Strategic Partnerships

Provide Value

TRENDING NOW: The majority of biopharma executives believe strategic partnerships positively impact their engagement with CROs.


Josef von Rickenbach

The majority of biopharma executives believe strategic partnerships positively impact their engagement with CROs, according to a recent report by Parexel International. Executives believe this more integrated approach to clinical development reduces their level of oversight, decreases fixed costs, and provides them with access to capabilities not found internally.

The industry executives interviewed for this report believe strategic partnerships are transforming the way new therapies are developed and commercialized. But they also note that the model must evolve to adequately and effectively meet the challenges of a constantly changing regulatory environment.

The report found that 85% of biopharmaceutical industry executives interviewed and who were engaged in strategic partnerships believe that the relationship between their companies and CROs were positively impacted. Executives believe this more integrated approach to clinical development reduces their level of oversight, decreases fixed costs, and provides them with access to capabilities not found internally.

"We believe that strategic partnerships provide companies with the level of integration, alignment, and collaboration that will support the future success of the biopharmaceutical industry," says Josef von Rickenbach, chairman of the board and CEO of Parexel.

For more information, visit parexel.com.

IMPACT OF STRATEGIC PARTNERSHIPS

Reducing the level of required oversight	**50%**
Reducing fixed costs/increasing variable costs	**50%**
Access to capabilities not found internally	**50%**
Improved global reach	**46%**
Accelerating time to market	**46%**
Reducing overall development costs	**42%**
Quality of execution	**23%**
Access to innovation not found internally	**15%**
Team stability/accountability	**8%**

Source: Parexel International

KEY FINDINGS IN PARTNERSHIP STUDY

- The operational efficiencies and impact seen by implementing strategic partnerships will continue to drive clinical development outsourcing.
- Biopharmaceutical executives most often equate strategic partnerships with oversight, governance, and the level of mutual partnership investment, rather than the volume of work, an important consideration for smaller and midsized companies.
- Executives believe showcasing consistent value and measuring results is critical for the future success of this integrated model.
- Strategic partnerships will continue to evolve away from the traditional transactional model toward more integrated relationships that drive value through increased alignment and efficiencies.
- The next generation of strategic partnerships must involve a greater alignment of commercial terms and a true collaboration of the best talent from the CRO and sponsor, according to biopharmaceutical executives.
- The hallmark of an optimized strategic partnerships model will be the measurable success of collaboratively bringing a compound to market faster.

Source: Parexel International

Engaging Digital Patients Can FOSTER BIOPHARMA PRODUCT DEVELOPMENT

Harnessing the power of the digitally connected patient can not only help produce enormous amounts of savings in the healthcare system, but can also improve patient outcomes.

This is one of the findings of a new study by Quintiles, Harnessing the Power of the Digital Patient.

Additional findings from the report include:

- Using digital techniques in an observational COPD study, Quintiles recruited 425 patients from its online patient community. The first digital patient was enrolled in the study in a mere six minutes with the last patient confirmed in only nine calendar days.
- Using a customized communication program in a 1,255-patient women's health study, Quintiles kept patient engagement high and resulted in a 59% increase in the retention rate.
- Quintiles' patient communities engage more than 3 million patients, some of whom have already provided direct, longitudinal data about their personal reported outcomes, medical records, lab samples, and device data across a number of studies.

For more information, visit quintiles.com.

Use of Digital Marketing CHANNELS TO INCREASE

The trend to multichannel marketing, with much attention focused on digital channels, gained pace in 2012 as pharmaceutical salesforces were cut in the United States and Europe, according to a recent report from Cegedim Strategic Data. Worldwide, total promotional spending by the pharmaceuticals industry in 2012 was flat compared with 2011 at a projected $90 billion.

Salesforce reductions in the United States (10%) and the Europe Top 5 (12%) were offset by continued increased total investment in emerging markets. Promotional spending in Brazil was up 7% and China saw total marketing spend increase by 20% to almost $2 billion.

Notably, however, overall spending declines in established markets occurred as investment in dig-


Christopher Wooden

ital channels surged in the same geographies. In the United States, spending on e-detailing, emailing, and Webinar/Webcast type promotions was up 65% over 2011.

Cegedim's Christopher Wooden, VP, CSD global promotion audit, observes that two main factors have helped drive this move to digital.

"First, the reality of the patent cliff leaves companies with less money to invest in salesforces," he says. "Second, technology has advanced to a point where its use as part of the multichannel strategy is becoming more attractive and less expensive. Pharma marketing in the United States is clearly leading the way but we expect to see continued rapid expansion in Europe as well."

For more information, visit cegedimstrategicdata.com.

Pharma Makes Digital a PRIORITY

Senior sales and marketing executives of large U.S. pharmaceutical companies — with corporate revenue in excess of $1 billion — plan to sharpen their focus on multichannel marketing and step up their use of digital technologies and analytics in 2013, according to a recent survey by Accenture Life Sciences.

More than four-fifths of the 200 executives surveyed, 83%, see cost reduction as their No. 1 strategic priority for the year. The survey results indicate they plan to combine their cost-cutting efforts with increased marketing efficiency through three primary strategies: greater use of analytics to target spending and drive improved ROI (87%); boosting their use of digital and multichannel interactions (83%); and using third-party service providers (72%).

"It's clear that mastering multichannel marketing — and realizing the full potential of digital technologies and analytics — is a top agenda item for sales and marketing executives, who intend to achieve greater marketing efficiencies and meet the needs of their customers," says Craig Robertson, North American managing director of Accenture's Life Sciences' Sales and Marketing practice. "From this survey, we believe a correlation can be drawn that cost-reduction is enabled by mastering multichannel marketing using digital interactions and analytics."

Additionally, the study found that almost one in four direct salesforce interactions at these companies has been replaced with digital interactions for targeting doctors, providers, payers, and patients.

Over the next two years, the executives surveyed plan to increase their use of such digital interactions by 26%, on average.

For more information, visit accenture.com.

New Protocol Designs Will IMPROVE TRIAL PERFORMANCE

Growing protocol complexity — responsible for longer clinical study times, greater difficulty in recruiting volunteers, and rising drug development costs — is spurring new approaches to optimizing protocol design, according to leaders from the research-based drug industry recently convened by the Tufts Center for the Study of Drug Development.

A key challenge for drug developers is to design protocols — plans detailing the methodology of a clinical study — that address increasing scientific, regulatory, and operating demands while maintaining patient safety and study feasibility, the panel agreed.

Failing to do so, they said, could seriously threaten future clinical success.

For more information, visit csdd.tufts.edu.

Challenges of ORPHAN DRUG RESEARCH


Angi Robinson

More than two-thirds (69%) of respondents said among the most difficult factors in recruiting patients into a rare disease clinical trial was not only finding and motivating patients to join and remain in trials, but identifying and setting up investigative sites for studies.

"Much of the success in patient recruitment is based on finding the appropriate site for the small patient populations we have to work with," says Premier Research Executive Director, Clinical Trials Management, Angi Robinson. "It's worth noting that these studies become even more difficult to manage when they are conducted outside of Western markets."

Nine of 10 (88%) respondents say the number of patients they are required to enroll in a rare disease and orphan drug study is reasonable, a surprising finding given the inherently smaller universe of patients available to enter such a study and the respondents' perception of the difficulty in finding qualified sites and recruiting patients.

Expanded access/compassionate use programs are fairly common among rare/orphan disease trials. More than two in five (43%) respondents say that securing regulatory approval for the design of their clinical study was difficult or extremely challenging. Nearly four in 10 (38%) said advocacy groups were most helpful in increasing the awareness of the clinical studies. Other findings:

- 24% said the patient advocacy groups needed more convincing as to how it would benefit them and/or their patients before they would assist;
- 17% said communications and logistics needed to be improved;
- 10% said there were contracting or legal issues;

For more information, visit premier-research.com. PV

ORPHAN DRUG TRIALS OFTEN OUTSOURCED

- Rare/orphan disease trials are highly outsourced and given the propensity to use adaptive designs, expanded access programs, advocacy groups, and medical networks, these trials could be quite a bit more complex, operationally, than traditional studies.
- The complexity of rare disease trials underscores why 75% of rare disease/orphan drug studies are outsourced to a contract research organization.
- The vast majority of respondents who outsourced their rare disease/orphan drug trials were satisfied (86%) with the CRO they selected.
- Sponsors outsource to gain access to additional capacity and to leverage service providers' expertise in these areas.
- Patient access and recruitment strategies, therapeutic area expertise, and regulatory expertise are the top CRO selection attributes.
- Half (50%) of survey respondents indicated that operational experience with small patient populations was among the most valued CRO attribute.
- Positive project manager traits (experience, goes the extra mile) are highly desirable.
- The adjectives used most to describe the ultimate rare/orphan disease CRO include committed, experienced, motivated, flexible, and innovative.

Source: Premier Research

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Pharma's Research for

Diseases Affecting Seniors

TRENDING NOW: Pharma is concentrating on senior disease and treatments.


John Castellani

America's biopharmaceutical research companies are developing 465 new medicines that target the 10 leading chronic conditions affecting seniors, according to a new report by the Pharmaceutical Research and Manufacturers of America (PhRMA).

With the population of Americans older than 65 on the rise and life expectancy climbing, chronic diseases remain a principal threat to the health and productivity of older Americans, as well as to rising healthcare costs. Innovative medicines have led to major advances against many chronic diseases and the robust discovery pipeline of new medicines portends continued progress for seniors and the healthcare system.

"Our ability to prevent, manage, and treat chronic diseases has progressed dramatically in recent years, due in large part to the discovery and availability of new innovative medicines," says PhRMA President and CEO John Castellani.

For more information, visit phrma.org.

MEDICINES BEING DEVELOPED FOR OLDER AMERICANS

- 142 drugs in development for diabetes, which affects 10.9 million Americans age 65 and older
- 92 drugs for rheumatoid arthritis and osteoarthritis, which affect 1.3 million Americans and 12.4 million people over age 65, respectively
- 82 drugs for Alzheimer's disease, which could afflict almost 8 million people in the United States by 2030, unless a treatment or preventive measure is found
- 48 drugs for heart failure (affecting 5.8 million Americans) and ischemic heart disease
- 40 drugs for chronic obstructive pulmonary disease, which impacts more than 13 million adults, with the highest prevalence rate in those older than 65

Source: PhRMA

Federal Markets Become TOP PRIORITY

Top 50 pharmaceutical companies' market access groups target their strategies on federal markets and commercial managed care organizations in addition to state-level Medicare and Medicaid groups.

Cutting Edge Information found that managed markets groups approach federal and state payers in significantly different ways than they would for commercial managed care organizations. Commercial payers have more latitude because they work with a wider spectrum of groups, from fully insured groups to self-insured employers.

Like small companies, device companies also differ more in what payer organizations they target. The majority of surveyed device companies target Medicare and Medicaid groups as well as commercial managed care organizations.

"Medicaid and Medicare policies often set the precedent for other payer groups," says Adam Bianchi, chief operating office at Cutting Edge Information. "A lot of commercial payers tend to follow what Medicare does. So it's no surprise, then, that almost all companies target federal and state Medicare and Medicaid groups at higher rates than other payer organizations."

For more information, visit cuttingedgeinfo.com.

EMR is Expected TO GROW

Driven by hospital IT upgrades and the lure of government incentives, the market for electronic medical records (EMR) exceeded $20 billion in 2012, a 15% increase from the $17.9 billion in 2011, according to Kalorama Information. The healthcare market research publisher says vendors should see robust sales this year and next as vendors try to avoid U.S. government penalties for paper record use.

For more information, visit kaloramainformation.com.

Regenerative Medicines SHOW GROWTH

Revenue from regenerative medicines products on the market in 2012 exceeded $1 billion, and more than another $1 billion in combined public and private funding was invested into the sector, according to a recent report by Alliance for Regenerative Medicine.

With more than 100 RM products on the market, and an estimated 2,500 ongoing clinical trials worldwide, the field is making a significant impact on the treatment of chronic and life-threatening diseases. Products currently available or in clinical development encompass diverse therapeutic areas such as oncology, cardiovascular, ocular diseases, wound healing, autoimmune disorders, and spinal cord injuries. There are now more than 700 companies worldwide with a RM focus, ranging from divisions of multinational corporations to small organizations.


Geoff MacKay

"Unlike many therapeutics currently available that are designed to address symptoms of disease or delay disease progression, RM products have the potential to cure or significantly change the course of disease," says Geoff MacKay, chairman of ARM and president and CEO of Organogenesis.

For more information, visit alliancerm.org.

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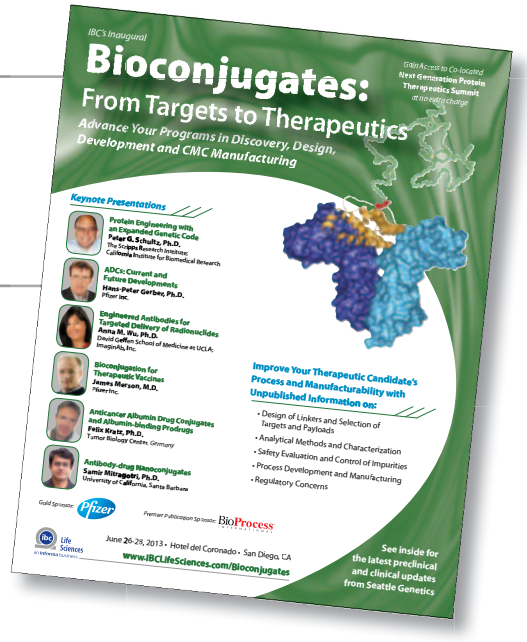

THERAPEUTIC TRAX...

AUTOIMMUNE

Surveyed U.S. and European rheumatologists indicate that new therapies for the treatment of systemic lupus erythematosus (SLE), that can positively differentiate themselves from current therapies in their effect on disease activity, would be well received by physicians and would be poised to benefit from strong uptake. The emerging therapies epratuzumab (Immunomedics/UCB) and Lupuzor (ImmuPharma's forigerimod, P140, CEP-33457) have the potential to offer improvements over IV belimumab (Human Genome Sciences/GlaxoSmithKline's Benlysta) in reducing disease activity.

Source: Decision Resources, DecisionBase 2013, Which Clinical Attributes Will Most Effectively Position Emerging Biologics Against IV Belimumab in the Moderate to Severe Patient Segment?

For more information, visit decisionresources.com.

2012 rheumatoid arthritis (RA) drug sales are expected to be $601.7 million in Australia. By the end of the forecast period, sales will grow to more than $834.6 million with a CAGR of 3.0%, which includes new pipeline therapies and the launch of biosimilars. This growth will be driven by the approval/launch of Pfizer's tofacitinib and the launch of other novel products, such as Lilly's anti-BAFF, tabalumab and Rigel/AstraZeneca's SYK inhibitor, fostamatinib. The uptake of biosimilars for the market leading TNF inhibitors and the growth of the aging population will also positively affect the market.

Source: Global Data, Rheumatoid Arthritis in Australia - Drug Forecast and Market Analysis - Event-Driven Update

For more information, visit globaldata.com.

BONE DISORDERS

Despite its maturity, the osteoporosis market is expected to undergo substantial change between 2012 and 2022. Most importantly, bisphosphonates will lose patent protection by end of year 2013, flooding the marketplace with less expensive generic versions of these physician-preferred medications. Additionally, Lilly's blockbuster Evista, the only available SERM in the United States, will lose patent protection in 2014, flooding the market with yet more affordable generic options.

Source: Global Data, PharmaPoint: Osteoporosis - Global Drug Forecast and Market Analysis to 2022

For more information, visit globaldata.com.

CANCER

The liver cancer therapeutics market in the top seven markets (the US, the UK, Germany, France, Spain, Italy, and Japan) grew at a CAGR of 21.7% during 2004-2011 to reach an estimated $374.3 million. In the coming years, the market is forecast to show a slower but steady climb at a CAGR of 8.1% to reach $644.3 million by 2018. Recent market growth has been driven by increasing annual costs of therapy, due to the approval of Nexavar in the United States and Europe, and the anticipated launch of late-stage pipeline drugs is expected to continue this trend.

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 U.S. market for therapeutic cancer vaccines is predicted to account for 96% of the total in 2013, decreasing slightly to 94% in 2019 with the approval of numerous vaccines in the EU and Japan, but remaining overwhelmingly dominant throughout the forecast period and into the foreseeable future. The therapeutic cancer vaccines market is anticipated to grow rapidly throughout the forecast period from an estimated $590 million in 2013 to about $7.59 billion by 2019, driven primarily by the approval of up to 12 vaccines across seven indications.

Source: GBI Research, Therapeutic Cancer Vaccines Market to 2019 - Pipeline Indicates Safer Treatments and Extended Patient Survival, though High Prices May Limit Uptake

For more information visit gbiresearch.com.

The Canada prostate cancer market was valued at an estimated $97.6 million in 2012. The market is expected grow to $230.5 million by 2022, at a CAGR of 9.0%. Major drivers of market growth will include the launch and continued success of safe and effective, orally administered therapies for metastatic Castration-Resistant Prostate Cancer (mCRPC), particularly Zytiga (abiraterone acetate) and Xtandi (enzalutamide).

Source: Global Data, Prostate Cancer in Canada - Drug Forecast and Market Analysis

For more information, visit globaldata.com.

CENTRAL NERVOUS SYSTEM

Surveyed U.S. neurologists indicated that they would prescribe Biogen Idec's Tecfidera to 20% of their patients with relapsing-remitting multiple sclerosis (RR-MS). Tecfidera will earn a patient share similar to surveyed neurologists' estimate in the United States. RR-MS market by 2021, owing to its robust efficacy — specifically, a greater reduction in annualized relapse rate (ARR) relative to first-line agents — and a strong safety profile relative to the most effective current therapies, such as Biogen Idec's Tysabri.

Source: Decision Resources, DecisionBase 2013, Where Do Physicians and Payers Signal the Greatest Need — and Greatest Opportunity — for New Therapeutic Advances

For more information, visit decisionresources.com.

A highly dynamic market scenario is expected in neurodegenerative diseases over the next few years, with a number of patent expiries and anticipated new drug approvals. In spite of a number of high-profile clinical trial failures such as bapineuzumab and, to an extent, solanezumab for the treatment of Alzheimer's disease, the overall pipeline for neurodegenerative diseases remains strong. It contains an estimated 678 pipeline products, most of which are being developed for the treatment of AD or Parkinson's disease (PD).

Source: GBI Research, Neurodegenerative Diseases Market to 2018 — New Product Entries in Both Niche and Broader Parkinson's Disease Treatment will Boost Market Despite Patent Cliff

For more information, visit gbiresearch.com.

The global epilepsy market was valued at an estimated $4.2 billion in 2012. The market will grow to $5.5 billion by 2022, with more than 50% of sales coming from the United States. Major drivers of market growth over this forecast period will include the introduction of novel antiepileptic drugs with higher prices in the United States and EU. By 2022, the AED market will be even more crowded, with almost 30 drugs. But there will still be a ready market among the remaining refractory patients who are the first to be treated with any new drug en-

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"Medicaid and Medicare policies often set the precedent for other payer groups," says Adam Bianchi, chief operating office at Cutting Edge In-

tering the market.

Source: Global Data, Epilepsy — Global Drug Forecast and Market Analysis

For more information, visit globaldata.com.

Several market-leading disease-modifying therapies (DMT) for multiple sclerosis are due to suffer patent expiries over the coming years, exposing therapy sales to significant brand erosion. DMT sales for MS across the global markets (US, France, Germany, Italy, Spain, the UK, Japan, Canada, China, and India) will grow from around $12.6 billion in 2012 to $13.6 billion in 2022, with a CAGR of 0.7%.

Source: Global Data, Multiple Sclerosis — Global Drug Forecast and Market Analysis to 2022

For more information, visit globaldata.com.

DIABETES

About 80% of PCPs and endocrinologists say they would prescribe a less expensive DPP-IV inhibitor to their patients with type 2 diabetes or hypertension, reflecting high cost-sensitivity. Among the DPP-IV inhibitors, physicians overwhelmingly prescribe Merck's Januvia more often because of its more favorable reimbursement while reducing their use of Boehringer Ingelheim's Tradjenta and, to a lesser extent, Bristol-Myers Squibb's Onglyza. This finding reflects the high rate of preferred coverage for Januvia in comparison with Tradjenta and Onglyza. Also, 84% of MCO pharmacy directors have seen physicians prescribing drugs with lower patient costs and fewer restrictions because of the information provided in e-prescribing solutions.

Source: Decision Resources, U.S. Physician & Payer Forum, E-Prescribing and Electronic Health Records: Impact of Technology on Prescribing for Hypertension and Diabetes

For more information, visit decisionresources.com.

INFECTIONS

Pandemic infections are causing concern with healthcare providers and organizations globally as pandemic infections such as human immunodeficiency virus/acquired immune deficiency syndrome (HIV/AIDS), hepatitis B and C, and tuberculosis continue to expand by geographic area as well as virulence. The total market for pandemic infectious disease products broken down by disease type was $31.6 billion in 2011 and $35.6 billion in 2012. The market is expected to rise at a CAGR of 9.3% and reach nearly $55.6 billion by 2017.

Source: BCC Research, Global Markets and Technologies for Pandemic Control

For more information, visit bccresearch.com.

Incident cases of HIV will increase 9.7% over the next decade in the 10 major markets, from 276,590 incident cases in 2012 to 303,365 incident cases in 2022. Throughout the forecast, India will have the largest number of incident cases of HIV and will grow 17.3% over the next decade to 144,642 in 2022. There were 170,388 cases of HIV/HCV co-infection in the 5EU, with 41% of cases in Spain.

Source: Global Data, Human Immunodeficiency Virus — Epidemiology Forecast to 2022

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. The overall MRSA prevalence has an escalating trend due to increased community associated MRSA infections. Other factors that have contributed toward the growth of the Information market have been the steady increase in the elderly and immuno-compromised populatio.n, an increase in the average number of days spent in hospitals and the emergence of multi drug resistant (MDR) bacterial strains. Various events that will affect the MRSA therapeutics market: patent expiries of Zyvox in 2015, Cubicin in 2017 and Tygacil in 2016, plus the expected approval of Teflaro in Europe and the expected launch of Torezolid around 2015.

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

For more information, visit globaldata.com.

Cubist Pharmaceuticals' Cubicin will be the leading antibacterial drug in 2017, with revenue of more than $1 billion. In that year, it will account for around 2.5% of the global antibiotics market. Other drugs forecast to experience strong revenue growth include Optimer Pharmaceuticals' Dificid. Revenue for that drug will grow with a compound annual growth rate (CAGR) above 25% through to 2023.

Source: visiongain, Antibacterial Drugs: World Market Prospects 2013 to 2023

For more information, visit visiongain.com.

RESPIRATORY

Surveyed U.S. pulmonologists estimate that only 19% of their severe, refractory asthma patients are treated with Genentech/Novartis' Xolair, the only approved drug that serves this population. By the end of 2018, when three novel biologics and biosimilar versions of Xolair are expected to be available, surveyed pulmonologists estimate that nearly 50% of their severe, refractory patients will be treated. This response demonstrates the great unmet need for this population that will be at least partially filled by the emerging biologics.

Source: Decision Resources, U.S. Physician & Payer Forum, How will U.S. Physician and Payer Attitudes and Decisions Shape the Asthma Market for Patients with Severe, Refractory Disease?

For more information, visit decisionresources.com.

VACCINES

The vaccines market, which was once considered by pharma giants as a low-profit segment, is showing a turnaround after Prevnar 13's resounding success. The pneumococcal vaccines segment for adults and adolescents is growing at a rapid pace, and is expected to reach a value of $1.7 billion by 2018. This market segment is expected to be dominated by Prevnar, leaving a marginal share for competitors but the strong global pipeline of adult and adolescent vaccines boasts a 52% share of vaccine candidates in the Phase III stage of clinical development.

Source: GBI Research, Adult and Adolescent Vaccines Market to 2018 — Promising Novel Candidates in Late-Stage Development and Prevnar Approval in Adults to Drive Growth

For more information, visit gbiresearch.com.

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