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Plan cuts drug trial cost

Pharmaceutical companies could cut the costs of clinical trials if they rethought their approaches, according to a leading epidemiologist. His methods may be useful in other sectors, where assessing product quality and suitability depends on complex data collection and analysis.

Professor Rory Collins is British Heart Foundation professor of medicine and epidemiology at the University of Oxford's Clinical Trial Service Unit (CTSU). In October 2004 he won the €72 500 (£50 000) Pfizer Innovation Award for his work using large-scale randomised trials to investigate heart attacks, stroke, diabetes and cancer. The work is credited with helping avoid tens of thousands of premature deaths by revealing the value of aspirin and clot-busting drugs in treating heart attacks.

"There's no reason why costs shouldn't be reduced by at least an order of magnitude, by not trying to control everything, by collaborating and by thinking through the data collection and monitoring," Collins said.

Collins contrasts academic trials, funded by government or charity, with industrial trials, which can be over-controlled and make little use of academic input. CTSU tries to bridge the gap by proposing to study how a treatment works in many circumstances, and then persuading industry of the study's value.

"It brings academic value to study design, rather than using the academics as a front," Collins said.

"There's a lot of value to be had from a much truer form of collaboration in industrial studies in terms of the quality of the study, which draws on input from both sides. Academic studies can also pick up industrial funding in this way and industry can get collaborations to address important questions at much lower cost."

Drug trial

from p1

Collins says one trial he was involved with, of 20 000 people with a five-year follow-up, cost \$30m. An industrial trial of 15 000 people with three additional related studies of 1000 people each, again with a five-year follow-up, is costing \$800m.

He says industry could re-design trials to fit their purpose more closely, and should avoid creating large-scale trials by scaling up small-scale approaches.

“There’s a tendency to take a standard protocol and multiply it up,” he said. “If you’re looking at the effect on death and major outcomes such as heart attacks, then you don’t need to record blood pressure. If you want to know what happens to blood pressure, then measure it in a few hundred people in the trial. In CTSU’s cholesterol trial of 20 000 subjects, we only made [such] measurements in a random sample of 1000 people a year. We got better data and more information, with the appropriate statistical reliability, at less than a tenth of the cost [of industrial approaches].”

Collins advocates making trials as large as possible, to get clearer results more quickly and to make it easier to address clinical questions about sub-groups.

“If you design studies that can only just get an overall answer then they will be unreliable for sub-group analysis,” he said. “If you have much larger numbers than you need for an overall result, then you can show any differences in the overall direction of an effect in various groups of interest.”

This can act as an insurance policy, providing the tools to handle regulatory or clinical concerns and to deal with truly random effects that appear significant.

Collins says meta-analyses, where several studies of similar treatments are considered as a group, can also be useful.

“Looking at one trial in the context of the others should show if the signals reinforce,” he said. Collins believes it’s useful to apply meta-analyses to a class of drugs. “It exposes very quickly whether there is a real hazard. And it’s in the interests of the companies. They’re used to stressing the differences between their drug and others. But it’s actually useful to look at the similarities.”

Innovation insights

- Develop true academic collaborations that engage scientists in studies that have both academic and market interest
- Don’t create large trials by scaling up small-trial approaches
- Avoid gathering data that doesn’t serve your trial’s aims
- Don’t assume you have to gather each type of data for the entire trial population
- Trade off the amount of data gathered for more trial members, to produce more robust results that can also be analysed by sub-groups
- Find truly impartial champions who have the credibility to stand up for your trial results

R&D spending in Europe slides while other parts of the world forge ahead

The top 500 European investors in industrial R&D (the EU500) cut research spending by 2% in 2003 while their counterparts outside the region boosted theirs by 3.9%, according to the European Commission’s first Industrial R&D Investment Scoreboard.

Twelve of Europe’s top 25 investors in industrial R&D cut spending in 2003, four by 10% or more. Only four of the US’s top 25 investors in industrial R&D did the same, with only one cutting spending by 10% or more.

The EU’s shortfall looks like a long-term trend. EU500 companies have increased R&D spending by an average of just 1.2% a year over the past four years, while their non-EU500 competitors have boosted annual spending by an average of 3.7%.

European industrial R&D is being concentrated in

fewer hands, fewer sectors and fewer countries.

Within the EU, the top 20 companies account for 55% of spend. Outside the EU, the figure is 37%. Companies with their headquarters in Germany, France or the UK account for 74% of European R&D investment.

Globally, the four largest sectors in industrial R&D spending are: automobiles and parts; pharmaceuticals and biotechnology; IT hardware; and electronics and electrical equipment.

There are different strengths in each geographic region, with more large North American firms in the research-intensive sectors of IT and biotechnology.

Further reading
European Commission
Industrial Research
Investment Scoreboard
eu-iriscoreboard.jrc.es

How the top 500 R&D investors in the EU and beyond are spending their money

FTSE sector	Within EU		Outside the EU	
	Sector R&D investment as % of all sectors	R&D/sales ratio (%)	Sector R&D investment as % of all sectors	R&D/sales ratio (%)
Automobiles and parts	23.8	4.6	15.7	4.1
Pharmaceuticals and biotechnology	17.0	15.2	18.5	15.1
IT hardware	12.4	15.6	22.9	8.6
Electronic and electrical equipment	10.3	6.5	10.9	5.7
Chemicals	7.2	4.2	4.2	3.8
Aerospace and defence	6.8	8.0	2.1	2.7
Engineering and machinery	4.6	2.5	2.5	2.8
Telecommunication services	2.8	1.0	2.0	2.5
Software and computer services	2.6	12.8	7.8	10.0
Oil and gas	1.9	0.3	1.2	0.5
Others (21 sectors)	10.6	1.5	12.2	2.1
Total (31 sectors)	100	3.2	100	4.5

Country Profile - Ireland

Ireland is taking steps to increase the use of R&D within its industrial base and to attract research teams from overseas to boost its economy.

"We've all become convinced of the value of R&D," said Dick Kavanagh, managing director of the Irish Industrial Research and Development Group (IIRDG). "In 1992 industrial R&D was drawing €5m from the government. In 2004 it was drawing €55m as part of a national development plan to spend this much a year for the seven years between 2000 and 2006."

Kavanagh says Ireland's industrial R&D has grown 12 to 13% per year over the past 12 years. The number of companies involved in R&D has increased from 900 to 1400, though most are small. The IIRDG is backing a proposed R&D Action Plan that sets out to increase business investment in R&D from €916m, or 0.9% of GNP in 2004, to €2.5bn, or 1.7% of GNP, by 2010.

The Irish government wants to increase the number of companies doing R&D and to increase industrial R&D spending. It has a number of ways of doing this.

Development agency Enterprise Ireland has an R&D Awareness Initiative, which has introduced 150 local companies to R&D in the past two years. Enterprise Ireland also has a Research Technology and Innovation Scheme, which offers grant support. Expertise Ireland offers sources of academic expertise, engineers, consultant and suppliers to help.

The government introduced an R&D tax credit in 2004. But as it sets out to attract inward investment it needs to decide how much commitment multinationals should make to its economy, and who owns intellectual property generated by public-private

partnerships. Ireland has led the development of codes of conduct on these issues.

Tom McCarthy, chief executive of the Irish Management Institute, says there's been increasing investment in basic science and research in Ireland since 1998. This has been done through two routes: the Program for Research in Third Level Institutes (PRTLTI) and Science Foundation Ireland (SFI).

PRTLTI has allocated €605m over three funding cycles to improve higher-education strategies, programmes and infrastructure. Institutions have competed for money, with 10% of their assessments being based on their ability to collaborate.

SFI helps Ireland recruit and retain research groups. It is investing €646m between 2000 and 2006 in the research teams most likely to generate new knowledge, technologies and competitive enterprises in biotechnology and information and communications technology.

"We've paid the entry price and have now gone into serious investment in research," said McCarthy. The government has now appointed a chief scientific advisor to guide the commercialisation of R&D. McCarthy says the government is well aware of the importance of R&D: "The minister for enterprise, trade and employment has two key issues: research and links to China."

Further reading

Enterprise Ireland

www.enterprise-ireland.com/ResearchInnovate

Expertise Ireland

www.expertiseireland.ie

Program for Research in Third Level Institutes

www.hea.ie

Science Foundation Ireland

www.sfi.ie

Population	4m
GDP	\$116.2bn (2003 est)
GDP growth	1.4% (2003 est)
Labour force	1.871m (2003 est)
Number of companies in the EU500 #	4
Gross domestic expenditure on R&D *	\$1 304.3m (2001)
Gross domestic expenditure on R&D as %age of GDP *	1.13 (2001)
Total researchers *	8949 (2001)
Government budget appropriations or outlays for R&D *	\$387.5m (2001)

(Source: CIA World Factbook, * OECD Science and Technology Indicators, # 2004 EU Industrial R&D Investment Scoreboard)

IQ briefs

France looks to national champions

France should set up an Industrial Innovation Agency, funded with €1bn per year, to back up to 12 major industrial innovation programmes, according to a report produced for the French government by Jean-Louis Beffa, chairman and CEO of materials company Saint-Gobain.

Each programme should be backed with between €30m and €50m of public money for around five years, in a 50:50 joint venture with the private sector. These 'Mobilising Programmes for Industrial Innovation' could run for up to ten years.

The report recommends the approach to other European countries and reiterates the idea of a similarly structured European approach.

www.rapport-jeanlouisbeffa.com

IBM opens up patent access

IBM has decided to allow the innovations covered by 500 of its software patents to be used by anyone working on open-source software, a major shift in the way it manages and deploys its intellectual property (IP) portfolio.

"We will increasingly use patents to encourage and protect global innovation and interoperability through open standards and we urge others to do so as well," said Dr John Kelly, IBM senior vice president, technology and IP.

www.ibm.com



Combining skills to make an impact

Europe has an exciting innovation culture that has all the ingredients for excellence, says Walter Steinlin

I love living among the multicultural richness of Europe, where each nation, region and community offers its own particular skills, behaviours and virtues. Most parts of Europe have learnt to respect each other, to cohabit and even to cooperate. Yet few have learnt to integrate, to combine their skills, behaviours and virtues. Even in little Switzerland, where I live, people want to live together in peace and yet remain distinct. This outlook brings the many advantages of diversity, yet promotes inefficiency and inertia.

There's a striking resemblance here with the state of European innovation, which has all the ingredients for excellent innovation, from cutting-edge scientific knowledge and creativity to a great ability to understand customers. Yet still Europe remains reluctant to combine these skills to build businesses that can enrich us all.

Innovation is about combining things and skills to have an impact. It takes more than a seed to make a fruit tree: you need to find the right soil, plant the seed appropriately, water it correctly, prune it intelligently and look after its environment. To stretch the analogy, a brilliant biologist in Europe might find or even design a perfect seed yet never harvest any of its fruit.

Innovation also means being ready to abandon your original idea when you realise you have been lucky enough to find a market niche, but that your first approach is not the best way to serve it.

Things are not entirely black and white. I think small enterprises worldwide are inherently good at combining skills, which allows them to innovate successfully in small steps. Unfortunately such small enterprises are often bad at dealing with deeply disruptive changes in their environment.

Europe's larger enterprises are getting better at combining skills. Industrial R&D has improved immeasurably since the days when ideas were passed 'over the wall' from one department to the next. Nowadays such departments interact

strongly, with some having been integrated into one entity and others having learnt to complement their skills with those of other internal and external groups. My experience is that the first approach is fine for quick wins but eventually wears out. The second is most effective in the long run, and more robust in the face of disruptive change.

The key management issue is to give researchers ample room to explore new ideas, while also requiring them to work and suffer alongside real customers. Thoughtful research managers have learnt a lot over the years and EIRMA has contributed immensely, sorting the successful from the well-meant ideas, spreading useful experience and helping adapt it to different industries.

Where European innovation falls short is in its ability to combine skills to create start-ups that thrive and grow. The Europeans' deep-rooted habit of conserving their separateness has become a mental block that prevents them from combining their skills from scratch. Just as Switzerland is learning that in today's world certain virtues are only valuable in combination with others, European start-ups must learn to combine their key skills with the less interesting but equally important skills that make a business work. Fortunately, today's youth increasingly thinks and acts this way.

Europe has an immense richness of skills. I am deeply optimistic that our ability to innovate in large enterprises is good and that we are learning a particularly European way of combining our skills to innovate through start-ups. So we need not look jealously across the Atlantic or to the Far East for an innovation culture. We are already engaged in the deeply satisfying task of using our own efforts and our own learning to grow our own. ■

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Can research revitalise Japan's growth?

Japan has embraced competition from China but needs to restructure to make the most of its research strength, says Nobuo Tanaka



Japan's economy faces various challenges as it tries to return to a reasonable level of growth after the economic slowdown of the 1990s. Japan's near neighbour China is growing rapidly and providing strong competition in local and global markets. Japan's economy, like that of many other developed nations, needs to move up the value chain to maintain its edge. Structural issues, such as an inefficient service sector, an inflexible labour market and a declining population, must be overcome for Japan to grow again.

China's rapid economic growth, currently around 9% a year, was initially seen as a threat to Japan. China's entry into the markets for low-cost manufactured goods, and its rapid move to making more complex products, provided the impetus to restructure Japanese manufacturing for much greater efficiency. Now China is seen as both a source of low-cost goods and a huge market for Japan's production of everything from components to basic raw materials. China has also become part of the network of supply chains that Japan has developed across the Asean region.

Japan's government has responded to its economy's growing reliance on China and other Asian countries by signing bilateral trade agreements and sorting out legal and tax issues with countries such as Singapore and Thailand, in a bid to create what amounts to a free-trade zone. This is important. Some spectators now think that if China's economy fails, so will Japan's.

Japan's efforts to develop strong trading relationships with China while also moving up the value chain bring the issue of intellectual property (IP) protection into sharp relief. China's respect for IP has improved since it joined the World Trade Organisation, and foreign companies are developing the confidence to launch private prosecutions if necessary. Japan has also strengthened its IP regime by making it easier for customs officials to block the importation of counterfeit goods.

Improving IP protection is vital to encouraging Japan to do more research and to make better use of its results. The

Japanese government is investing public money researching topics such as nanotechnology and biotechnology. It is also making it easier to apply academic research, by opening technology transfer offices in universities and allowing professors to work as consultants for private companies. The issue of IP ownership remains clouded, though, and needs sorting out.

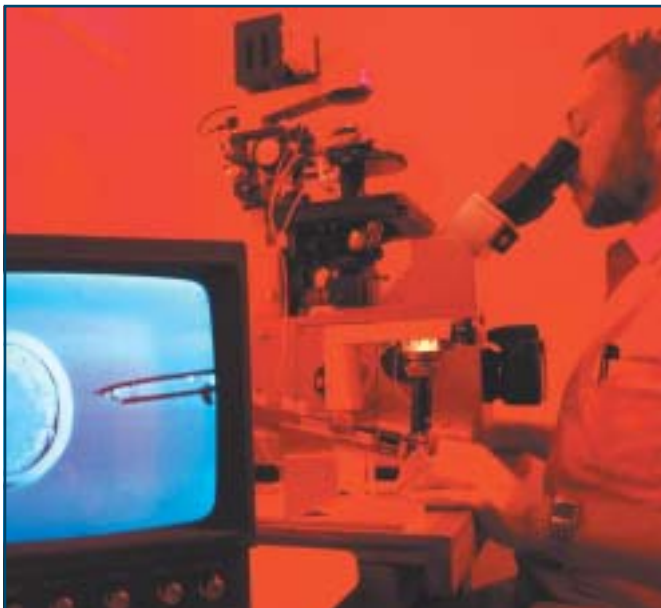
Good trade relations, fair IP protection and greater volumes of well-applied research can only help Japan regain its economic vitality if structural issues are also addressed. Japan is very good at making information technology products, but has yet to apply it aggressively enough to see the kind of improvements in service-sector efficiency that the Americans have enjoyed. Many service sectors are also over-regulated, protecting them from the competition that could improve their economic performance.

The labour force also needs to become more flexible, as a response to both deregulation and a declining population. Japan needs more of its women to go out to work, and needs to develop the infrastructure to enable this.

In the longer term, Japan must respond to the increasing importance of intellectual capital in a knowledge-driven global economy by making itself a more attractive place for the best minds to work.

A recent visit to Ireland has shown what a country can do to make itself attractive to knowledge workers, and although this small-country model cannot be applied to the whole of Japan, it could be applied to individual regions. Some regional governors have already recognised this and are taking steps to attract vital human capital. Perhaps people as much as policy will be the key to Japan's future. ■

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The public's relationship with science, particularly when carried out for commercial ends, is less trusting than it was. Researchers need to engage with public opinion, especially if their work raises ethical issues, in order to understand the concerns and inform the debate. This article describes some of the tools that can be used for engaging with public opinion and addressing ethical concerns. It also highlights the importance of engaging with public opinion as part of a positive move towards Open Innovation.

Public opinion represents a growing force in industrial research. The public's trust in scientists, spawned when science meant academics satisfying their curiosity in university labs, has fallen away as the divide between pure research and commercial exploitation has blurred. The methods and motives of scientists are under increasing public scrutiny, and companies need to understand and engage with the issue if they want to avoid private research successes becoming public-relations disasters.

If researchers can recognise and engage with the public's concerns, they may be able to learn from the public and shape attitudes to emerging technologies. Nanotechnology, for example, is at a similar stage in research terms as biotechnology was in the late 1970s and early 1980s, with its final form and applicability yet to be fully understood. Researchers still have time to influence how nanotechnology will be perceived: as threatening 'grey goo', or the next step in mankind's mastery of materials.

Getting engaged

Public engagement with science is nothing new: academics and governments have been promoting the 'public understanding of science' for years. But its initial basis, as a 'mission to inform', is now seen as outmoded.

"Putting out a lot of information about what you're doing

Is it time to get engaged?

Public opinion is increasingly important in shaping the research environment. Luke Collins find out how to tap into it

isn't the best way of engaging with people," said Ruth Chadwick, professor of bioethics and director of the Centre for Economic and Social Aspects of Genomics (CESAGen) at the University of Lancaster.

"Sometimes when researchers are asked to explain their science, it can become too much of a lecture. They should think about listening as well as informing. Public engagement needs to be about dialogue."

Analysts at the independent think-tank Demos agree. In a September 2004 paper called *See-through Science*, they argue that the problem with the 'public understanding of science' approach is that it assumes the public is ignorant and that science is unchanging and universally comprehensible. This makes it harder to generate a real dialogue, and for scientists to recognise that they might learn from working with the public. In disease research, for example, those who suffer from a disease often have an expertise about living with it that scientists could gain from.

Once companies recognise that their engagement with the public should be more dialogue than lecture, the next step is to understand when to start. Demos believes few organisations engage with public opinion during their research, preferring to have the work finished and legally protected first. But this can lead to nasty surprises.

"We have done research on tuning in to social intelligence, trying to pick up currents of concerns that might be out there that researchers weren't expecting, such as with BSE and GM foods," said Chadwick. "People need to do some of this tuning in, and they should try to do this at an early stage rather than getting to the end of the research and then trying to explain it to the public."

This 'upstream engagement' is now regarded as a better way of working with the public than simply trying to develop the public understanding of science or engaging in a dialogue after research is finished. It's also appropriate in a world of

increasingly sophisticated consumers who want more influence over the products they are offered.

Tooling up

So how do you engage with public opinion? There is a variety of well proven techniques available, each with its own utility (see box overleaf).

“One thing you can do is establish a ‘learning circle’, a panel of people you engage with at the beginning of a research programme and then bring back to see if their views have changed,” said Chadwick.

The UK’s Advisory Committee for Novel Foods and Processes, of which Chadwick is a member, holds open meetings that use case studies as a way of sharing information. But companies need to take care that such meetings represent public opinion.

“There’s no such thing as ‘the public’ for meetings like that, where you tend to get people who are committed in some way. It’s useful to try and get the views of people who aren’t involved in those groups,” said Chadwick. She says this can be achieved by forming panels drawn from the general public to give their views.

Professor John Harris, the Sir David Alliance Professor of Bioethics at the University of Manchester and coordinator of the FP5 EuroStem project on the ethics of stem cell research, also believes in the value of engaging with both public and stakeholder opinion. He was recently invited by a large pharmaceutical company to a private conference on human reproduction. The company wants to bring its scientists

together with people such as Harris to see what they think about emerging technologies, such as creating synthetic gametes made from egg and sperm derived from stem cells.

“You might find that staging a day to talk about a technology or product that might have a public impact is worthwhile. Invite some people and see what they say.”

The ethical dimension

Many of the most difficult issues in science have an ethical dimension, which researchers may not be trained or practised in considering. Fortunately, there are tools for handling these issues. One of them is the Ethical Matrix (see box), a way of relating a decision to basic ethical principles and the interest groups it might affect.

Harris recommends applying the basic tools of the humanities: “reading, writing and thinking”.

He says researchers should read widely about an issue of public concern, such as human cloning, and then try to decide whether the ethical issues have been correctly identified and if the responses are adequate. Researchers can look for consistency among the responses to see if a common truth emerges, and between the issue and related topics, for example whether the public’s attitudes to human cloning are matched by its attitudes to natural identical twins.

Researchers can also use empirical evidence to test assertions, consider the quality of the evidence for such assertions and ask ‘what if’ questions. In the cloning debate, for example, it makes sense to ask what the uptake of cloning would be if it were possible. ▶

Understanding the Ethical Matrix – in theory and in practice

The Ethical Matrix is based on three principles: respect for wellbeing, autonomy and justice. These principles provide reference points that can help identify and test assumptions, and help understand the impact of factual uncertainty.

The principles form the columns of the Matrix. The rows describe an issue’s interest groups, which in this food production example could include consumers, animals or the environment. Each cell specifies the criterion that would be met if a principle (such as justice) were respected for an interest group (such as animals).

The Ethical Matrix offers a checklist of concerns based on established ethical theory. It can also provoke structured discussion, helping decision-makers by enabling them to put themselves in the place of others.

Respect for	Wellbeing (Health & welfare)	Autonomy (Freedom of choice)	Justice (Fairness)
People in the food industry	Income and working conditions	Freedom of action	Fair trade laws and practices
Citizens	Food safety and quality of life	Democratic, informed choice	Availability of affordable food
Farm animals	Animal welfare	Behavioural freedom	Intrinsic value
The living environment	Conservation	Maintenance of biodiversity	Sustainability

The Ethical Matrix’s strengths are that it:

- does not make users follow one ethical theory or prioritise one principle
- focuses deliberation onto key concerns
- makes abstract principles concrete
- highlights the implications of a decision for each interest group
- helps find a solution to conflicts, rather than giving a false sense of consensus

"It's revealing to see what questions are implicit and what questions are being begged," Harris said.

Ethical issues are likely to be among the most difficult problems that a researcher's work will throw up. Although there are tools for considering these issues, both Chadwick and Harris advocate using professionals. Harris said: "I wouldn't try to be an industrial chemist. These things require training. In the same way that you would call a lawyer to have a contract analysed, you might need to call a philosopher to have the ethics analysed."

Harris says companies should think about employing ethicists, especially in fields where there is continuing controversy. Ethics committees can approve particular research protocols, or an ethicist can be retained to form the nucleus of an ethics board.

Selling the benefits

It takes time, money and effort for researchers to start a dialogue with public opinion about their work. The process may be complicated by intellectual property and commercial confidentiality issues. So why do it?

The least positive way of looking at public engagement is

as a way of forestalling the development of public anxiety. A more positive way of looking at this is as a form of open innovation, in which you gather ideas and inputs from as wide a front as you can.

Since the public is often the end consumer for the output of research, having your customer help shape its direction is likely to lead to greater uptake.

There's a third good reason for researchers to engage with public opinion: all research happens in a context set by politicians. Most politicians react to public opinion, which researchers can shape by diligent and continuing engagement with it. ■

Further reading

CESAGen www.cesagen.lancs.ac.uk/index.htm

Demos www.demos.co.uk

Ethical Matrix basics
www.nottingham.ac.uk/bioethics/theory_pages/matrix.htm

Ethical Matrix as applied to food issues
www.foodethicscouncil.org/tools/matrix/matrix.htm

EIRMA resources on ethics
www.eirma.asso.fr/ethicsinresearch

Tools and techniques for engaging with public opinion

Decide what you want from engaging with the public before choosing your tools. Consider:

- if you want a snapshot of public opinion or a dialogue
- what sort of group you want to work with
- whether you want to learn as much as you teach
- whether you expect to come to consensus or just to exchange views

Learning circles

Small groups discuss an emerging issue as your research starts. The same group is invited back later to see how their attitudes have changed.

Deliberative polling

A large, representative group has a debate, usually with the opportunity to cross-examine key players. The group is polled on the issue before and afterwards.

Focus groups

A representative group of eight to ten people is asked to discuss an issue, usually with a facilitator. The group is not asked to reach conclusions, but its discussion is studied.

Citizens' juries

A small group questions and evaluates presentations from experts on an issue, often over three to four days. The group is then asked to make recommendations.

Consensus conferences

A small group meets in private to decide the questions they want to raise. During a public phase the group interrogates expert witnesses, before writing a report.

The differences between a consensus conference, a citizens' jury

and a focus group are: how much time people have to understand the subject; how much initiative the group is allowed; whether the press and public is admitted; and cost.

Stakeholder dialogues

Processes that bring together affected and interested parties to discuss and negotiate about an issue. Stakeholders can range from individuals to interest groups.

Internet dialogues

This approach can collect many responses quickly, and these can be analysed using search engines. One drawback is that participants are likely to be self-selecting, and so may be unrepresentative.

Deliberative mapping

Citizens' panels and specialist panels meet and interact, enabling them to interrogate each others' views and knowledge, exposing assumptions on both sides.

Think about how you engage with the public:

- recognise the value of many forms of expertise
- avoid framing the debate as scientific expertise versus the public
- avoid giving the impression that you think that people's concerns are because they don't understand your work
- work out who is the right person to convey information and who will command trust
- when you know ethical issues exist, with different perspectives in different countries, take steps to ensure your approach is consistent and transparent

The midwife of wealth

The future of Western economies is in the hands of technology-transfer professionals, says the former head of NASDAQ

Alfred Berkeley, former head of NASDAQ, argues that the West will have to invent its way to a higher standard of living. Effective technology transfer from academic research is vital to this process, but the role of technology-transfer professionals is not yet recognised strongly enough. Companies, universities and national economies should structure themselves to form supply chains that enable this research to create wealth.

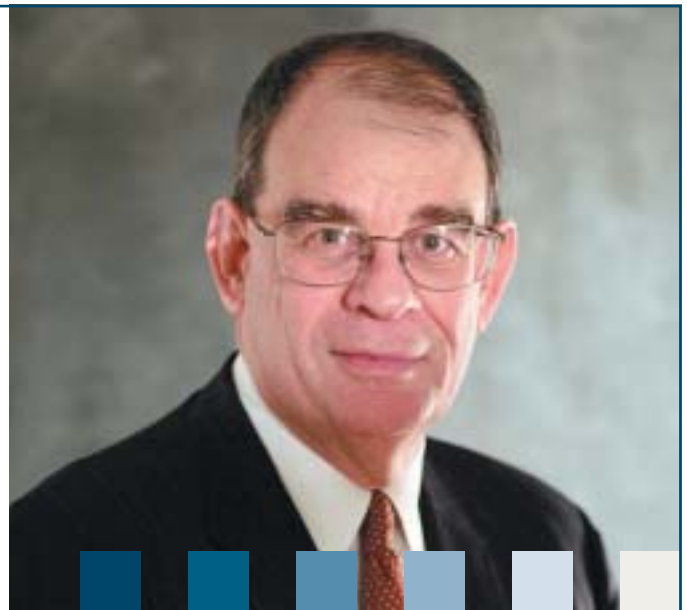
Western economies need to take the transfer of technology from academic research into industry more seriously if their standards of living are to keep on rising. That's the stark outlook of a leading American capitalist who has spent much of his career acting as midwife to the technology-led wealth creation process.

Alfred Berkeley helped fund Microsoft, Oracle and Computer Associates in his role as co-founder of the technology group at US investment bank Alex. Brown. The group, started in 1975, undertook approximately 500 financial offerings during his time there and became synonymous with funding high-technology companies. Berkeley left in 1996 to become president and later vice-chairman of NASDAQ, the US stock market most closely associated with the growth of America's technology-led economy.

Berkeley retired from NASDAQ in August 2003 and now has a portfolio of roles that focuses on making it easier to create wealth from good science and technology. He has become convinced that technology transfer is a vital part of this process.

"If you look at the basics of an economy, that is capital, labour and materials, we don't have a cost advantage on labour or materials. So I think the only way forward for the West is to invent its way to a higher standard of living," he said.

"The message is very simple, that technology transfer professionals are the boundary layer between invention and commercialisation and, like a catalytic converter, they can either increase or decrease the pace of wealth creation."



Berkeley has recently been addressing groups of technology-transfer professionals in the US and Europe, in a bid to help them realise their importance to national economies.

"I was trying to encourage them to think bigger about their role and what is possible, and to describe some win/win behaviours," he said, "such as marketing their products."

Berkeley makes the point that in the finance world, new products are backed up with legal filings and research documents, both of which are used as promotional tools. Technology transfer professionals should handle the innovations they are managing in the same way.

"You need to tell the story in an interesting way, talk about the promise and potential of the invention," he said. "You can't do this in the dry language of patent filings."

Encouraging the discipline

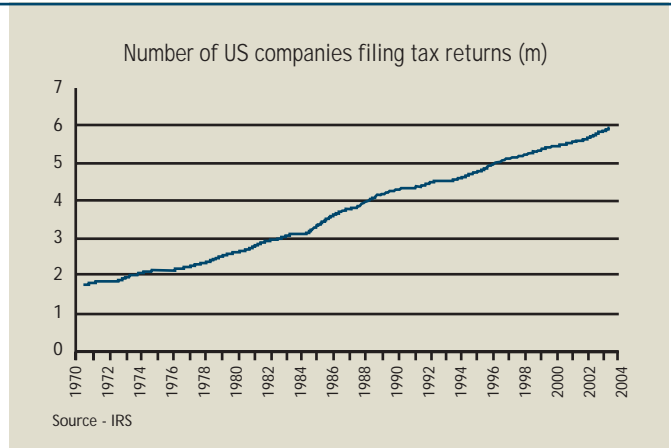
Berkeley believes that the discipline of enabling technology transfer from research organisations into industry is important and yet in its infancy. He draws a parallel with the software industry that he helped shape in the 1970s.

"This is like the software industry was 30 years ago – small and fragmented," he said. Turning it into the vital industry that it is today meant selling the benefits to an investment community that showed little initial interest.

"We did that by getting out and marketing the economic and investment value of the software industry to a group of people who had no idea of its worth," said Berkeley. He had to overcome objections from potential investors who were reluctant to invest because they felt that 'all the intellectual property walked out the door every evening'.

"But that's a naïve view," he said. "It's the nature of intellectual property."

The ideal technology transfer professional, therefore, is "someone with a sense of technology and a sense for a deal, an investment banker with an engineering degree".



Technology transfer is becoming increasingly important as global competition grows and developing nations enter the knowledge economy. Berkeley recognises this.

"History is not going to deny China and India the opportunity to grow, so we have to adjust to that, we have to compete," he said. "I'm just back from my fifth visit to India and you know, they're just like us. They are smart, ambitious and hard working. We'd be stupid to ignore that."

He believes that science and technology, and their transfer from lab to industry, are rapidly becoming the only competitive edge that Western economies are likely to retain in the mid term. Despite this, they are not taken as seriously as they should be in Western society.

"I do think that what is going on in technology transfer is very important but not well understood," said Berkeley. "In the US there's a kind of 'motherhood and apple pie' attitude to technology transfer, but no impetus to make sure it happens and happens right."

He says there should be rewards for those who do technology transfer properly, and celebrations for those who produced the inventions, did the deals and took the technology on and transformed it into wealth-creating businesses. Berkeley points out that plenty of Western parents will celebrate their children's athletic successes, "but how many take their kids out to celebrate good grades?"

"So it's partly about what we do as a society," he added. "There needs to be technology transfer so we can take inventions and raise them up into things that make people's lives better and improve their standard of living."

Intellectual property

One key sticking point in technology transfer, especially from academics, is ownership of the techniques and inventions developed with government funding. Some governments have centralised all technology exploitation through national organisations, with very mixed results. Some universities have claimed ownership of all academic intellectual property (IP), helping to defray the costs of protecting it but causing resentment among academics when the process is badly handled. The most successful have charted a middle course.

Berkeley says the US has handled the ownership of IP developed under government funding in several ways. Initially such IP was publicly owned. Although this was apparently fair, it meant industry showed little interest in commercialising such work because of the lack of exclusivity. "Something owned by everyone ended up being owned by no-one."

The Bayh-Dole Act of 1980 introduced a new model in which publicly funded IP could become private property by being transferred to individual academics or universities for development and commercialisation. This has prompted a blossoming in technology transfer from US universities.

"The learning from this is that property rights trump do-gooder feelings," said Berkeley. "If you want to raise the standard of living then you've got to give people some incentives."

"Something owned by everyone ended up being owned by no-one"

Berkeley says that the way each university shares the ownership of IP with the academics involved has to be handled pragmatically. He points to two prominent US examples: MIT and Stanford University.

Berkeley says MIT holds IP rights more closely to itself than Stanford, and yet has still enabled the creation of a ring of technology companies in the Boston area where MIT is based. Stanford, on the other hand, passes much ownership of the IP to its academics and yet is reputed to get substantial sums back in gifts and alumni contributions from successful entrepreneurs.

Whichever model is chosen, Berkeley wants research organisations to develop their technology transfer offices to help academic work find its way from the lab into industry. He wants such offices to have to compete with other commercialisation strategies for rights to the academics' work.

"Technology transfer offices need competition from the professors. They shouldn't be allowed to choke off licensing," he said. He also wants more incentives for those who work in technology transfer. "I wouldn't be opposed to technology transfer officers having a stake in the royalty streams they help create."

Getting IP ownership right is just one of the things Berkeley believes are necessary to enable good science to be turned into wealth. He uses a historical perspective on the US's approach to technology transfer to provide a guide for economies looking to improve their own outlooks.

Berkeley says one of the key underpinnings of US success with technology development has been a robust patent system, which provides the property rights that ensure that people who back a technology can protect their investments. The second major plank of the US's success is its history of government funding for research, especially through military spending.

Structural changes

A series of structural changes to the US economy throughout the 1970s and 1980s further improved conditions for emerging technologies. Berkeley says that the US had an anti-equity outlook at the start of the 1970s, following a stockmarket reversal. The US also taxed capital gains at up to 90% during the Second World War and at 50% thereafter. These high taxes made it hard to create a portfolio of investments in relatively risky emerging companies. If a portfolio of ten companies held two companies that failed, six which succeeded modestly and two that did very well, capital gains tax made it pointless to take the risk. The steady reduction of capital gains tax to 20% has helped reverse this position.

The next important step the US took was to allow pension funds to be judged on the performance of their entire portfolios. Prior to the Employee Retirement Income Security Act of 1974, pension funds' trustees were liable for the performance of all the companies they invested in and so were unable to back start-ups that might fail.

The introduction of the 401K pension legislation in 1981, which enabled individuals to save pre-tax income in an untaxed pension vehicle, also helped. Since most people didn't want to manage a portfolio of investments directly, mutual funds emerged to do it for them. This increased the pool of potential investors in the technology companies that venture capitalists were bringing to market.

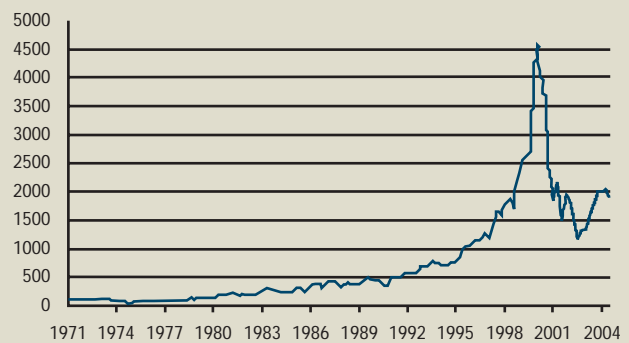
NASDAQ provided a market for these technology start-ups, by allowing companies that had yet to show profits to go public. This gave investors the right to make their own decisions about the value of risky start-ups, and a place to trade their stakes in such companies.

Berkeley says this sequence of structural changes to the US economy has helped create a supply chain linking innovative technologies to the investing public.

"It took the US out of the slow-growth, debt-oriented model it had in the early 1970s," he said. In contrast, Berkeley argues, European economies have a greater emphasis on risk-averse debt financing, rather than equity, because of the pump-priming exercise that followed the Second World War when major banks were given substantial sums to loan to businesses and equity capital was scarce.

Whether you agree with Berkeley's thesis or not, the US has

The NASDAQ Composite index since its launch



created a very successful mechanism for developing technology and transferring it into wealth-creating industries. Berkeley played a substantial enabling role in his time at Alex. Brown and NASDAQ, and is continuing to do so as president of Pipeline Trading Solutions, a new stock market designed as a neutral environment for investors and dealers.

"We're attacking a \$25bn information leakage [in the market] that is due to the way that traditional markets require you to show your hand before the trade. In game theory that's known as a win:lose game. We wanted to create a symmetrical market which provides a win:win game," said Berkeley. "The idea is to stop this inappropriate wealth transfer from true investors to speculators."

Berkeley's interest in enabling research and innovation has also led him to a role as chairman of the board of Community of Science, an online database that holds details of \$40bn of unawarded research grants and a database of research skills. Berkeley says that around half of the total is EU money.

"What we've done is created a dating service of money and research, a simple little market with \$40bn of money yet to be awarded," he said.

Berkeley has also recently been appointed chairman of the board of Collexis, a Dutch software development company that has invented a way to index and categorise millions of scientific articles so that users can do relevance-based searches.

"It's phenomenal technology," he said. He is now encouraging Collexis and Community of Science to explore whether they should be working together for mutual benefit.

This and a number of other roles make it seem likely that Berkeley will continue his role as midwife to the technology-led wealth creation process for some time to come. ■

Further reading

NASDAQ	www.nasdaq.com
Pipeline Trading Solutions	www.pipelinetrading.com
Community of Science	www.cos.com
Collexis	www.collexis.com

EIRMA and its European sister organisations are working to create a Responsible Partnering programme to bring to life the points that Berkeley makes, in ways that meet the needs of European societies. More at www.eirma.asso.fr



Many companies sense the need for radical changes in their research organisations to deliver better results more quickly, support new business models and take advantage of new approaches and competencies that external partners can offer. These opportunities also present risks, taking established groups into uncharted territories. This article discusses how some companies have tackled this issue, and highlights the importance of people and the sustained backing of the board to the introduction of radical changes in the R&D process.

How can businesses radically change the way they do research and development in order to keep ahead? It's an issue of particular concern for Europe's cast of mature industries, many of which are based on capital-intensive processes that are approaching the end of their innovation cycle. Their dilemma is that they need new ways to innovate, yet the scale of existing structures and investments make it risky to apply them.

Metso, a Finnish company specialising in paper machinery, minerals processing and automation, is meeting the issue head-on. According to Antti Niemi, manager of technology and innovation management, Metso faces three trends: a declining demand for heavy industry; increasing commoditisation; and a more rapidly changing market that makes forecasting difficult. Its response is to move from being an equipment and process supplier to providing a service throughout the lifecycle of new and installed equipment. Offering customers tools to improve and automate their processes gives Metso a way around declining sales opportunities. In addition, it shifts the focus of the company on to service.

Metso's R&D function is adapting to this new approach, learning how issues such as marketing, finance and service delivery can be brought together with product and process development to create new sources of value.

"You can imagine that customer relationship management

Changing up a gear in research

How do you make a major step forward in the way you do R&D?
Luke Collins finds out

is a huge issue in that," said Niemi. The research function must learn skills that underpin the business's lifecycle approach, and practise open innovation to draw in specialist knowledge from outside. As R&D changes from being largely technical, Metso is involving its business side in the process, using cross-functional project teams to draw the strands together.

"We have a good understanding of processes, but business dynamics is something our customers know much better," said Niemi. "Part of the knowledge can be in our open innovation partners, and part in marketing and the customer interface."

Finding common vision

Siemens faces its own innovation challenges: the size and scope of its operations, which spend €5.1bn on R&D each year, and the need for speed. According to Dietmar Theis, head of strategic marketing co-operation and media at Siemens, 80% of the company's sales in 2010 will be of products that have not yet entered development. With 45 000 R&D staff in Siemens, including 1700 in corporate technology, aligning their work with a common vision is vital.

One approach, adopted by many companies, is to make research more business oriented. For example, Siemens' corporate group stopped being solely funded from the centre in 1995, and now earns 58% of its funding from the business units and 7% externally. It has also introduced account managers to liaise with key business unit customers.

Despite this focus on customer needs, the corporate technology group maintains a role in identifying and providing technology drivers for the rest of Siemens. It runs a forecasting effort called *Pictures of the Future*, a database of trends in each of the company's key business areas. A permanent staff tracks trends in society, markets, customer behaviour and the structure of business and technology, refining the vision each year. This provides insight and a useful place to develop a common outlook.

This points out that this approach gives the company a long-term vision that supports major changes in the way that R&D is carried out. A strict focus on short-term business goals, in contrast, demands that companies stick with incremental innovation strategies regardless of whether they are effective in the long term.

Speciality chemicals company Degussa has established a separate unit, Creavis Technology and Innovation, to watch emerging technologies, manage ideas, handle new business development outside the company's current portfolio and to act as a project house with allied funding. Michael Droescher, senior vice president, corporate innovation management, said that if a number of business units become interested in a technology, experts can be gathered into a 'project house' inside Creavis, with its own space, budget and a three-year span. The team focuses on developing the technology for multiple end users, with exit options including a start-up, re-absorption into a business unit or development into a service centre.

Reinventing the wheel

Tyre company Pirelli reorganised its factories to reduce work in progress, in the process making links between R&D and end customers much shorter. Pirelli's modular, integrated and robotised system cuts the number of steps in the tyre-making process from 14 to three, reducing the lead time to make a tyre from six days to 72 minutes. The company has matched the gains achieved through introducing robots with improvements in its information technology, so R&D staff worldwide can design prototype tyres for customers (such as BMW) and have them ready for testing within a day.

Pirelli has created an environment in which R&D can flourish because of good tools, good access to corporate knowledge and short links between researchers and customers. But perhaps it is more than that. Dr Marco Spinetto, standards, legislation and project planning manager at Pirelli, said: "You need emotion in your company, people who love what they do and know how to break the rules in meetings. And you need to know how to manage and reward them."

In each of these examples, R&D managers have had to manage upwards, engaging with the business's top management to get the long-term support they need to enable major changes. As industries mature and opportunities to add value emerge as much from services as from manufacturing, R&D will become an even more central part of business strategy. Perhaps the most important thing R&D managers can do to enable major changes in the way they work is to persuade their boards of this fact. ■

Further reading

This feature is based on the output of a representatives' round table meeting, held in Nice in January 2005. For a full meeting record, go to www.eirma.asso.fr/newparadigms

Four ways to enable radical change in R&D

Shift from pure manufacturing to services
thinking about the lifecycle of your offering opens new areas for innovation

- embedded intelligence
 - design for maintenance and for the environment
 - materials
 - usability and user interface
 - service and performance packages
- develop matching innovation skills**
- greater emphasis on IT
 - new portfolio-planning and management techniques
 - business model innovation

Use automation to enable culture change

- automate processes in a way that also enables faster innovation
- develop tools that enable innovators to take advantage of automated processes to explore options
- develop project management in support of mass customisation
- integrate core competencies and knowledge around the process

Find new ways to reward innovators

- introduce a venture bonus plan, in which employees invest in their ideas and are rewarded on their performance as a business
- persuade senior managers to invest in the same way
- offer innovation prizes and prioritise those practising open innovation
- offer a "not invented here" prize, for ideas intelligently sourced from elsewhere

Use storytelling to build a common culture and vision

analyse future trends as a way to:

- gather competitive information
- develop a shared vision
- break down barriers within and outside the company
- plan for future needs such as staffing, skillsets
- engage management attention

Improving knowledge transfer

How responsible partnering can boost collaborative research

There is growing evidence that collaborations between companies and public research organisations (PROs) are becoming stronger. The forces that push companies towards open innovation are combining with the forces placed on universities to become market-oriented. In many cases, this is creating value for everyone involved.

It is important to develop approaches to these collaborations that are efficient and seen to be equitable (see *IQ Spring 2004*), to get the best out of them. The 'open science' approach to knowledge transfer, mediated by publication and informal co-operation, is commonplace, but cannot deal with all of today's realities. Purely commercial approaches, such as university-led licensing and spin-outs, are not universally successful and only address part of the requirement for better knowledge transfer. The real objective is to secure the connections that will ensure stronger scientific institutions, successful companies and well educated human talent.

Companies and PROs face practical difficulties in trying to establish such collaborations, including:

- lack of professionalism, especially on project and IP management
- diverging interests and cultures, leading to volatile relationships
- slow negotiations
- issues over ownership of results and exclusivity
- inadequate compensation for indirect costs and background knowledge
- unfair returns in the event of successful commercialisation

It is often hard to find the right partners and it then takes too long to establish the research agreement. Carrying out joint research is only a means to an end, so there must be evidence that objectives and interests can successfully be aligned if the approach is to be more widely used.

Proper intellectual property (IP) protection is central. Yet there are widely differing levels of understanding about where the value rests, what is meant by proper protection and what this entails. Some of these questions disappear with experience, but it is important to recognise that there are fundamentally different objectives to reconcile. Practical stumbling blocks include making the distinction between ownership, rights of use and exclusivity. All the partners need to understand the consequences of the agreements they establish: few universities have yet defended their IP in the face of a challenge. Joint ownership is worth considering, but may be worth rejecting because of the uncertainty it introduces if things change substantially.

Institutionalising good working



practices requires effort at several levels. EIRMA member companies have worked on these questions for the past two years with counterparts in the European University Association (EUA), the European Association of Research and Technology Organisations (EARTO) and ProTon Europe (the pan-European network of knowledge transfer offices), with help from the European Commission.

The outcome is the Responsible Partnering initiative, which provides insight, guidelines and a voluntary code of conduct that companies and PROs can use to establish effective collaborations. It highlights the need to place IP and the collaborative research agreement within a broader discussion of how each organisation wants to work with others to meet its objectives. Success depends upon developing the organisational approaches and professional skills that achieve effective outcomes and respect others.

Responsible Partnering complements the efforts of national governments and the Commission to establish codes of conduct for collaborative research. The value of a voluntary, bottom-up approach lies in greater acceptance. We hope the initiative will be widely supported. Work continues to broaden the scheme to deal with the special needs of the SME community, links with education and the development of Technology Platforms as vehicles for establishing common research agendas. ■

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adearing@EIRMA.asso.fr



Marion Braks

Managing director (the Netherlands), Willems & van den Wildenberg

How do you manage an innovation consultancy when the staff needs to be interested in novelty yet the job is about repeating a process? It's a tricky balancing act that Marion Braks performs each day, in her role as managing director for the Netherlands branch of innovation and business development consultancy Willems & van den Wildenberg (W&W).

The company employs 30 and Braks is responsible for half of them. She also runs projects, gets new business and works on developing W&W's business. Her background, as an industrial engineer, has equipped her to consult on technologies from solar cells and chemicals to logistics and biomass.

So how do Braks and her colleagues spend their days?

"New business development and R&D management are interrelated," she said. "R&D is about turning money into knowledge and new business development is about turning knowledge into money. We combine the two."

This means offering companies various skills, from setting up stage-gate processes to working on management schemes to meet milestones within time and budget frames.

The W&W approach is to research a technology or business in depth and then structure that knowledge into a

picture of a market and its opportunities. This is backed up by talking to people involved in a topic to get a sanity check.

"A lot of information and logical thinking doesn't necessarily help you," said Braks. "You need to have interaction with people in the market."

The second part of the W&W approach is to consider a market as a moving target, which helps with scenario planning and aids working with clients.

"The concept of a moving target helps avoid a lot of discussions," said Braks. "People always have a lot of very fixed opinions, but with the concept of a moving target you can accept many ideas as going towards that target."

"We don't have arguments with clients – we're patient. We tend to have our own opinions and to keep them until we're convinced they're not good. Most of the time we are able to convince clients they are good. We're also not ashamed to override the clients."

"We are not like the conventional consultancies who work in the boardroom. We like making schemes, facilitating processes and doing a lot of the work ourselves. We're more of a sparring partner than a helping hand."

"I team up with clients, giving some leads, drawing them in to gather their experience. I like to create tandems,

with a senior consultant and a junior consultant, coupling the grey-hair's experience with creative passion."

The output of W&W's work is often a visualisation of a new technology-based product group and the investment plans for its realisation: many of its staff are industrial designers with an innovation management background. Braks contrasts the outlook of engineers, who tend to converge on a solution, with that of industrial designers, who tend to alternate between converging on and diverging from a solution to find the best answer.

"Industrial designers have learnt to think in the way that you need to think to do pragmatic innovation, creating options and then selecting from them," said Braks.

The paradox in managing the consultancy is that the staff needs to like novelty, yet the business must repeat approaches and processes in order to be most effective.

"Our people don't like repetition, so we're trying to set up a coaching model so that young academics can learn the processes, and do it as the basis for creating continuity," said Braks. "It's the same as in business development units in large organisations, which need systems where people can develop their personalities and also coach others." ■

>> Upcoming activities

Research in China and India

An EIRMA conference in April will discuss working with companies and institutions in China and India. Later in the year, senior delegates will have the chance to make a joint visit to Beijing with members of America's Industrial Research Institute.

Find out more at www.eirma.asso.fr/indiachina

Bringing ideas successfully to market

This year's annual conference in Copenhagen (26-27 May) examines bringing ideas to market. Speakers include the new European Commissioner for Science and Research, Janez Potočnik.

Find out more at www.eirma.asso.fr/2005

<< The 2006 Millennium Technology Prize

Nominations for the 2006 Millennium Technology Prize, worth €1m, open soon. EIRMA is supporting this prize, the world's largest for technology, and encourages members to make submissions. The Award is organised by the Finnish Technology Award Foundation. EIRMA member companies based in Finland are acting as partners.



The prize acknowledges innovations that promote quality of life, are based on humane values and encourage sustainable development. Sir Tim Berners-Lee, the 2004 Prize winner, invented the worldwide web and ensured its uptake by not charging for the technology.

Find out more at www.technologyawards.org

>> Catching up...

IP issues in open, global innovation

Protecting and handling intellectual property (IP) in light of the trend to global open innovation was the subject of the November EIRMA meeting. China has had patent law since 1980, and recently became a member of the Paris Convention and a party to the PTC but there is still little experience with IP. If you want to collaborate in China, prepare thoroughly and negotiate carefully over rights of access to background knowledge and rights to use foreground knowledge. Chinese scientists can find Western partners arrogant during negotiations, so take care.

Since the Bayh-Dole Act in 1980, American universities have retained title to inventions made with federal funding but can grant exclusive term-of-patent licences. But it took them more than ten years to come to terms with these rights and there can still be fundamental differences in terms of time horizons between universities and industry.

Find out more at www.eirma.asso.fr/sig2

≡ About EIRMA

"The best management development happens when experienced managers come together to learn from each other, to discuss common concerns and visit each other's companies" – *Financial Times*, 31 March 2004

The European Industrial Research Management Association (EIRMA) is an independent, not-for-profit organisation, which aims to enhance innovation through more effective market-oriented research and development. Unique features of the Association include the networking and personal contact that the *Financial Times* recommends. It's been offering this forum for 40 years.

EIRMA provides a platform for discussing ideas and exchanging practical experience. Its activities support companies in benchmarking and improving their innovation processes through well managed and well organised research and development. These activities establish EIRMA as a natural first point of contact for policy makers and others seeking the business community's insight.

EIRMA's website provides further information on the items featured in *IQ*, other key aspects of research and innovation management and records of recent meetings and all publications.

Find out more at www.eirma.asso.fr/about

>> Look ahead

In our next issue

- How does the effective company manage its portfolio of projects?
- What part do the corporate and business functions play in the whole structure?
- What is the emerging paradigm for effective research management in a world of global Open Innovation?

The May issue of *IQ* will examine these questions and look at companies that handle them well.

Events

- From project to multi-project management
 - Strategies for research globalisation: India and China
 - Bringing ideas successfully through to market
 - Communicating effectively
 - Management study group
- For full details, visit www.eirma.asso.fr, which offers records of EIRMA meetings and reports**

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