virginia W. Cabot Professor of Health Sciences and Technology, a member of MIT's Institute for Medical Engineering and Science, and one of the leaders of the research team. "They serve as the gateway into and out of tumors and have been the focus of research in vascular and cancer." ^{PV}

Global Cancer Incidence



New cancer cases annually per 100,000 people (age-adjusted)

>0 >60 >120 >180 >240 >300

Chad

Cancer cases annually per 100,000 people	94.2
HDI* Rank	170 of 179
GDP per capita (USD)	\$784
Health expenditure per capita (USD)	\$28
Life expectancy	49 years

Source: GLOBOCAN 2008 v2.0, World Bank, UNDP (2008)

*Human Development Index (HDI) is a combined indicator of life expectancy, education and income.

lack of medical care. But first come all those other threats.

Cancers that arise in poorer countries are far less likely to be survived. A disproportionately large number of these cases are caused by infectious agents. Infection is also a major factor in cervical,