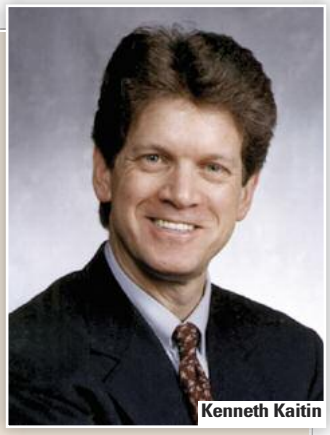
Developers Need to Identify Causes of
R&D Inefficiency

TRENDING NOW: In a world shaped by increased patent expirations, diminished cash flow, and fewer promising breakthrough products, companies will need to hone their efforts to streamline development.


Kenneth Kaitin

While patent expirations on many top-selling medicines is spurring the research-based drug industry to embrace new development paradigms to replenish sparse R&D pipelines, drug developers need to more fully identify and address root causes of R&D inefficiency, according to the Tufts Center for the Study of Drug Development.

"Many companies are taking steps to improve clinical success rates and reduce the cost of new product development, including utilizing enhanced clinical trial designs, making greater use of biomarkers, and adopting sophisticated statistical analyses," says Tufts CSDD Director Kenneth Kaitin.

Mr. Kaitin says he is optimistic about the future of bioinnovation.

"The emergence of open innovation models, where scientists worldwide openly share knowledge, and novel partnerships and alliances hold significant promise to transform the nature, pace, and cost of new drug development to the benefit of patients, as well as to drug sponsors, their development partners, and investors," he says.

For more information, visit csdd.tufts.edu.

Outlook for 2013

- Drug companies will accelerate their move from traditional trial-and-error approaches to exploratory drug development and adopt new R&D paradigms based on biomarkers, modeling and simulation, novel formulation techniques, and adaptive clinical trial designs.
- In an effort to simplify clinical trial operating complexity, sponsors and contract research organizations will scale back the number of investigative sites they operate and the number of countries where they locate their trials.
- The biosimilar market is poised for significant growth following the creation of an abbreviated approval pathway for biological products that are demonstrated to be interchangeable with an FDA-approval biologic, as required by the Patient Protection and Affordable Care Act.
- Prescription drug policy will be shaped by global concerns to a greater degree than ever before, with international coordination growing in relation to the development of personalized medicines as well as drugs for neglected diseases.

Source: Tufts CSDD

E-Prescribing Market
EXPECTED TO GROW

The e-prescribing systems market is estimated to grow at a CAGR of 26% from 2012 to 2017, according to MarketsandMarkets. The expenditure on e-health is slated to increase as a percentage of national health budgets in this decade. As governments look to encourage physicians and pharmacies to adopt the technology, e-prescription is likely to grow to $794 million by 2017 globally. Spread of awareness and realization of the growing need to switch to e-health will boost this technology.

The market is driven by a few established companies and many small companies operating in this industry, which are striving to gain maximum market share. The predominant strategy followed by all players of this market is launching of new products by means of modifying the product based on technology changes and needs of the end users, which results in development of either new innovative product or modification of the existing product.

For more information, visit marketsandmarkets.com.

Up Front Planning is
KEY FOR ONCOLOGY TRIALS


Ryan McGuire

Phase I oncology trials are particularly troubled by enrollment delays, more so than any other area, according to a report by Cutting Edge Information.

The study, Optimizing Clinical Pharmacology Programs: Cost-Drivers of Phase I Trials, found that the overall averages for planned and actual trial duration are 15.3 months and 20.6 months, respectively, representing an average of 5.3 months of delays. Oncology trials had planned durations of 23.8 months but the actual average was 36.1 months, over a year of delays on average.

"When delays do occur, companies can implement amendments to the trial design that can broaden the criteria for enrollment and ease the recruitment process," says Ryan McGuire, lead research analyst at Cutting Edge Information.

For more information, visit cuttingedgeinfo.com.

MHealth Market to
EXPERIENCE GROWTH

The global mHealth market is expected to reach $10.2 billion by 2018, up from $1.3 billion in 2012, a CAGR of 41.5% from 2012 to 2018, according to a report published by Transparency Market Research. The monitoring services segment contributed about 63% of the global mHealth market revenue in 2012.

The global mHealth market is being driven by the increasing adoption of smartphones and rising incidences of chronic diseases. The development of smartphone applications has created new and interactive ways of communication between patients and healthcare providers.

The most impactful trend in the mHealth market is the growth in remote patient monitoring. Remote monitoring of patients can help reduce costs significantly by reducing the amount of time the patient spends in hospitals and also by lowering the frequency of follow-up visits to the physician.

For more information, visit transparencymarketresearch.com.

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CLINICAL DIAGNOSTICS
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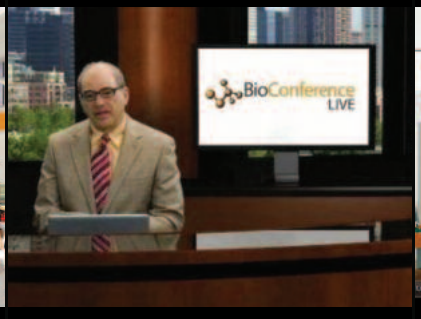

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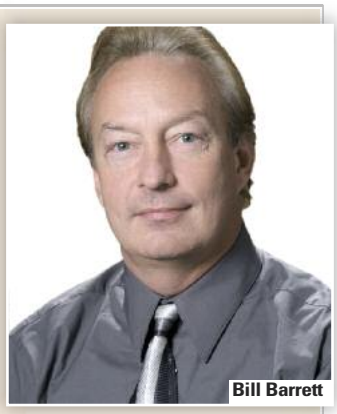
Life Sciences Industry Driven By R&D Productivity,

Emerging Markets Sales

TRENDING NOW: Life-sciences companies are choosing cities where they can capture market opportunities for sales, drive R&D productivity, and optimize operations.


Bill Barrett

The areas where life sciences companies locate their facilities, commonly called industry clusters, are shifting worldwide as these companies respond to rising demand for new drugs in Asia and Latin America, significant patent expirations and the need for increased R&D productivity and innovation, according to Jones Lang LaSalle's second annual Global Life Sciences Cluster Report.

With downward pricing pressure and the need to control facility costs, life-sciences companies are making calculated and strategic decisions for their facilities investments. The historical dynamic of mature-market R&D discovery vs. offshoring lower-value operations is slowly evolving as emerging markets increasingly drive consumer demand.

While every regional cluster is unique, the interplay at a global level reveals clear trends separating mature vs. emerging markets. Established life-sciences clusters in mature markets are being driven by R&D success and proven innovation, while the potential for significant sales growth continues to push expansion in Asia Pacific and Latin America.

"Major life-sciences companies are optimizing their real estate and location strategies to be prepared for patent expirations, as well as to capture market opportunity in the Asia Pacific and Latin American regions," says Bill Barrett, executive managing director, life sciences at Jones Lang LaSalle. "Strategic facilities investments have become critical to keeping a tight rein on costs while continuing to find success through R&D investment and new drug discovery."

For more information, visit joneslanglasalle.com.

Plant-Derived Drug Market TO SEE GROWTH

The global botanical and plant-derived drug market was valued at $21.4 billion in 2011 and should reach $22.1 billion in 2012, according to BCC Research. Total market value is expected to reach $26.6 billion in 2017 after increasing at a five-year compound annual growth rate (CAGR) of 3.7%.

Botanical drugs are expected to have a value of $10 million in 2012 and $599 million in 2017, a CAGR of 126.7%. As a segment, all other plant-derived drugs should total $22.1 billion in 2012 and $26.6 billion in 2017, a CAGR of 3.7%.

Botanical drugs have arrived, albeit slowly, as an official U.S. Food and Drug Administration designation. Even though its outlook is optimistic for regulatory approvals and sales for botanical drugs, this report is more conservative compared with BCC's previous forecast of the botanical market when it seemed that the economy might not be as much as a factor in companies' progression and the regulatory pathway appeared to be more clearly understood. Going forward from 2012 to 2017, pharmaceutical companies and investors are still struggling with understanding and adhering to the requirements in the botanical regulatory pathway, slowing some of the progress here.

For more information, visit bccresearch.com.

Cell and Tissue MARKET MATURES

The global cell and tissue analysis market was valued at $6.9 billion in 2011 and should reach $7.1 billion in 2012, according to BCC Research. Total market value is expected to reach $9.6 billion in 2017 after increasing at a five-year compound annual growth rate (CAGR) of 6.2%.

The segment made up of biospecimen-prepar-

THERAPEUTIC FAST TRAX

AUTOIMMUNE DISEASES

More than 75% of surveyed rheumatologists have a high familiarity with Bristol-Myers Squibb's Orencia SC, after one full year on the market. Additionally, the vast majority of surveyed physicians have prescribed Orencia SC, and both the familiarity and usage represent significant increases versus the previous report. According to surveyed physicians, the majority of Orencia SC patient starts were switched from other agents, primarily the more established TNF inhibitors: Abbott's Humira, Pfizer/Amgen's Enbrel and Janssen Biotech's Remicade.

Source: BioTrends Research Group, LaunchTrends: Orencia SC report

For more information, visit bio-trends.com.

In the United States, about 80% of current prescribers of Janssen Biotech/Merck/Mitsubishi Tanabe's Remicade and/or Biogen Idec/Roche/Chugai/Zenyaku Kogyo's Rituxan indicate they would prescribe biosimilar versions of these agents within a year of their approval. But about half of these physicians expect to prescribe biosimilar versions of Remicade or Rituxan only if a patient requests it and/or insurance plans demand it. Among insurers that currently cover Remicade or Rituxan, half of commercial plans will not likely cover biosimilar versions of either agent by 2015. In contrast, only about one-third of surveyed Medicare Part D Plans (PDPs) that cover each drug expect to exclude biosimilars.

Source: Decision Resources, Will the Launch of Emerging Oral Kinase Inhibitors be a Game-Changer for the Rheumatoid Arthritis Market?

For more information, visit decisionresources.com.

BIOLOGICS

The global biologics market is valued at an estimated $149 billion in 2010 and is expected to reach $239 billion by 2015, a CAGR of 9.9% from 2010-2015, according to a recent report by BCC Research. Driving this growth is the need for a more extensive drug pipeline, attractive targets against challenging diseases, a push to pursue biosimilars, and enabling manufacturing technologies that reduce the cost to produce profitable products.

Source: BCC Research, Biologic Therapeutic Drugs: Technologies and Global Markets

For more information, visit bccresearch.com

CANCER

The global market for the prevention and treatment of prostate cancer was valued at $26.1 billion in 2011 and should reach about $29.3 billion in 2012. Total market value is expected to reach $50.3 billion in 2017 after increasing at a five-year CAGR of 11.4%. The diagnosis and screening segment is expected to total $12.1 billion in 2012 and $17.4 billion in 2017, a CAGR of 7.5%.

As a segment, surgical and radiation therapy should total $9 billion in 2012 and almost $14.3 billion in 2017, a CAGR of 9.7%. Drug therapeutics are expected to reach $8.1 billion in 2012 and nearly $18.6 billion in 2017, a CAGR of 18%.

Source: BCC Research, Prevention and Treatment of Prostate Cancer: Technologies and Global Markets

For more information, visit bccresearch.com.

The market for liver cancer therapeutics in the top seven markets (the U.S., the UK, Germany, France, Spain, Italy and Japan) was estimated at $374.3 million in 2011, having grown at a CAGR of 21.7% from 2004. Growth was driven by an increase in the patient volume and the annual cost of therapy per patient, which increased due to the approval of Nexavar (sorafenib) in the U.S. and Europe. The market is forecast to reach revenue of $644.3 million by 2018, growing at a CAGR of 8.1% from 2011.

Source: GBI Research, Liver Cancer Therapeutics Market to 2018 - Nexavar, the Only Approved Targeted Therapy for Advanced Disease, Continues to Dominate as Other Late Stage Trials Fail

For more information, visit gbiresearch.com.

The value of the chemotherapy-induced nausea and vomiting (CINV) therapeutics market is forecast to show moderate growth in the next eight years, reaching a value of $1.8 billion by 2019. This is due to the patent expiries of Aloxi and Emend, and the subsequent launch of generics in the forecast period. The global CINV therapeutics market was found to be worth $1.2 billion in 2011 and grew at a CAGR of 6.1% from $892 million in 2006.

Source: GlobalData, Chemotherapy-Induced Nausea and Vomiting (CINV) Therapeutics — Pipeline Assessment and Market Forecasts to 2019

For more information, visit globaldata.com.

The cancer kinase inhibitor market is estimated at $12.1 billion worldwide for 2012, representing annual revenue growth of 16.9% over 2007. The effectiveness of kinase inhibitors has sparked interest from major pharmaceutical companies. Novartis' Gleevec leukemia treatment is among the better-selling products in the category and it competes with Bristol Myer Squibb's Sprycel. As Gleevec faces patent expiration, Novartis is marketing a newer kinase inhibitor called Tasigna.

Source: Kalorama Information, The Next Wave in Cancer Treatment — Kinase Inhibitors

For more information, visit KaloramaInformation.com.

Small-molecule targeted cancer therapy revenue will reach $32.7 billion worldwide in 2016. That drug market generated $21.7 billion in 2011. Rising disease prevalence, along with advances in pharmacotherapy and diagnostics, will stimulate that drug market. Many small-molecule targeted technologies — including heat shock protein (HSP) modulators, HDAC mechanisms, transcription factor regulators and siRNA products — are in development for treating cancer. The R&D pipeline for those treatments is strong and vast, the report shows and discusses. Therapies are being studied for use alone, in combination with other targeted drugs, and combined with chemotherapy.

Source: Visiongain, Small-Molecule Targeted Cancer Therapies: World Market 2013-2023

For more information, visit visiongain.com.

CARDIOVASCULAR DISEASES

The market for atrial fibrillation in urban China will increase at a rate of 21% per year over the next five years, driven by the launch of three novel oral anticoagulants. Market development will also be determined by an expanding drug-treated population, which is expected to increase 86% during this period due to expansion of government-sponsored insurances and annual health check-ups. The key driver of growth in the atrial fibrillation drug market will be the launch of Bayer/Janssen's Xarelto (rivaroxaban), Boehringer Ingelheim's Pradaxa (dabigatran) and Bristol-Myers Squibb/Pfizer's Eliquis (apixaban), capturing 29% of the market by 2016.

Source: Decision Resources, Atrial Fibrillation in China

For more information, visit decisionresources.com.

CNS DISEASES

Between 30% to 40% of relapsing and progressive multiple sclerosis (MS) patients in the care of surveyed neurologists are dissatisfied with their current disease-modifying therapy (DMT) and would be eager to switch to a new drug. In a related finding, neurologists report that up to 25% of DMT-treated relapsing-remitting MS (RR-MS) patients respond suboptimally to, and/or cannot tolerate, their current DMT.

Source: Decision Resources, Multiple Sclerosis in the U.S.: How Will Payers and Prescribers Shape the Future of Disease-Modifying Treatment?

For more information, visit decisionresources.com.

The global multiple sclerosis (MS) therapeutics market was valued at $9.24 billion in 2011. The global MS therapeutics, which includes disease modifying drugs (DMDs) and drugs for symptom management, is forecast to grow at a CAGR of 3.2% to reach $11.9 billion by 2019. The MS therapeutics market is expected to witness slow growth (in terms of CAGR) through the forecast period to 2019 in comparison with the historical period 2006-2011. The slow growth in the market is the result of the cumulative effect of both positive and negative factors within the market. The patent expiry of Copaxone is expected to negatively impact the U.S. market; Copaxone has a high cost of therapy and has a strong presence in the U.S. market. But the introduction of pipeline products will neutralize the value erosion of the market, resulting in slow growth through to 2019.

Source: GlobalData, Multiple Sclerosis Therapeutics - Pipeline Assessment and Market Forecasts to 2019

For more information, visit globaldata.com.

The overall world market for drugs to treat Parkinson's disease will reach $3.4 billion in 2016. New first-in-class drugs will boost the Parkinson's disease market. Adenosine receptor antagonists will gain approval in the near term followed by new glutamatergic drugs, with Novartis' AFQ056 (mavoglurant) and Addex's dipraglurant vying to be the first in this class. These approvals will invigorate the market and offset patent expiries for older drugs such as Boehringer Ingelheim's Mirapex.

Source: Visiongain, Parkinson's Disease: World Drug Market 2013-2023

For more information, visit visiongain.com.

GASTROINTESTINAL DISEASES

The prescription IBS market is poised for significant growth through 2021 to reach $3.2 billion, given the unmet need for more effective therapies for patients with moderate to severe disease, and the launch of novel therapies to treat subpopulations of IBS patients. Linaclotide (Ironwood/Forest/Almirall/Astellas's Constella/Linzess), which launched in the United States in December and received marketing authorization in Europe in November 2012, will capture significant market share from Sucampo/Takeda/Abbott's Amitiza, because of linaclotide's superior efficacy in treating motility, as well as the drug's demonstrated efficacy in addressing other important symptoms of IBS with constipation (IBS-C), including abdominal pain and bloating. In 2021, linaclotide will achieve blockbuster sales of $1.2 billion in the United States, France, Germany, Italy, Spain, the United Kingdom and Japan.

Source: Decision Resources, Pharmacor Irritable Bowel Syndrome

For more information, visit decisionresources.com.

The ulcerative colitis drug market will double over the next decade, increasing to $3.7 billion in 2021 in the United States, France, Germany, Italy, Spain, the United Kingdom, and Japan. The uptake of two premium-priced tumor necrosis factor-alpha (TNF-alpha) inhibitors — Abbott/Eisai's Humira and Janssen/Merck/Mitsubishi Tanabe's Simponi — and two novel therapies, Takeda's cell adhesion molecule (CAM) inhibitor vedolizumab and Pfizer's oral Janus-activated kinase inhibitor tofacitinib, will primarily drive growth during this period, as will the expanding number of diagnosed prevalent cases of ulcerative colitis.

Source: Decision Resources, Pharmacor Ulcerative Colitis

For more information, visit decisionresources.com.

INFECTIOUS DISEASES

Metronidazole and oral vancomycin continue to be the workhorse drugs for the treatment of clostridium difficile-associated diarrhea (CDAD), but metronidazole is likely to lose market share, owing to metronidazole treatment failures. Furthermore, physicians perceive both oral vancomycin and Optimer/Cubist/Astellas' Dificid (fidaxomicin)

as the leading performers in areas that are important to prescribing practices for CDAD, including lower risk for relapse, efficacy in severe CDAD, and efficacy in recurrent infections. Moreover, about half of surveyed physicians indicate that fidaxomicin, Salix's Xifaxan (rifaximin), and fecal transplants stand to gain from increases in physician use in the next 12 months

Source: BioTrends Research Group, TreatmentTrends: Clostridium Difficile Infections (U.S.)

For more information, visit bio-trends.com.

The global market for treatment and diagnosis of sexually transmitted diseases was valued at $28.2 billion in 2011 and should reach nearly $33.3 billion in 2012. Total market value is expected to reach almost $52 billion in 2017 after increasing at a five-year compound annual growth rate of 9.3% The pharmaceutical market is currently dominated by HIV pharmaceuticals, which are expected to grow at a CAGR of 5.5%, and generic HIV pharmaceuticals, with a projected growth rate of 17.4%.

Source: BCC Research, Global Markets for Treatment and Diagnosis of Sexually Transmitted Diseases

For more information, visit bccresearch.com.

From 2011 to 2021, growth in the hepatitis B virus (HBV) drug market will be driven by continued uptake of oral nucleoside/nucleotide analogues, such as Bristol-Myers Squibb's Baraclude (entecavir) and Gilead's Viread. But the entry of generic Baraclude in 2015 and 2016 in the United States and Europe, respectively, will curtail sales of branded versions of both agents. The launch of Bristol-Myers Squibb/ZymoGenetics' pegylated interferon lambda-1a in 2017 will help to slow the decline spurred by the entry of generics in the HBV market.

Source: Decision Resources, Niche Markets and Rare Diseases: Hepatitis B

For more information, visit decisionresources.com.

For the treatment of hepatitis C virus (HCV), the elimination of interferons (IFNs) from treatment regimens is highly desirable because of their side effects, which prevent a significant number of HCV-infected individuals from receiving antiviral therapy. Interviewed physicians expect that all-oral, IFN-free regimens will be more efficacious, better tolerated and enable treatment of patients who are contraindicated to IFN-alpha. The first IFN-free regimens are expected to launch in the United States and Europe by 2014. Overall, the HCV market will grow from about $3 billion in 2011 to about $21 billion in 2018 and will then drop to $17 billion in 2021, because of a decline in the size of the treatment-eligible population.

Source: Decision Resources, Pharmacor Hepatitis C Virus

For more information, visit decisionresources.com.

The global hepatitis B therapeutics market was $3.06 billion in 2011 and forecast to grow at a CAGR of 4.8% to reach $4.4 billion by 2019. The low growth can be attributed to the high vaccination coverage rates in developed countries, resulting in lower incidence rates of hepatitis B. The market is also set to witness the patent expiry of most of the nucleoside analogues between 2013 and 2017. The patent expiry of the immunologic Pegasys (peginterferon alfa-2a) in 2018 will, however, not impact the market significantly. The current competitive landscape consists mainly of interferon therapy and nucleoside analogues. Intron A (interferon alpha 2b) and Pegasys are the two approved interferon therapies for hepatitis B therapeutics.

Source: GlobalData, Hepatitis B Therapeutics - Pipeline Assessment and Market Forecasts to 2019

For more information, visit globaldata.com.

The global MRSA market will grow at a CAGR of 3.4% to reach $3.47 billion by 2019. Although the number of hospital associated MRSA cases has been decreasing, the overall MRSA prevalence has an escalating trend due to increased community associated MRSA infections. Other factors that have contributed towards the growth of the market have been the steady increase in the elderly and immuno-compromised population, an increase in the average number of days spent in hospitals and the emergence of multidrug resistant (MDR) bacterial strains.

Source: GlobalData, Methicillin-resistant Staphylococcus aureus (MRSA) Therapeutics - Pipeline Assessment and Market Forecasts to 2019

For more information, visit globaldata.com.

PAIN THERAPEUTICS

The market for pain therapies will grow at an annual rate of 1.8% over the next 15 years, surpassing $49 billion in sales in 2026. The loss of sales due to the generic entry of blockbuster pain therapies over the next several years will be offset by the uptake of branded and emerging agents in current drug classes such as tapentadol extended release (Johnson & Johnson/Grünenthal's Nucynta ER/Palexia SR), orally inhaled dihydroergotamine (MAP Pharmaceuticals/Allergan's Levadex) and opioid reformulations. Market growth will be driven primarily by the launch of the first biologic pain therapies, Pfizer's tanezumab and Johnson & Johnson/Takeda's fulranumab, beginning in 2016.

Source: Decision Resources, Pharmacor Novel Approaches to Pain Therapy

For more information, visit decisionresources.com.

The global osteoarthritis (OA) pain therapeutics market was worth $4.52 billion in 2011 and is forecast to grow at a CAGR of 3.7% over the next eight years to reach $6.06 billion. The overall growth of the market is expected to witness a steady but slow growth, characterized by market share wars during the forecast period. The current OA pain therapeutics market is dominated and well served by generics, which will provide stiff competition for new entrants. Moreover, presence of weak late-stage molecules will restrict their ability to compete with the existing and established generic products.

Source: GlobalData, Osteoarthritis Pain Therapeutics - Pipeline Assessment and Market Forecasts to 2019

For more information, visit globaldata.com.

RESPIRATORY DISEASES

Merck/Kyorin's Singulair is a dominant player among maintenance therapies in the asthma market, attaining sales of about $3.2 billion and the second-highest patient share in the major markets in 2011. But generic versions of Singulair launched in the United States in 2012, and analysts expect further sales losses as generics enter the European markets in 2013 and the Japanese market in 2016. As a result, sales of Singulair will shrink to $360 million in 2021 in the United States, France, Germany, Italy, Spain, the United Kingdom, and Japan.

Source: Decision Resources, Pharmacor Asthma

For more information, visit decisionresources.com.

ing techniques should total nearly $2.2 billion in 2012 and $3.1 billion in 2017, a CAGR of 7.3%. As a segment, cell and tissue separation is expected to reach nearly $1.8 billion in 2012 and nearly $2 billion in 2017, a CAGR of 2.4%. Cell and tissue characterization is expected to total nearly $3.2 billion in 2012 and $4.5 billion in 2017, a CAGR of 7.5%.

The cell and tissue analysis (CTA) market is seeing an increasing number of novel analysis products being utilized in the current industry. This industry is seeing an increase in the development of next-generation cell-analysis tools that target cancers and other diseases, including autoimmune diseases.

For more information, visit bccresearch.com.

Centralized Portfolio MANAGEMENT TEAMS GUIDE DECISIONS

More than three-quarters (77%) of surveyed pharmaceutical companies have created dedicated portfolio management teams, according to a study by Cutting Edge Information. Furthermore, 79% of these dedicated teams are centralized so that drug manufacturers can better harness their product portfolios' true potential.

Though the majority of surveyed companies reported centralized departments, portfolio management teams' alignments still varied. Cutting Edge Information's data show that 47% of surveyed companies with dedicated teams reported a single centralized team.

Another 32% of companies reported therapeutically aligned teams that worked to identify therapeutic area opportunities, but that ultimately reported into a larger centralized team who set the final corporate strategy. Of the remaining surveyed companies, 21% reported no centralized portfolio management team; 16% reported having therapeutically aligned teams; 5% reported regional management teams.

For more information, visit cuttingedgeinfo.com. PV

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