

PUBLIC-PRIVATE PARTNERSHIPS: A RECIPE FOR SUCCESS?

The global financial crisis has beaten down science budgets everywhere. So it's no surprise that science-spending forecasts for Europe are grim. The EU's gross domestic product shrank by 2.5 percent this year. Consequently, politicians might cut science budgets to plug other shortfalls. In Italy, for example, Prime Minister Silvio Berlusconi's center-right government already has cut university budgets by 10 percent and has allowed them to fill only one in five vacant academic positions. Amidst the gloom over potential cutbacks, however, there are a few bright spots. **By Gunjan Sinha**

On the European Union level, science budget cuts are unlikely. The framework through which the EU funds research—Framework Programme 7 (FP7)—is dedicated money. Member states are legally committed to the €51 billion budget through 2013. Perhaps more important, FP7 initiatives that aim to stimulate economies are finally getting off the ground.

This spring the European Commission (EC) announced the first 15 research projects that will receive funding as part of the Innovative Medicines Initiative (IMI)—a unique public-private partnership that brings together large biopharmaceutical companies, small- and medium-sized enterprises, patient organizations, academia, hospitals, and public authorities to work through bottlenecks in developing new drugs.

IMI is one of six Joint Technology Initiatives (JTIs). Through this scheme, industry must at least match money offered by the EC in six predefined areas. A JTI focuses on one specific industrial area, aims to develop new precompetitive technologies, addresses a market failure, and is funded by a combination of private and public investment.

The other JTIs are: Aeronautics and Air Transport (or Clean Sky); Embedded Computing Systems; Nanoelectronics Technologies 2020; Global Monitoring for Environment and Security; and Hydrogen and Fuel Cells.

“This might really be an important change in the way that the EU funds research projects,” says **Peter Tindemans**, a Euroscience spokesperson who runs a consulting company that issues advice on science policy. “JTIs are focusing on key areas that present problems for all EU countries, and they’ve created a new system whereby the players themselves are responsible for funding the science that needs to be done.”

So great is the enthusiasm over JTIs that some member states have launched similar initiatives. In 2007, Spain set up the National Strategic Consortiums for Technological Research (CENIT) program that makes €750 million available to companies that at least match government funding. The same year, Germany launched a Pharmaceuticals Initiative which aims to distribute €800 million in public funds over *continued »*



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“The more data you have, especially when it is generated by different groups, the more sure you can be of your results.”
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five years through measures that aim to boost pharmaceutical and biotechnological research and development in Germany.

Through such measures, nations hope not only to boost their economies in the short term, but also to foster relationships that will ensure companies continue to invest within their borders in the future.

New Medicines Needed

Fostering long-term relationships is part of IMI’s goal, too. Because rather than funding the development of new medicines, the IMI aims to pool scientific expertise to create better methods and tools that streamline the drug development process.

For example, among the first 15 projects selected for funding is one involving 12 academic institutions and 10 different companies that aims to find biological markers of chronic pain. Called EUROPAIN, the project will comprise six programs of research and has an estimated budget of at least €12.5 million through 2013. Two of the research programs will try to identify novel pain mediators and elucidate nervous system changes that contribute to pain. They will also refine ways to measure pain. Three programs will explore human pain mechanisms; one program will develop ways to integrate data from all five programs.

“The problem in pain management is that we are limited to very few classes of drugs,” says Märta Sörgerdahl, medical science director at AstraZeneca—the company that is coordinating EUROPAIN. Pain medication is effective in less than one in every three patients, she adds, and while that ratio is good for many diseases, it isn’t adequate for pain management because people suffer. “There is a great need for new drugs,” she says.

And while many academic groups involved in the consortium have worked together and worked with industry before, this consortium offers the opportunity and the resources for academia and industry to work together to generate data more quickly. For example, industry and academia will jointly develop guidelines on how specific experiments should be done. These in turn can be used by all members in the consortium to conduct future research. “The more data you have, especially when it is

generated by different groups, the more sure you can be of your results,” Sörgerdahl says. Each consortium member can then take any tools or technology developed by EUROPAIN and use it internally or with collaborators to develop proprietary drugs.

The US Comparison

IMI is similar to the US Food and Drug Administration’s (FDA) Critical Path Initiative launched in 2004. However, they rely on different paths to improve drug development. FDA initiated Critical Path, but the program has no established structure nor does it have significant funding. By contrast, IMI aims to have its own governing body and will administer its own calls for funding—plus its budget is upward of €2 billion over five years.

Companies point to positive experiences with the Critical Path Initiative as proof that such collaboration can produce results. Responding to Critical Path, Novartis spearheaded three cooperative research projects in 2004, one of which was a precursor to an IMI project for which the company has also been selected to receive EU grant money. In one of those earlier efforts, in collaboration with Merck, Novartis focused on drug-induced kidney toxicity. The goal was to identify and validate biomarkers that can flag early insult to the kidney—before the organ’s pathology has changed. Company scientists were also looking for markers that would specifically identify which part of the kidney was affected. Both companies had already identified nephrotoxicity biomarkers, but they needed to validate them. Ultimately both ran antibody-based assays on two different platforms to correlate and confirm each other’s results.

The results were later folded into the Critical Path Initiative’s Predictive Safety Testing Consortium, officially established in 2006, that enables member companies to share internally developed laboratory methods to predict the safety of new treatments before they are tested in humans. Critical Path scientists acted as neutral arbiters so that other consortium members, which included 16 companies in total, could cross-validate Novartis’s and Merck’s results.

“It sounds pretty simple, but it was extremely complicated,” says Jacky Vonderscher, former global head of biomarker development at Novartis. Vonderscher wasn’t just referring to the science. Sorting out intellectual property and data sharing issues ate up a lot of time. At one point there were 35 lawyers sitting around a table to negotiate the consortium contract, Vonderscher recalled—and this was regarding research that wasn’t yet competitive.

Organized to Avoid Bureaucracy

Indeed, such bureaucratic legal wrangling is one major gripe about JTIs. European scientists often complain about the amount of paperwork involved when working with EU grant money. But Sörgerdahl remains unconcerned. “Most of the major pharmaceutical companies are involved with EUROPAIN including GlaxoSmithKline, Pfizer, sanofi-aventis, and Eli Lilly and Company. These companies have in-house expertise that is accustomed to streamlining bureaucracy *continued »*

Focus on Europe

and organizing research,” she says. “We all want to work efficiently,” Sörgerdahl continues. “I’m confident this is going to work.”

Certainly the projects funded by IMI won’t be alone in this regard. But this is precisely why each JTI will have its own governing body, independent of the EC, say organizers. “My intent is to make it reactive, flexible, and involved,” says **Eric Dautriat**, executive director of the Clean Sky Initiative. Dautriat is in the process of recruiting about 20 people who will comprise the Clean Sky Joint Undertaking—an entity that will manage the program. “There is no reason why we should be smothered by bureaucracy,” he adds.

Clean Sky’s mission is to develop environmentally friendly aircraft. Without a financial boost from the EU, green aircraft technologies would not develop quickly, says Dautriat, because there isn’t enough market pressure right now. But Clean Sky gives companies a structure through which they can collaborate to develop mutually beneficial technologies.

So, for example, one project seeks to develop an open rotor—a propeller design that can potentially burn up to 30 percent less fuel compared to current engines as well as reduce

emissions and noise. Different companies are taking their own tack to achieve the same goal. Chichester, England–based Rolls Royce, and Snecma of Courcouronnes, France, are focusing on direct-drive turboprops with slightly different designs; in parallel Munich-based MTU Aero Engines in collaboration with Pratt & Whitney is preparing a demonstration of a geared turboprop. Each of these different solutions will be evaluated and compared with one another. All European companies involved in civil aviation are participating in Clean Sky and there are a total of 86 members, in addition to which hundreds of partners will be added through calls for research proposals.

“Clean Sky embraces all sectors of commercial aviation and combines the strengths of all stakeholders,” says Dautriat. “This is already a significant achievement.”

Spain On Board

JTIs have the potential to garner so much private investment that EU member countries have adopted similar programs to boost each nation’s research productivity. For example, in 2007, Spain launched Ingenio 2010—a series of measures aimed to boost the nation’s research and development spending from a low of 1.13 percent of gross domestic product to be more on par with the EU average of 1.77 percent.

One arm of the program, CENIT, offers grant money to research consortiums that in turn at least match the amount of government money. It makes €750 million in public money available over four years to research consortiums that aim to pursue projects in predefined areas including biomedical sciences, information technology, and renewable energies.

Similar to IMI, one project aims to design new methods to better predict toxicity of new molecular entities to speed up preclinical research. “The organizers noticed that they had the potential to tap our expertise on hepatic cells,” explains **Joan Guinovart**, head of the project at Barcelona’s Institute for Research in Biomedicine (IRB). The IRB is one of nine academic institutions collaborating on the project together with eight companies. Called MELIUS, the project was spearheaded by Madrid-based Noscira and is operating with a total budget of €20.5 million over five years.

The benefits of such collaboration flow both ways. “We have explored avenues that we otherwise would not have explored,” says Guinovart. Working with molecules that inhibit specific pathways, for example, has revealed that they don’t always exert an effect in predictable ways, he explains. “We have learned to be more cautious and keep an open mind.” Moreover, the MELIUS project has fostered a relationship between Guinovart’s research group and the companies involved; they are presently discussing collaborating on projects outside of MELIUS.

Germany Boosts Pharma R&D

It was with these same goals in mind that Germany launched the Pharmaceuticals Initiative in 2007. Unlike Spain, where pharmaceutical and biotechnology investment represent a small slice of the economy, Germany is home to the largest number of biotechnology companies in the EU. *continued »*



Featured Participants

AstraZeneca
www.astrazeneca.com

Clean Sky
www.cleansky.eu

European Commission
ec.europa.eu/index_en.htm

Euroscience
www.euroscience.org

German Federal Ministry of Education and Research
www.bmbf.de/en

Innovative Medicines Initiative
www.imi.europa.eu

Institute for Research in Biomedicine
www.irbbarcelona.org/index.php/en

Max Planck
www.mpg.de/english/portal/index.html

Merck
www.merck.com

National Strategic Consortiums for Technological Research
www.transport-research.info/web/programmes/programme_details.cfm?ID36682

Novartis
www.novartis.com

US Food and Drug Administration
www.fda.gov

Focus on Europe

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Yet hardly any therapeutics developed by biotech companies originate from Germany today, says **Benedikt Wolbeck**, a spokesperson for the German Federal Ministry of Education and Research (BMBF). The record for German pharmaceutical companies is almost as grim. Even though Germany is home to several such companies, a survey by the European Commission revealed that German pharmaceutical companies had developed only six of the 140 active substances licensed in 2005 in the EU. While German companies may carry out early research, most market innovations are generated in the USA, the UK, and Switzerland, Wolbeck adds.

To promote technology transfer at home, the Pharmaceuticals Initiative is dedicating over €800 million through 2011 to promote pharmaceutical and biotechnology research. Although the funds will finance both basic and application-oriented measures, the way in which the funds will be doled out is part of a new strategy to focus on strengthening the pipeline from research to market. And unlike JTIs or Spain’s CENIT, matching funds from industry aren’t a requirement. Rather, the BMBF has created other structures through which industry can contribute, such as investment funds.

One measure, called the BioPharma Competition, selected three projects out of 37 to receive a total of €100 million over five years, beginning this year. One winner is the Max Planck Drug Discovery & Development Center in Dortmund. The center will pool the most promising research on new compounds from all 12 Max Planck Institutes and come up with a strategy to further develop them. This includes technology licensing deals and handling decisions to conduct further research by taking compounds through phase IIa clinical trials to make them more attractive to industry. To finance the BioPharma projects, BMBF has created a fund that will be managed by London-based Inventive Capital Advisor, LLP. Companies will have the opportunity to invest in research by contributing to the fund or by contributing money to specific projects.

Another winner, the Neuroallianz consortium, consists of 12 partners that aim to bring research on new treatments and diagnostic tests for neurodegenerative diseases to the market. The third winner will focus on multiple sclerosis, specifically on moving basic research on therapies and diagnostic tools to market.

The BioPharma Competition is just one part of a package of measures. The remaining €700 million will be spent on various other measures to support clinical research, molecular diagnostics, and research on technology that can speed up drug development.

Through such initiatives, “we are unlikely to become *the* world’s pharmacist in the long term,” said BMBF State Secretary Frieder Meyer-Krahmer during the BioPharma award ceremony in Berlin, “but we should at least be *one of* the world’s pharmacists.”

Other Benefits

Certainly the idea to offer incentives to the private sector to invest within a nation’s borders is a time-tested method to create jobs and grow economies. But such incentives often take the form of tax-breaks, reimbursement of capital expenditure, or other types of financial benefits. Offering public money to the private sector in ways that encourage development in specific areas represents a paradigm shift: profit and job growth are no longer the only end-points.

“As a publicly funded scientist I have a moral obligation to contribute to the industry of the country,” says Guinovart, who spends most of his time involved in basic research. But collaboration with industry gives him the opportunity to generate more concrete results. “I feel like I am returning something to society,” he says.

Moreover, the results of such focused research can potentially benefit everyone. “Each JTI is very specific,” comments **Catharine Ray**, spokesperson for science and research at the European Commission. “Each of them has an application in a strategic field and should allow a quicker commercialization of truly break-through technologies.”

At the EU level, public-private research collaborations are also supported by the Cooperation program, part of FP7. But many European scientists complain that project grants are often barely enough to cover costs. By contrast, JTIs leave open the possibility of higher investments from industry with fewer restrictions on how the funds should be spent. Industry partners in the EUROPAIN project, for example, are contributing €7.5 million to the budget as compared to the EC’s €5 million, and are prepared to invest even more, says Sörgerdahl.

More important, adds Tindemans, JTIs should perhaps serve as a model for how to conduct public-private research collaborations in the future. “The EC should really move away from funding all of these small projects [supported under Cooperation],” says Tindemans. JTIs enable very large projects with all the major players involved. “This should be a focus of even more EU funding.”

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