

# Biotech reinvented

## Where do you go from here?





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## Introduction

The biotechnology industry (Biotech) is now about 30 years old – a long enough time in which to evaluate how it's done. Unfortunately, despite some notable successes, it hasn't completely fulfilled its promise.

The business model on which Biotech has historically relied is also breaking down, as the research base moves east and raising funds gets harder. And the distinctions between Biotech and the pharmaceutical industry (Pharma) are disappearing, with the convergence of the two sectors. But Biotech can't turn to Pharma for guidance because Pharma's business model has other flaws – as we explained in "Pharma 2020: Challenging business models", the White Paper we published in April 2009.<sup>1</sup> So what should Biotech do?

We believe it should capitalise on the opportunities emerging in the healthcare

### What is Biotech?

Biotech isn't a distinct sector so much as it's a collection of disruptive technologies for discovering and developing new medicines, and diagnosing and treating patients more effectively. We're going to focus here on Biotech's business model – more specifically, its impact on pharmaceutical productivity, and its sustainability (or otherwise) in the current economic and scientific environment.

arena – and reinvent itself by adopting a more collaborative approach. In the following pages, we'll look at the main trends dictating the need for a new way of conducting research and development (R&D), and two organisational concepts that would help biopharmaceutical companies become far more efficient. We'll also touch on the implications for other parts of the value chain.

## How well has Biotech really done?

If the birth of modern biotechnology can be pinned down to any particular date, it's probably 1980, when the US Supreme Court ruled in *Diamond v. Chakrabarty* that a genetically modified microorganism could be patented.<sup>2</sup> Amgen was formed the same year, and Genentech (now part of Roche) was four years old.<sup>3</sup> Since then, Biotech has profoundly changed the sort of research Pharma conducts and the sort of products it makes (see sidebar, What is Biotech?). But how well has Biotech really done?

The good news is that it's produced some valuable new platform technologies and treatments. RNA interference has, for example, provided a way of analysing gene activity to identify novel disease targets. More than 100 different recombinant protein-based drugs and at least 40 'companion' diagnostics have also been

launched, and some of these therapies have proved very effective in treating complex conditions.<sup>4</sup> Five of the 10 top-selling medicines in 2009 originated in Biotech's labs (see **Table 1**).

The bad news is that Biotech hasn't made a significant difference to Pharma's productivity, measured in terms of the number of new treatments reaching the market. Between 1950 and 2008, the US Food and Drug Administration (FDA) approved 1,222 therapies (1,103 small molecules and 119 large molecules). Given that it takes about 10 years to develop a drug, the total number of approvals should have started rising in about 1990, if Biotech had succeeded in improving Pharma's output. But, as **Figure 1** shows, the number of approvals has remained broadly constant.<sup>5</sup>

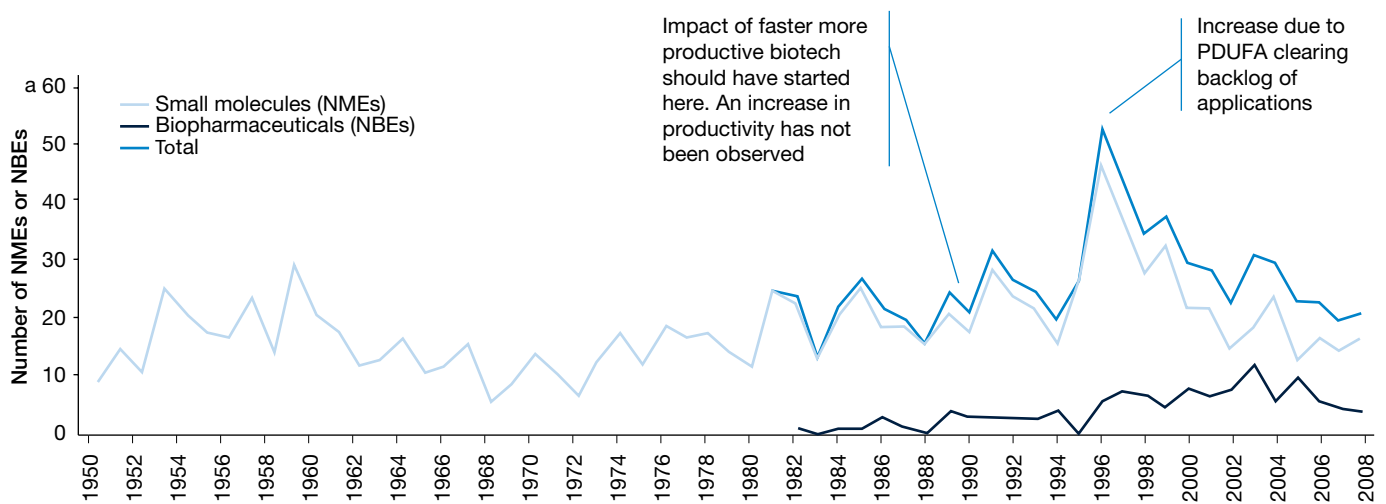
The reason's simple: Biotech hasn't reduced the inherent risk in drug discovery and development. Average development times for the kind of molecules on which biotech firms generally focus – i.e., recombinant proteins and monoclonal antibodies – are slightly longer than they are for small molecules (97.7 months versus 90.3 months). Average development costs are much the same (US\$1.24 billion versus US\$1.32 billion). And the overall success rate is still only 9.1%, compared with 6.7% for a small molecule.<sup>6</sup> In other words, biotech companies don't develop new medicines much more quickly or economically than pharma companies do.

**Table 1: The best sellers of 2009**

Rank	Product	Therapeutic Subcategory	Technology	Worldwide Sales (\$m)
1	Lipitor	Anti-hyperlipidaemics	Chiral chemistry	12,511
2	Plavix	Platelet aggregation inhibitors	Small molecule chemistry	9,492
3	Seretide/Advair	Other bronchodilators	Small molecule chemistry	7,791
4	Enbrel	Other anti-rheumatics	Recombinant product	6,295
5	Diovan	Angiotensin II antagonists	Small molecule chemistry	6,013
6	Remicade	Other anti-rheumatics	Monoclonal antibody	5,924
7	Avastin	Anti-neoplastic MAb	Monoclonal antibody	5,744
8	Rituxan	Anti-neoplastic MAb	Monoclonal antibody	5,620
9	Humira	Other anti-rheumatics	Monoclonal antibody	5,559
10	Seroquel	Anti-psychotics	Small molecule chemistry	5,121

Source: EvaluatePharma

**Figure 1: A flat performance**



Source: Bernard Munos, "Lessons from 60 years of pharmaceutical innovation"

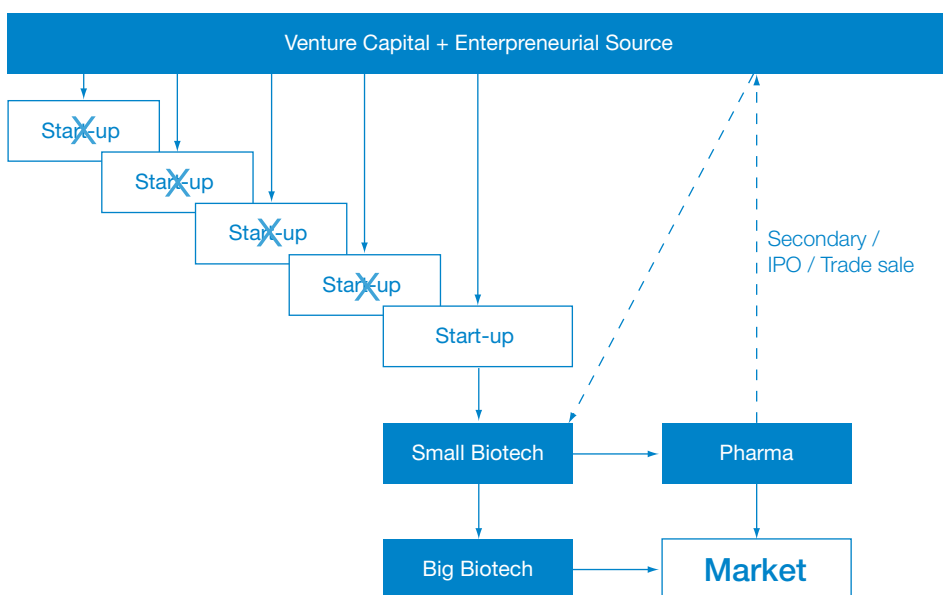
## A business model that's bust?

Worse still, the business model on which Biotech has relied for the past 30 years is now breaking down. This model is based on external investment – typically, venture capital – in an innovative idea arising from an entrepreneurial source, often a group of academics (see **Figure 2**). It assumes that investors can realise value through one of two routes: flotation on the public markets or, more frequently, a trade sale to an established pharma company. And it carries a very high risk of failure. In one recent study of 1,606 biotech investments that were realised between 1986 and 2008, 704 investments resulted in a full or partial loss, while 16 only covered their costs.<sup>7</sup>

The same study shows that the gross rate of return on these 1,606 biotech investments was 25.7%, compared with a pooled average return of 17% on all venture capital invested over the same period. But costs and the 'overhang' from unrealised investments reduced the net rate of return to about 15.7%, and there were huge variations in the cash multiples earned by the 886 investments that made a profit (see **Figure 3**).<sup>8</sup> Ten-year returns have also deteriorated dramatically since 2008. The average return on a 10-year investment ending in December 2008 was 35%, thanks to the lingering effects of the technology bubble. In March 2010, it had plummeted to -3.7%.<sup>9</sup>

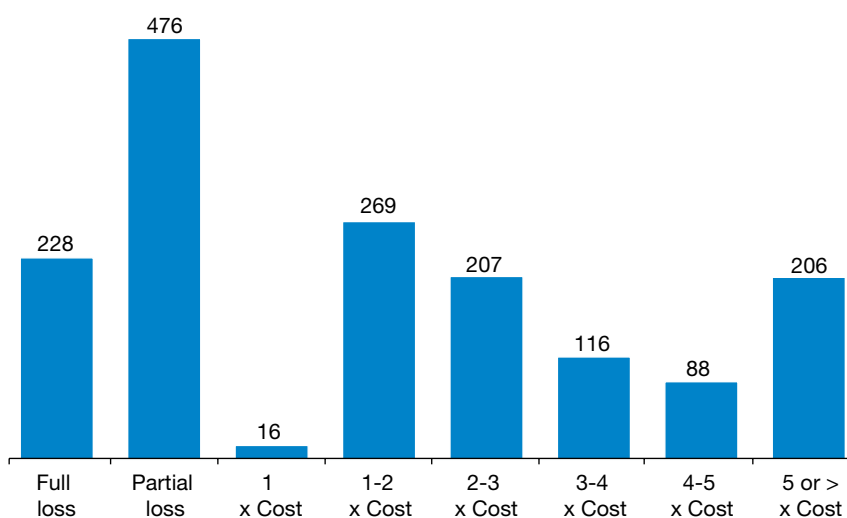
So what distinguishes the successes from the failures? Our analysis of the companies behind some of the top-selling biologics on the market shows

Figure 2: Biotech's business model



Source: PricewaterhouseCoopers

Figure 3: Big variations in cash multiples



Source: Iain Cockburn & Josh Lerner, "The Cost of Capital for Early-Stage Biotechnology Ventures" (2009)  
Note: Figures include all exited biotech deals as of December 31, 2008

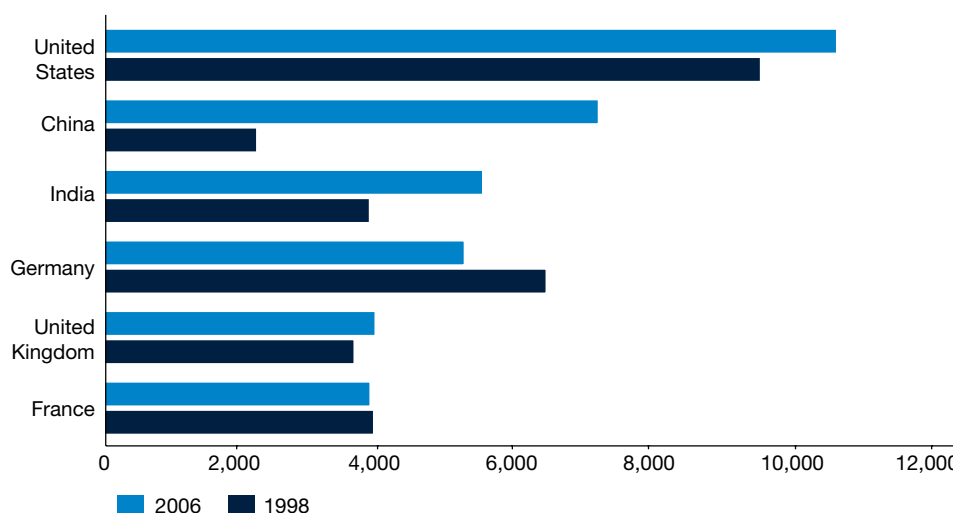
they have several common features. Most of them started up in the US in the late 1970s and 1980s, floated very early in their history and raised a substantial amount of funds in the process. They were all subsequently acquired by big pharma companies, and the products they make are now marketed by one or more such firms (see **Table 2**).

However, many of the external conditions that enabled these biotech companies to thrive are rapidly vanishing. The research base is shifting geographically, the emerging economies are competing more aggressively and financial investors are getting more cautious.

### Eastward ho!

The research base is moving East, as Asia's emerging economies invest more in higher education and the 'reverse brain drain' picks up pace. Between 1998 and 2006, the number of students graduating with doctorates in the physical and biological sciences soared 43% in India and a staggering 222% in China, far outstripping the rate of increase in the West (see **Figure 4**).<sup>10</sup> The 'returnee' trend has been equally

**Figure 4: Asia's higher degrees of change**



Source: US National Science Foundation

Note: Data are for 1999-2006 in the case of France and 1998-2005 in the case of India

**Table 2: Winning ways**

Product	Originator Company Founded	Product Launch	Origins in US	Initial Public Offering	Well Financed	Big Pharma Acquisition	Marketed by Big Pharma	2009 worldwide sales (\$m)
Herceptin	1976	1998	✓	✓	✓	✓	Roche	4,862
Avastin	1976	2004	✓	✓	✓	✓	Roche	5,744
Remicade	1979	1998	✓	✓	✓	✓	Centocor/J&J	5,924
Enbrel	1981	1998	✓	✓	✓	✓	Amgen/Pfizer	6,295
Rituxan	1985	1997	✓	✓	✓	✓	Roche/ Biogen Idec	5,620
Humira	1989	2002		✓	✓	✓	Abbott	5,559

Sources: PricewaterhouseCoopers and EvaluatePharma

pronounced. In the past two decades about 100,000 highly skilled Indian and Chinese expatriates have left the US for their native countries. Another 100,000 are expected to follow them in the next five years, as the opportunities at home improve.<sup>11</sup>

### Hotter competition

Some of the emerging countries are also actively building domestic biotech industries. Singapore launched its Biomedical Sciences Initiative in 2000 and has already created a powerful biopharmaceutical nexus. South Korea set up a similar scheme in the late 1990s, and has earmarked \$14.3 billion for its 'BioVision 2016' programme.<sup>12</sup> China has invested \$9.2 billion in technological R&D, including biotech, in the last 18 months alone.<sup>13</sup> And India is currently exploring plans to become one of the world's top five biosimilars producers by 2020.<sup>14</sup>

What's more, many of the companies based in the emerging economies aren't just imitating the West; they're learning from its mistakes. They're dispensing with the costly infrastructure that burdens companies in developed countries to create new business models that are leaner and more economical, as well as pioneering innovative products and processes. So the US is gradually losing its pre-eminence as a centre of biomedical research. It still leads the way and is likely to do so for at least another five years. But it's no longer the only gorilla on the block.

### Capital constraints

The recession has also made it much more difficult for biotech companies in the developed economies to raise capital. In 2008, Biotech raised just \$16.3 billion in the US, Europe and Canada – 45% less than the previous year. The situation improved in 2009, but the total amount raised fell well short of historical levels, and nearly half of it went to a handful of established public companies in follow-on offerings (see **Table 3**).<sup>15</sup>

There are plenty of other signs of the toll the past two years have exacted. In 2009, for example, 10 biotech firms (including the highly regarded deCODE genetics) filed for bankruptcy in the US, while another nine firms closed up shop without being officially bankrupt.<sup>16</sup> And though financing conditions have now started easing, most industry observers believe the window for initial public offerings won't open again anytime soon.

This has inevitably deterred many

venture capitalists – particularly European venture capitalists – from investing in the sector. In 2009, the amount of venture capital raised by biotech companies based in Europe was just €800 million (\$1.1 billion), less than at any time since 2003.<sup>17</sup> And money's likely to remain very tight, as most biotech executives recognise; 84% of the participants at a recent biopharmaceutical conference thought funding was the industry's single biggest challenge.<sup>18</sup>

They've got good reason to worry. According to one estimate, 207 of the 266 private and public European biotech companies with products or platform technologies in the clinic or already on the market urgently need to raise funds – and they need a good \$4.8 billion between them.<sup>19</sup> Given that the total amount of European venture capital invested in the sector was just €501 million (\$666.6 million) in the first half of 2010, it's very doubtful they'll all succeed.<sup>20</sup>

**Table 3: Fundraising below pre-recession norms**

	2009	2008	2007	2006	2005
Initial Public Offerings	823	116	2,253	1,872	1,785
Follow-on Offerings	6,579	1,840	3,345	6,303	4,600
Other	10,044	8,244	16,928	14,930	8,442
Venture	5,765	6,131	7,407	5,448	5,425
Total	23,211	16,332	29,932	28,553	20,252

Source: Ernst & Young, Beyond Borders: Global Biotechnology Report, 2010  
Note: Numbers may appear inconsistent because of rounding

## Blurring boundaries

However, yet another change is taking place: the boundaries between Biotech and Pharma are blurring. One sign of the change is the fact that several large pharma companies have established corporate venture capital arms specifically to make strategic, as opposed to financial, investments in Biotech. Novartis has created an option fund with the right to in-license innovative products or technologies from the companies it backs, for example.<sup>21</sup> Similarly, Merck Serono has set up a fund ‘to support scientific excellence in [its] core fields of interest and provide start-up companies with the opportunity to interact’ with it.<sup>22</sup>

Many pharma companies are also focusing on developing biologics and specialist therapies for orphan diseases, because they offer a faster and more focused route to market. In 2006-2008, Big Pharma produced more than half the orphan drugs approved by the FDA

– up from a third in 2000-2002 – and the industry leaders have piled in even more heavily over the past year.<sup>23</sup> In November 2009, for example, Pfizer licensed the rights to a new treatment for Gaucher disease, a condition fewer than 6,000 Americans suffer from.<sup>24</sup> In February 2010, GlaxoSmithKline launched a standalone business unit for orphan drugs, and Pfizer did likewise a few months later.<sup>25</sup>

Some of the oldest biotech companies are simultaneously repositioning themselves as biopharmaceutical companies, and several pharma companies are restructuring their R&D functions to emulate Biotech’s more entrepreneurial approach to discovering new medicines. GlaxoSmithKline started this trend in 2000, when it divided thousands of its researchers into groups of 400 or so and gave them their own budgets to manage. It subsequently created even smaller Discovery Performance Units of 20 to 60 people, each focusing on a different disease or technology. AstraZeneca is now

following suit, while Novartis has moved its research headquarters to Cambridge, Massachusetts, and hired a Harvard professor to run it.<sup>26</sup>

So Biotech and Pharma are effectively becoming one industry – the biopharmaceutical industry – although there’s a limit to how far Pharma can go down the Biotech route. First, biotech companies typically perform a few key trials, rather than using the belt-and-braces strategy favoured by Pharma. This is partly because most of them have fewer resources. It’s also because small companies are less likely than large companies to ask for scientific advice from the regulators and, even when they do ask, they’re less likely to comply with the advice they get.<sup>27</sup> But biotech companies pay a price for taking the fast route, with much higher failure rates in late-stage development (see **Table 4**).<sup>28</sup>

Second, therapies for very small patient populations can’t deliver the returns produced by mass-market medicines, unless they’re sold for very high prices. However, patients in many countries can’t afford such prices and, even in more affluent markets, cash-strapped healthcare payers are pushing back. The European Union recently altered its orphan drug law, for example, to let regulators reduce the 10-year period of market exclusivity for orphan drugs, where they think the profits from non-orphan indications are ‘unseemly’.<sup>29</sup>

In short, the external conditions that helped produce a drug-discovery powerhouse like Genentech have all

**Table 4: Biotech companies fall more often at the final post**

	FDA approvals	Percentage of FDA approvals	Phase III failures	Percentage of Phase III failures
Biotech	47	45%	68	74%
Biotech-pharma alliances	16	16%	18	21%
Acquisitions/licences by pharma	4	4%	0	
Pharma	36	35%	5	5%
Total	103		91	

Source: Elizabeth A. Czerepak & Stefan Ryser, “Drug approvals and failures: implications for alliances” (2008)  
 Note: All products were approved for the first time by the FDA between January 2006 and December 2007

but disappeared. Pharma can't copy Biotech's discovery and development methodology too closely and, even if it could, Biotech hasn't brought a golden era of productivity that would justify doing so. All biopharmaceutical companies – whether they're biotechnological or pharmaceutical in origin – will ultimately, therefore, have to adopt a very different business model.

## Putting up a united front

So what might such a model look like? If it's to be successful, it's got to be more efficient – and one way of becoming more efficient is to become more collaborative. Sequestering intellectual property in different organisations impedes innovation,

because each has access to only one part of the biochemical puzzle. This not only slows down the discovery and development process, it also increases costs, as numerous organisations replicate the same studies on the same targets. Conversely, collaboration accelerates and facilitates the process, and two new concepts – precompetitive discovery federations and competitive development consortia – lend themselves to just such an approach.

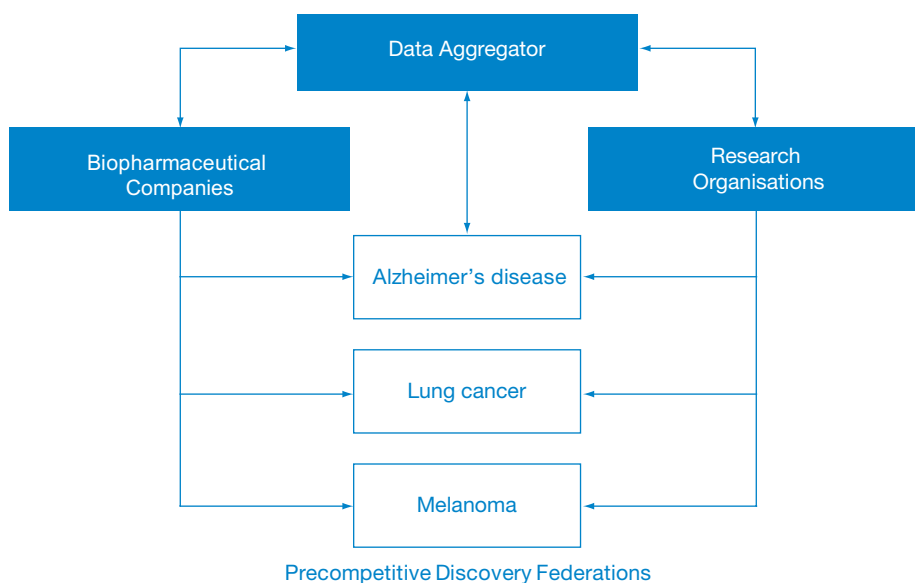
### Precompetitive discovery federations

Precompetitive discovery federations are public-private partnerships in which biopharmaceutical companies swap knowledge, data and resources with one another, as well as with government

agencies, universities, academic medical centres, research institutes and patient groups. They aim to overcome common bottlenecks in early-stage biomedical research by enabling the participants to piece together the scientific data on the pathophysiology of specific diseases and potential targets sitting in their separate organisations (see **Figure 5**).

A number of precompetitive discovery federations have already been established. Most of these collaborations have been set up fairly recently and lie towards the philanthropic end of the spectrum. They focus on areas of unmet need in the less developed world or diseases for which it's particularly difficult to develop safe, effective medicines. Alternatively, they aim to make a particular region

**Figure 5: Precompetitive discovery federations facilitate and accelerate innovation**



Source: PricewaterhouseCoopers

more competitive (see sidebar, **Connecting the dots**).<sup>30</sup> But at least one such alliance has already proved an outstanding success. This is the Structural Genomics Consortium – backed by GlaxoSmithKline, Merck and Novartis, among other organisations – which published 450 protein structures within three years of starting work, and aims to publish another 660 structures by July 2011.<sup>31</sup>

Translating such findings into useful new therapies is another matter – and it's much too early to assess the impact of precompetitive discovery federations in terms of reducing lead times and costs, or treating intractable diseases. Nevertheless, the industry clearly isn't averse to the idea of collaborating, and we think that, by 2020, all precompetitive research will be conducted in this way.

Experts from numerous organisations will assemble to solve a specific problem, regardless of whether they work in industry or academia, and whether they live in the Americas, Europe or Asia. Much of the work

they do will be performed virtually, as the world becomes increasingly interconnected. And each federation will be disbanded once it's solved the problem it was set up to deal with, although the insights it generates will live on – just as filmmakers form syndicates to produce different films and the films they create outlast the syndicates themselves.

There are many advantages to this approach. It would enable each participant to save money by investing less than it would have to do to support its own internal research or exclusive external research programme. It would also reduce unnecessary duplication, help all the participants make faster, better progress by combining their insights and permit them to take more informed investment decisions. To put it another way, precompetitive discovery federations could end the “current modus operandi in which commercially driven clinical trials fall like dominos in the clinic – to the detriment of each company, to the detriment of the patients and with relatively little [shared] learning”.<sup>32</sup>

### Connecting the dots

In early 2010, Eli Lilly, Merck and Pfizer formed the Asian Cancer Research Group to promote research on lung and gastric cancers, and other forms of cancer commonly found in Asia. The three companies plan to create one of the ‘most extensive pharmacogenomic cancer databases known to date’ over the next two years. Meanwhile, the Coalition Against Major Diseases is focusing on the development of quantitative disease progression models for complex neurodegenerative diseases like Alzheimer's disease and Parkinson's disease. And the Innovative Medicines Initiative (IMI) is orchestrating the European Union's efforts to address major obstacles in drug discovery by pooling the resources of biopharmaceutical companies, research institutions and patient groups throughout Europe. It has a €1 billion grant from Brussels and is currently supporting 15 research alliances.

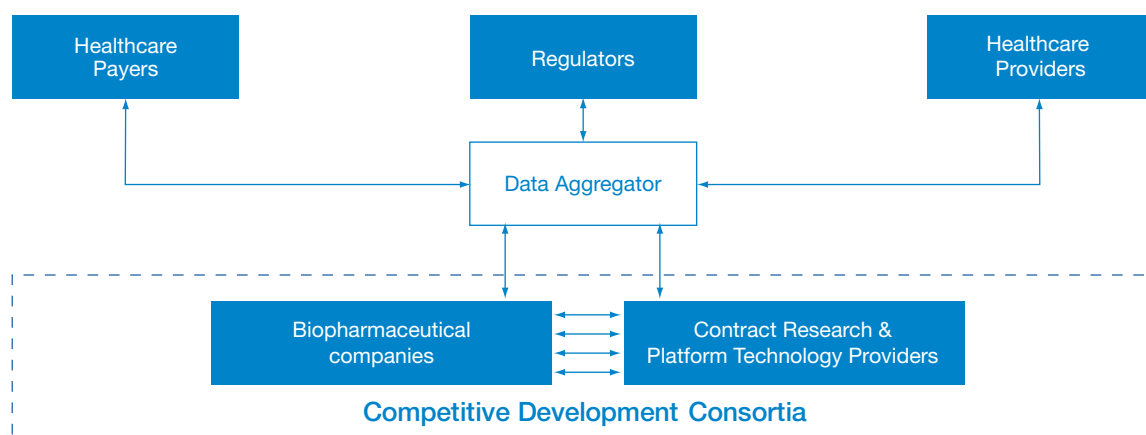
Of course, determining the boundaries between precompetitive and competitive research is difficult – and opinions will vary, depending on the interests of the respective parties. Nevertheless, it's possible to see how some of the lines might get drawn. Data preceding the point of filing for a patent (e.g., data on genes, pathways and bioactivity) could provide various opportunities for precompetitive collaboration, for example. And some companies might well be prepared to go considerably further. GlaxoSmithKline is one such instance; it recently proposed an industry-wide, open-access 'patent pool' and offered to license all its patented knowledge for free, as long as the knowledge is used solely to develop treatments for neglected diseases in the 50 poorest countries.<sup>33</sup>

The potential cost savings might also prove incentive enough to stimulate a new attitude to intellectual property management. Pharma companies typically patent all the information they hold to block their rivals from working in the same area. But evidence from other industries suggests that most patents remain uncommercialised; Siemens and Procter & Gamble recently reported, for example, that they've only used 10% of their patent portfolios.<sup>34</sup> It would therefore be far more sensible for all companies to segment their information into three categories: information they can openly share; information they can safely sell to a third party; and information they plan to use themselves.<sup>35</sup>

### Competitive development consortia

The discovery process isn't the only area of scientific R&D that would benefit from closer collaboration. The development process could also be improved with the introduction of competitive development consortia (as we've called them) in which rival biopharmaceutical companies join forces with each other, as well as with contract research organisations and platform technology providers (see **Figure 6**). At present, four or five firms often focus on the same target at the same time, and each might develop two or three compounds to hit that target. But if they pooled their portfolios, they could concentrate on the best drug candidates, regardless of which

**Figure 6: Competitive development consortia minimise waste and enhance productivity**



Source: PricewaterhouseCoopers

company had invented them, thereby eliminating a great deal of waste.

Big Pharma has traditionally shied away from such arrangements, yet competing heavyweights in a number of other industries have successfully come together to develop new products. General Motors, Daimler and BMW collaborated to create the hybrid petroleum-electric powertrain solution, for example. And there's evidence that some large pharma companies may now be willing to take a more open stance (see sidebar, **New best friends**).<sup>36</sup>

### Robust data aggregators

The success of precompetitive discovery federations and competitive development consortia clearly hinges on the existence of data aggregators capable of collecting and synthesising data from all the participants in a particular group. No such organisations currently exist. Nor, indeed, do some of the tools required to manage vast amounts of biological and chemical data.

The challenges – including the sheer heterogeneity of the data, lack of data standards, limitations of the available data-mining technologies and immaturity of the IT platforms needed to let researchers share data easily

and securely – have been extensively documented. Making sense of disparate pieces of information and identifying meaningful correlations between superficially unrelated phenomena is still an incredibly labour-intensive task.

However, solutions to all these problems are slowly emerging. The Human Proteome Organisation's Proteomics Standards Initiative has already released standards for representing and exchanging proteomic data from mass spectrometry, molecular interactions and protein separation techniques, for example, while the Clinical Data Interchange Standards Consortium (CDISC) is developing standards for exchanging clinical research data and metadata, and various other data standards are well underway.<sup>37</sup>

Similarly, use of semantic technologies for integrating and analysing data is growing. Johnson & Johnson is conducting a pilot semantic project to capture metadata on biological data sources and make the information easier to retrieve.<sup>38</sup> Pfizer, Merck, Novartis and Eli Lilly are also experimenting with the semantic web.<sup>39</sup> And technologies like cloud computing are evolving to create a secure, reliable and flexible infrastructure for sharing data and applications.

### New best friends

AstraZeneca and Merck recently embarked on a landmark partnership to develop a combination therapy for cancer, with each contributing an investigational compound to the mix. Combination therapies for cancer are common, but they're usually tested late in clinical development or after registration. Or a new potential treatment is tested in combination with the standard therapy. However, AstraZeneca's compound was still in Phase II, and Merck's compound had only been tested in 100 people when the two companies decided to join forces.

They entered into a staged agreement, beginning with preclinical trials. When the results proved promising, they decided to collaborate further and jointly devised a plan for testing the treatment in Phase I trials. Under the terms of the deal, the two companies will share the decision rights and costs, and any intellectual property that arises from the collaboration. The big question is how the regulators will respond if they're successful, since nobody has ever co-registered two unregistered drugs before.

Meanwhile, several big technology providers have entered the computational bioinformatics space. IBM leads the way. It's currently engaged in about 20 projects, ranging from the development of sophisticated analytical tools to original research on 'junk' genes and RNA interference in eukaryotes and viruses.<sup>40</sup> Oracle, Hewlett-Packard and Intel are also actively focusing on bioinformatics.

Some formidable obstacles remain, but we believe these companies will eventually play a major role in analysing genomic and clinical data to help individual consortia research new medicines and the regulators evaluate submissions more accurately. Some of them may even assume responsibility for developing disease models and predicting the interaction of different molecules with a given target. We outlined how this might work in "Pharma 2020: Virtual R&D", where we discussed how the largest technology vendors could host 'virtual patients' on behalf of the industry as a whole.<sup>41</sup>

### An innovation culture

Reliable data aggregators aren't the only prerequisite for success; an

'innovation culture' is equally important. In view of the investment levels and risks associated with drug discovery and development, all the members of a precompetitive discovery federation or competitive development consortium will need to be agile, willing to explore new ideas and open to insights produced outside their own walls. Senior management will also need to encourage creative brainstorming, networking, calculated risk-taking, experimentation and questioning of the status quo.<sup>42</sup>

### A new spirit of realism

That's not all. If this new business model is to work, it will require greater realism on the part of everyone involved. Biotech executives and academics sometimes complain of Big Pharma's 'arrogance', for example.<sup>43</sup> But size isn't everything and the biggest pharma companies can't expect to have everything their own way. So they'll need to become more flexible.

The research institutes and biotech firms they join forces with will also need to have more realistic expectations. Whereas academic researchers prize scientific knowledge for its own sake,

industry researchers need discoveries that have commercial potential. And it's all too easy for a biotech company with a single platform technology or molecule to overvalue its intellectual property. It's only by understanding such differences in perspective and negotiating fairly that a precompetitive discovery federation or competitive development consortium can prosper.

If the venture capital industry is to play a major part in the future of biotech, it will have to be more pragmatic, too. The most successful funds aim for returns of two to four times the initial investment, which is the equivalent of a compound annual growth rate of 7-15% over a typical 10-year investment period. By way of comparison, the FTSE Small-Cap Index generated a total annual return of 1.1% between May 2000 and May 2010 – evidence of just how high the bar has been set.<sup>44</sup>

### The size of the prize

So there are some considerable cultural, behavioural and practical hurdles, and some of them may be difficult to overcome. But we believe they're well worth resolving, given the rewards

collaboration can bring. It's no accident that IBM has doubled its software revenues to more than \$20 billion, since embracing open-source computing.<sup>45</sup>

Precompetitive discovery federations and competitive development consortia could collectively enable the biopharmaceutical industry to use precious resources more intelligently, make more astute investment decisions and develop better medicines more economically (see **Figure 7**). Even incremental improvements could yield significant savings. We estimate that, given average development costs and lead times, a 5% increase in success rates for each phase transition and a 5% reduction in development times

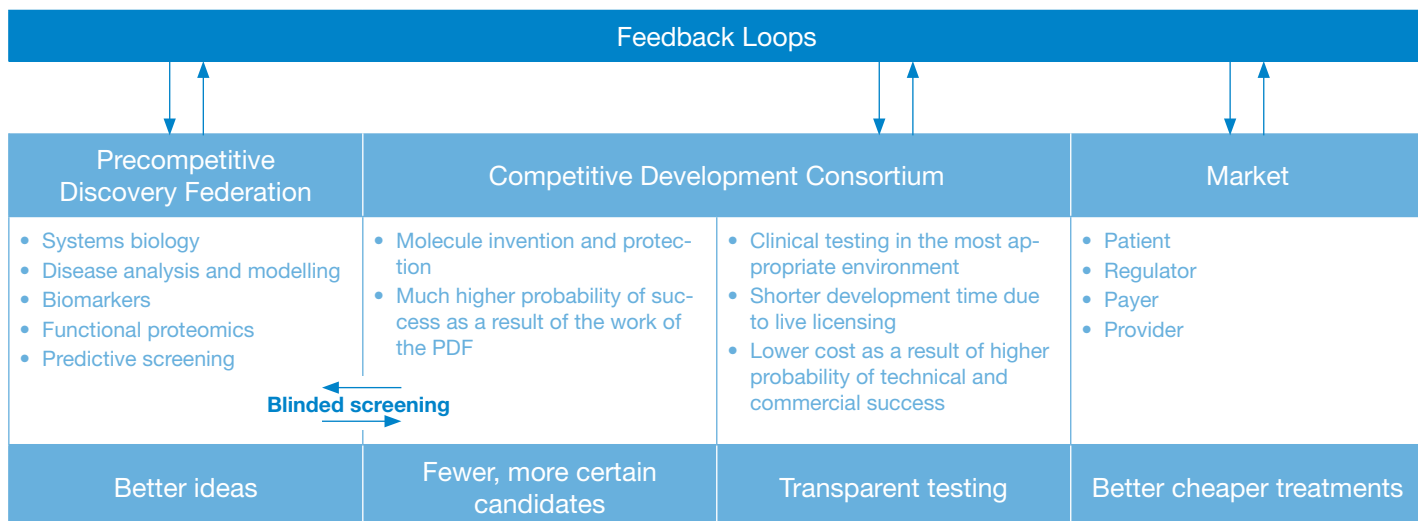
would cut R&D costs by about \$160m, as well as accelerating market launch by nearly five months. In fact, a 5% improvement in phase transition rates alone would trim about \$111m from the tab.<sup>46</sup>

However, the participants would profit individually, too. We envisage that the largest biopharmaceutical companies will be responsible for coordinating and funding the federations and consortia in which they participate. They'll also draw on their huge compound libraries to develop new molecules and shepherd them through the regulatory evaluation process to the marketplace. Meanwhile, smaller biopharmaceutical companies, research institutes and academic

medical centres will be responsible for generating original ideas and providing disease biology and platform technologies on a fee-for-service basis.

The biggest companies will thus benefit by getting access to more innovation, cutting their costs and becoming more productive – improvements that will help them fend off criticism from healthcare payers and patients angered by the high prices of many new medicines. Meanwhile, the smaller ones will get more stable, long-term financing, better opportunities for benchmarking the value of their own contributions and access to critical regulatory and marketing skills.

**Figure 7: Greater collaboration will help everyone**



Source: PricewaterhouseCoopers

## Chain links

We've focused on R&D so far, but greater collaboration will be required in the rest of the value chain, too – and any company that masters the art of working closely with other R&D organisations will have a head start over its competitors because it will be able to apply the lessons it's learned to the other parts of its business. Take commercialisation. Most treatments perform much better in clinical trials than they do in everyday life, and healthcare payers almost everywhere are demanding more for their money. The opportunities for generating value from standalone products are therefore getting smaller.

That means biopharmaceutical companies will have to switch from selling medicines to managing outcomes. They'll have to bundle different products together and supplement their therapies with health management services like compliance monitoring, dietary guidance and fitness regimes. However, most companies won't be able to create packages of branded medicines and generics for different conditions singlehandedly, so they'll have to collaborate with rival manufacturers. And few, if any, companies will be able to deliver all the services patients need, so they'll have to collaborate with numerous other organisations, including hospitals, clinics, technology vendors and lifestyle service providers.<sup>47</sup>

The shift from product provider to outcomes manager has yet more consequences. Information will become as important a part of the sales proposition as the products themselves, and much of the information that's generated will come from external sources. In effect, each biopharmaceutical company will need to create its own information supply chain and manage it as carefully as it does manufacturing and distribution.

The changes taking place in the traditional supply chain have similar implications. Biologics are much more difficult to make and move around than small molecules because they're more susceptible to impurities in the production process and more vulnerable to damage during shipping. And since most such therapies can't be taken orally, new delivery devices – e.g., micro needles, magnetically targeted carriers, nano-particles and polymer capsules – are being developed. But these devices are also hard to manufacture.

The industry will therefore have to collaborate much more extensively, both with contract manufacturers capable of making biologics and complex devices, and with specialist carriers capable of transporting sensitive pharmaceutical freight in cold-chain conditions. If it's to capitalise on the increasing prosperity of the emerging markets, it will also have to build a much more geographically dispersed supply chain – and it will only be able to do this by joining forces with local manufacturers and service providers.

## Making the sums add up

The English philosopher Thomas Hobbes famously described life in the 17th century as 'nasty, brutish and short'.<sup>48</sup> Healthcare has come a long way since then; life expectancy at birth is now at least 75 years in large swathes of the world, compared with 35-40 years when Hobbes was writing his *Leviathan*.<sup>49</sup> But greater longevity brings new challenges, and few people can afford to pay many thousands of dollars for the most advanced treatments. Hard-pressed governments with a growing number of elderly citizens will be equally unable to foot the bill. So, if we're to make the most of the years we've gained, more effective, more economical medicines will be vital – and that entails collaboration between everyone concerned.

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Mr David Dally, CFO, Merlion Pharmaceuticals Pte Ltd.

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Ms Nandita Chandavarkar, Director, Association for Biotechnology Led Enterprises

Peter Keen, Non Executive Director, Ark Therapeutics

Ray Spencer, Founder & CFO, Saturn BioSciences Ltd; Founder & Director, MGB Biopharma Ltd

Rob Arnold, Chairman, Clasemont Limited (& former PwC Life Sciences Partner)

Sam Smart, Independent Consultant

Dr Vijay Chandru, President, Association for Biotechnology Led Enterprises.

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# Territory contacts

## Argentina

Diego Niebuhr  
[54] 11 4850 4705

## Australia

John Canning  
[61] 2 826 66410

## Belgium

Thierry Vanwelkenhuyzen  
[32] 2 710 7422

## Brazil (SOACAT)

Luis Madasi  
[55] 11 3674 1520

## Canada

Gord Jans  
[1] 905 897 4527

## Czech Republic

Radmila Fortova  
[420] 2 5115 2521

## Denmark

Torben TOJ Jensen  
[45] 3 945 9243

Erik Todbjerg  
[45] 3 945 9433

## Finland

Janne Rajalahti  
[358] 3 3138 8016

## France

Anne-Christine Marie  
[33] 1 56 57 13 42

## Germany

Georg Kämpfer  
[49] 69 9585 1333

Martin Schloh  
[49] 89 5790 5102

## India

Sujay Shetty  
[91] 22 6669 1305

## Ireland

John M Kelly  
[353] 1 792 6307

Enda McDonagh  
[353] 1 792 8728

## Israel

Assaf Shemer  
[972] 3 795 4681

## Italy

Massimo Dal Lago  
[39] 045 8002561

## Japan

Kenichiro Abe  
[81] 80 3158 5929

## Luxembourg

Laurent Probst  
[352] 0 494 848 2522

## Mexico

Jorge Luis Hernández Baptista  
[52] 55 5263 6106

## Netherlands

Arwin van der Linden  
[31] 20 5684712

## Poland

Mariusz Ignatowicz  
[48] 22 523 4795

## Portugal

Ana Lopes  
[351] 213 599 159

## Russia

Alina Lavrentieva  
[7] 495 967 6250

## Singapore

Abhijit Ghosh  
[65] 6236 3888

## South Africa

Denis von Hoesslin  
[27] 117 974 285

## Spain

Rafael Rodríguez Alonso  
[34] 91 568 4287

## Sweden

Mikael Scheja  
[46] 8 555 33 038

## Switzerland

Clive Bellingham  
[41] 58 792 2822

Peter Kartscher  
[41] 58 792 5630

Markus Prinzen  
[41] 58 792 5310

## Turkey

Zeki Gunduz  
[90] 212 326 64 100

## United Kingdom

Andrew Packman  
[44] 1895 522104

Kate Moss  
[44] 20 7804 2268

## United States

Michael Swanick  
[1] 267 330 6060

# For further information, please contact:

## Global

### Simon Friend

Partner, Global Pharmaceutical and Life Sciences  
Industry Leader  
PricewaterhouseCoopers (UK)  
simon.d.friend@uk.pwc.com  
[44] 20 7213 4875

### Steve Arlington

Partner, Global Pharmaceutical and Life Sciences Advisory  
Services Leader  
PricewaterhouseCoopers (UK)  
steve.arlington@uk.pwc.com  
[44] 20 7804 3997

### Michael Swanick

Partner, Global Pharmaceutical and Life Sciences  
Tax Services Leader  
PricewaterhouseCoopers (US)  
michael.f.swanick@us.pwc.com  
[1] 267 330 6060

## United States

### Doug Strang

Partner, US Pharmaceutical and Life Sciences Advisory  
Services Leader  
PricewaterhouseCoopers (US)  
douglas.s.strang@us.pwc.com  
[1] 267 330 3045

## Middle East

### Sally Jeffery

Partner, Healthcare Advisory Services, Middle East  
PricewaterhouseCoopers (United Arab Emirates)  
sally.jeffery@ae.pwc.com  
[971] 4 304 3154

## Europe

### Jo Pisani

Partner, Pharmaceuticals and Life Sciences, Strategy  
PricewaterhouseCoopers (UK)  
jo.pisani@uk.pwc.com  
[44] 20 7804 3744

### Sandy Johnston

Partner, European Pharmaceutical and Life Sciences  
Advisory Services  
PricewaterhouseCoopers (UK)  
sandy.johnston@uk.pwc.com  
[44] 20 7213 1952

## Asia Pacific

### Sujay Shetty

Director, Pharmaceutical and Life Sciences  
Advisory Services, India  
PricewaterhouseCoopers (India)  
sujay.shetty@in.pwc.com  
[91] 22 6669 1305

### Beatrijs Van Liedekerke

Director, Pharmaceutical and Life Sciences  
Advisory Services  
PricewaterhouseCoopers (Singapore)  
beatrijs.vanliedekerke@sg.pwc.com  
[65] 6236 4322

## Marketing

### Attila Karacsony

Director, Global Pharmaceutical and Life Sciences  
PricewaterhouseCoopers (US)  
attila.karacsony@us.pwc.com  
[1] 973 236 5640

### Marina Bello Valcarce

Global Pharmaceutical and Life Sciences  
PricewaterhouseCoopers (UK)  
marina.bello.valcarce@uk.pwc.com  
[44] 20 7212 8642



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