European research crisis: the cancer community must make its voice heard

Anna Wagstaff

The European Union aims to become "the most competitive and dynamic knowledge-based economy in the world". Why then does it put so many obstacles in the way of research? And why is a world-beating breast cancer trial left short of funding and support?

A clinical trial of breast cancer treatment in Europe is about to set new standards for the future of research by focusing on the molecular biology of tumours, rather than simply asking whether one treatment is better than another.

This is the first large trial anywhere in the world to put to the test the best system for choosing which tumours respond best to which treatment. It could put Europe in the forefront of the drive to target treatments to the genetic fingerprint of individual breast cancers.

But this revolutionary approach is being held back by a culture of bureaucracy, lack of coordination and lack of funding which threatens Europe-wide research. The European Commission says it has learned lessons from an avalanche of criticism. It may have one last chance to put money where it is needed and to remove barriers that hold back Europe's scientists and clinicians, before cutting edge research moves decisively to the USA or to .China and other parts of Asia.

The world's first trial of tailored treatments, MINDACT, is being masterminded by TRANSBIG – the translational research arm of the Breast International Group – from a small office in the Jules Bordet Institute in Brussels. It will analyse the molecular biology of every tumour in the trial, to gain information on which types of tumour respond best to which types of treatment.

MINDACT (MIcroarray for Node negative Disease may Avoid ChemoTherapy) aims to find out whether the genetic signature (gene expression profile) of an early-stage breast cancer tumour is more effective than traditional clinical and pathological criteria at predicting which women will benefit from adjuvant chemotherapy following surgery. The ultimate aim is to avoid giving chemotherapy to women who do not need it – to the benefit of both patients and health care budgets.

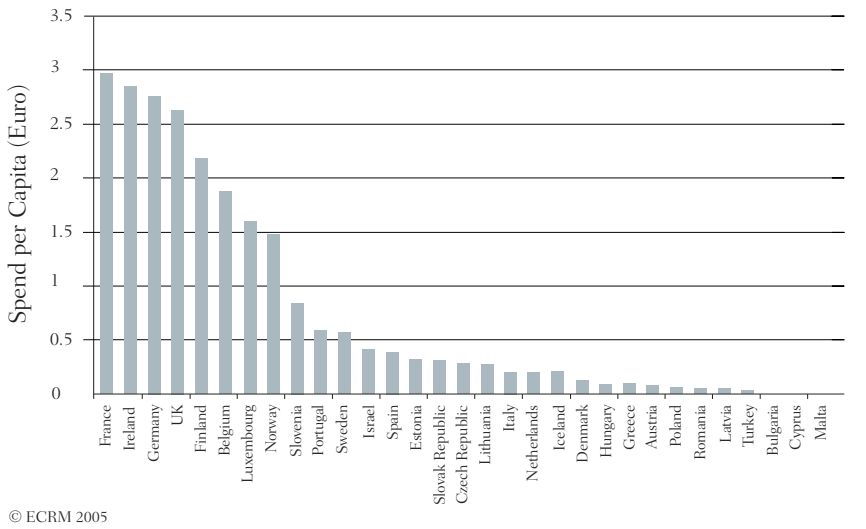
It is a huge logistical challenge that requires lab-based specialists in genomics, proteomics and bioinformatics in a number of centres around Europe to work in harmony with hospital-based clinicians – medical oncologists, surgeons, pathologists and nurses.

More than 6,000 patients will be recruited and enrolled by more than two hundred centres in Europe, Latin America, and in other countries around the world. Clinicians will use current clinical and pathological criteria to categorise each patient as high or low risk.

Tumour tissue will be sent to Milan for pathology quality control.

Philippe Busquin, former Commissioner for Research, was a leading force behind the 2000 'Lisbon agenda', which aimed to turn the EU into the world's leading knowledge-based economy. But his recent book, *The Decline of the European Scientific Empire*, strikes a pessimistic note

TABLE 1. GOVERNMENT FUNDING OF CANCER RESEARCH



Two-thirds of European countries spend less than 1 euro per head on cancer research each year

Source: European Cancer Research Funding Survey, European Cancer Research Managers Forum, 2005. The data are for the years 2002-2003. A full copy of the report can be downloaded from *www.ecrmforum.org*

Meanwhile, frozen tumour tissue samples will be sent to the Netherlands Cancer Institute (NKI) in Amsterdam, where genomics specialists will work with the microarray company Agendia to categorise them as high risk or low risk according to a prognostic gene expression pattern – known as the '70-gene signature' or MamaPrint – which was developed in Amsterdam.

Patients categorised as high risk by both methods will be treated with chemotherapy, and those categorised as low risk by both will be treated with hormonal therapy (so long as their tumours express hormone receptors). Those categorised as high risk by one method and low risk by the other will randomly have their treatment decided either by clinical-pathological criteria or by genetic signature. The hypothesis being tested is that the genomic signature will prove a more accurate marker of risk, and so reduce unnecessary chemotherapy.

Meanwhile, tumour and blood samples from every patient will be flown to a proteomics lab in Wales, where specialists will analyse their protein profiles, to try to identify "protein signatures" associated with risk, or with responses to particular therapies. Many scientists believe that proteins will ultimately prove more useful than genes in distinguishing cancers, and this method requires only blood rather than frozen tissue.

One of the main aims of TRANSBIG is to develop user-friendly tools for risk assessment and to predict response. To this end, molecular biologists will use polymeric chain reaction (PCR) and other widely used techniques to determine whether the genetic profile of the tumour can be evaluated using these less expensive and less demanding methods. Validation of such straightforward techniques will be essential if cancer treatment centres are to be able to act on the outcome of the trial.

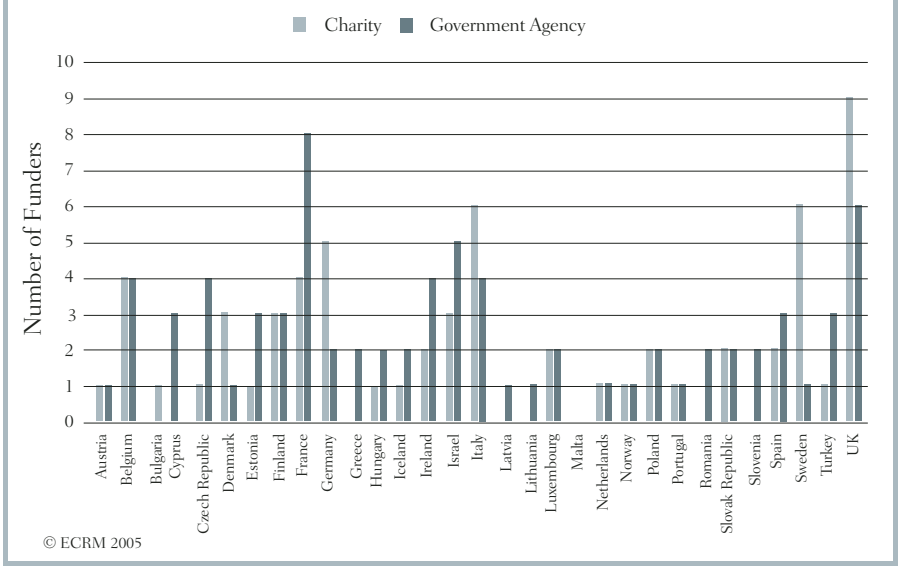
To add to the complexity, two additional questions are posed in this trial. Patients treated with chemotherapy will receive either anthracycline or taxane plus capecitabine, with the aim of comparing their efficacy and serious side-effects. Patients treated with hormonal therapy will receive either 2 years tamoxifen plus 5 years aromatase inhibitor, or 7 years aromatase inhibitor.

As far as the scientists are concerned, these are tag-on questions, but revealingly, their inclusion will finance much of the trial. Pharmaceutical companies have no great interest in differentiating high-risk from low-risk patients, but finding markers that predict which patients respond best to their products is of value to them, so the chemotherapy and hormone therapy questions tie in their support.

MINDACT is a magnificent trial opening up new frontiers in the prized and fast-expanding field of 'omics' biotechnology. It will take a sizable step towards true individualised treatment in the future based on the 'fingerprint' of a woman's tumour. It should be the pride and joy of the European Union (EU) which, at a landmark conference in Lisbon five years ago, committed itself to becoming "the most competitive and dynamic knowledge-based economy in the world by 2010".

The sad reality, however, is that MINDACT, like most European research, receives far too little funding, relies on clinicians doing research in their 'spare time', struggles with the heaviest clinical trials regulation in the world, and depends on a continually depleted pool of European scientific expertise as researchers are attracted by funding and career prospects in the US.

TABLE 2. DISTRIBUTION OF FUNDING ORGANISATIONS BY COUNTRY



Half of all European cancer research funding comes from charities. This reflects very poorly on government funding – it also highlights the importance of involving cancer charities in strategic planning at national and European levels

THE DECLINE OF EUROPEAN RESEARCH

Europe's record on supporting research and researchers leaves a lot to be desired. Some 400,000 European scientists are currently working in the US, and a survey published last year by the Commission indicated that only 13% are currently intending to return home. While 15 years ago the pharmaceutical industry invested 50% more in the Europe than in the US, today it is investing 40% more in the US than in Europe, and Europe's base of expertise in drug development has suffered as a consequence. Today, the US itself fears being overtaken by the fast growing economies of China and South Asia, which are investing heavily in biotechnology. For the first time, the number of scientists from these regions returning home from jobs in the US is outstripping the number flowing the other way. American analysts predict a serious shortfall in scientific personnel – and this will exert a further pull on Europe's postgraduates.

No wonder former Commissioner for Research, Philippe Busquin is sounding the alarm. His book, *The Decline of the European Scientific Empire*, charts the path of European science from after the Second World War to the present day. He issues a rallying cry for European leaders to support the vision of a knowledge-led economy set out in Lisbon in 2000, and to fulfil their pledge to increase funding for research and development to 3% of gross domestic product (GDP).

THE FUNDING GAP

The cancer research community has been complaining about the shortfall in European research funding for many years. The European Cancer Research Managers (ECRM) Forum – a body supported by the EU – commissioned a study into non-commercial funding of cancer research in Europe, which published its results at the end of March 2005. Even they were shocked at what they found.

Europe spends 2.56 euros per head on cancer research – one seventh of the 17.63 euros per head spent in the US (see Table 1). If the ten countries that joined last year are excluded, the figure rises slightly, to one-fifth of the US per capita spend. Moreover, government agencies account for only half of the total European spend of 1.43 billion euros, the rest coming from charities. In other words, Europe's cancer research relies on philanthropy (see Table 2).

Funding of cancer research via EU research grants came to 90 million euros. This was sufficient to finance only one in five fundable projects, and only 50% of the projects judged to be of a very high standard.

No country comes out of the survey well, but there are some real surprises. At 6.43 euros per head, Sweden ranks second after the UK in per capita spend on cancer research, but only 0.56 euros of this comes from the government, with more than 90% being contributed by Swedish cancer charities. The Swedish government contribution is only 0.002% of GDP. This compares with 0.0078% in Slovenia, 0.0063% in the Slovak Republic, 0.0063% in Estonia, and 0.0042% in Lithuania – all poorer countries that could be expected to concentrate more heavily on service provision rather than research.

Sweden is by no means the worst. Out of 31 countries in the European Free Trade Area, it ranks 17th on cancer research spend as a proportion of GDP – ahead of Italy, the Netherlands and Iceland, (23rd to 25th). In Denmark and Austria, ranked 27th and 28th, the governments spend a

shameful 0.0003% of GDP on cancer research – around one fortieth of the proportion spent by France, Germany and the UK.

This goes some way to explaining why even flagship research projects such as the MINDACT trial, which uses precisely the cutting-edge techniques and technologies the EU says it will invest in, is finding it hard to get sufficient funding.

This technology doesn't come cheap and MINDACT will cost around 30 million euros. Although the EU Research Framework Programme promises support for "clinical research aimed at validating interventions", its support for the MINDACT trial is only indirect. TRANSBIG has been given 7 million euro under the EU Networks of Excellence Programme, to be spent largely on the network's "integrating activities" related to MINDACT. None of this money will go towards the costs of the actual clinical trial or microarray studies.

TRANSBIG is urging national governments and health insurers to contribute towards the costs, following the lead of the Dutch medical health insurers who helped finance some of the clinical research with the 70-gene signature. So far, however, not one government or health insurer has pledged any funds.

Fatima Cardoso, TRANSBIG's scientific coordinator, is baffled at the lack of support. "You would think that a trial like MINDACT, which has the potential of telling you that we can reduce the number of chemotherapy prescriptions by 10–20%, would be of extreme interest to governments, health insurance companies and the Commission," she said.

Clinical trials – the poor relation

One of the six key messages from the ECRM survey is that the funding shortage is "seriously damaging" clinical research.

The gap between US and European funding for clinical cancer research is even greater than that for basic research. One reason is that most clinical trials need to be conducted at an international level to recruit enough patients, yet national charities and government research funds rarely contribute to the international initiatives. One key recommendation from the survey is for greater coordination between major non-commercial funding bodies at European level.

Another reason is the EU refuses to help fund clinical trials, despite the fact that most cannot be undertaken by a national group acting alone. Françoise Meunier, Director General of the European Organisation for Research and Treatment of Cancer (EORTC), which is running the clinical arm of MINDACT and is responsible for the vast majority of clinical trials in Europe, is exasperated at this lack of support. She has spent years trying to convince the Commission to accept a responsibility for helping to fund non-commercial clinical research.

The Commission says that this research is too expensive for public funding and should be financed by cancer charities, national governments and the pharmaceutical companies. The net result is that clinical research – which has the greatest immediate impact on patient care – is left largely in the hands of the industry. However, as Meunier has tried to explain, many clinical trials are of no interest to the pharmaceutical industry.

Pharmaceutical companies focus their attention on the four most prevalent cancers – breast, lung, prostate and colorectal. There are regulatory incentives to encourage companies to research treatments for 'rare diseases', but most cancers do not qualify as rare. Meunier points out that breakthrough drugs like temozolamide for glioblastoma or novel indications such as imatinib (Glivec) for use in gastro-intestinal stromal tumour (GIST) came out of academic research.

Child cancers is another neglected area. Companies may soon have to provide data on the use of their drugs in paediatric populations, where appropriate, as a condition of getting approval. However, as children rarely suffer from the cancers that are common in adults, this is unlikely to be of great use. Conversely, the vast majority of children's cancers are rarely found in adults; the question is who will fund research into these diseases?

Some clinical trials do not concern drugs at all. Many important benefits have resulted from refining radiotherapy techniques, improving surgical procedures, and finding more effective ways to combine radiotherapy, surgery and drug treatment. If only drug trials were funded, women would still rou-

Doctors and nurses who want to participate in research usually have to do it in their spare time

THE CLINICAL TRIALS DIRECTIVE

Europe's spectacular own goal

In May 2003, the EU adopted a directive governing the way clinical trials are conducted. Clinical researchers hoped this might boost trans-European clinical research by harmonising national regulations governing insurance requirements, ethical approval, reporting requirements and so on. It didn't.

Not only did the Clinical Trials Directive leave the original obstacles in place, but it added new ones. Each trial is now obliged to have a 'sponsoring' research body or institution. Among a raft of bureaucratic, financial and legal obligations, the sponsors will be required to pay for every drug used by every patient enrolled in the trial, and to meet the costs of any inspections. The requirements of data validation and reporting go well beyond anything that regulatory bodies demand when assessing a new drug for approval, and in many cases the researchers find themselves having to report the same data in two different ways in order to satisfy both EU and national requirements.

The Directive was drawn up by the directorate general for Enterprise as a 'single-market measure'. It aimed to provide a level playing field for the free movement of medicines in the EU, and therefore included regulations on how the pharmaceutical industry conducts its research on patients. But it ended up dragging down non-commercial research in the same net.

Europe's research community warned at the time that the Directive could threaten the future of non-commercial clinical trials. They have been proved right. At the end of April, almost exactly one year after the directive came into force, the EORTC, Cancer Research UK and other bodies involved in clinical research sat down with the Commission and representatives of the member states to report on the damage. They were able to show that all over Europe non-commercial trials activity has been reduced by 50% while the costs and the administrative burden have doubled. The new requirement for sponsorship has stopped many national clinical trial groups from opening any centres in other EU countries. Though the point has been proved, the Directive will stand unless Europe's cancer researchers mount concerted pressure to force the EU to rethink its whole approach.

tinely lose their breasts and throat cancer patients their voice boxes.

Lack of funding means that the EORTC has to be highly selective, and as a result many urgent questions regarding treatment options are simply not investigated. This situation is exacerbated by the extra costs associated with the EU Clinical Trials Directive, which came into force in May 2004 (see box).

Missing the drugs train

Silvia Marsoni, head of the Milan-based Southern Europe New Drug Organisation (SENDO), says that lack of investment is also crippling the EU's ability to compete in the potentially lucrative drug development market. Advances in molecular biology offer the promise of effective treatments for many diseases and even have the potential to alter natural physiological processes such as ageing. Economically, this represents a goldmine. "The US, China, India and Korea are all pouring money into this field," says Marsoni. "The EU risks missing the train."

Europe lost much of its pharmaceutical industry to the US in takeovers and mergers in the 1980s and '90s. However, a lot of innovative work is now coming from smaller science-driven biotechnology companies, and the EU is pinning its hopes on this sector.

Marsoni says that some countries, such as the UK, France and Sweden, are trying to create an environment to ease the route from scientific discovery to marketable product. But in much of Europe, this is not the case. "The concept of venture capital does not exist in Italy. You cannot get a loan unless you have a house to give as security."

But even a thriving European biotech sector will not develop drugs and take them to market without scientific expertise in many different areas.

SENDO is one of very few non-commercial bodies to offer drug development services in Europe, along with Cancer Research UK and the EORTC. It struggles to maintain a base of drug development expertise in Europe, without which the biotech companies will have to look elsewhere.

Marsoni says, "It's a niche area. You need very skilled people, and you need to invest in them. It takes me five years to train up good people. Unless I have money to pay for their training, it's not going to happen." In addition, the Clinical Trials Directive has made research so much more bureaucratic that SENDO had to hire three extra people just to deal with the paperwork.

If the EU is to avoid being left behind, it will need to simplify its bureaucracy and start investing in infrastructure and research personnel – from clinicians to scientists and data managers.

Marsoni says that Europe has a short period of breathing space, because the rush to develop Glivec-style treatments aimed at a single tar-

Scientific innovation is not amenable to the top-down approach

get turned out to be a blind alley – but the next decisions have to be the right ones. "Five years ago, when the public understood the potential of molecular biology, we thought that with the genome we were on our way to solving the problem. Now we know we are dealing with pathways and networks. We are in a period of reflection. Either we understand what we have to do and we do it within 2005–2006, or we will definitely miss the train."

Losing the Lisbon plot

The Lisbon conference, which set the goal for Europe to lead the world in a knowledge-based economy, set out a strategy to build a European Research Area and Networks of Excellence in priority areas. These were spelt out in the Sixth Framework Programme (FP6) drawn up by the Commission's Directorate General for Research, covering the period 2002–2006.

FP6 was given twice the budget of its predecessor. "Life sciences, genomics and biotechnology for health" is one of seven major themes, within which support is concentrated on advanced genomics and applications for health and combating major disease.

The priorities are a cancer researcher's dream. Basic research includes gene expression and proteomics, structural genomics, bioinformatics, multidisciplinary approaches in functional genomics and fundamental biological processes and the application of knowledge and technologies in the use of biotechnology for heath. It also includes the development of patient-oriented strategies for diagnosis and treatment, translational research and clinical research aimed at validating interventions.

Some researchers argue that it not only reads like a dream, but is just as insubstantial. While a number of basic science projects have benefited from FP6 funding, scientists complain that funding instruments define research topics too narrowly, force people into unhappy partnerships, involve small businesses where they don't belong, and create an administrative nightmare.

To top it all, the EORTC itself is disqualified from receiving support even as a Network of Excellence, because only new networks are eligible for support. The same rule was applied to disqualify the Breast International Group (BIG), which receives no support from governments or the EU. TRANSBIG was created as a new consortium to get around this requirement.

You will study X

The Commission allocates most research grants after putting out calls for proposals on topics specified within the Framework Agreement. It has justified this approach by referring to the need to build a "critical mass" in priority areas.

Richard Sullivan, director of Clinical Research at Cancer Research UK, Europe's largest cancer research organisation, says that scientific innovation is not amenable to this top down approach.

"The whole point about innovation and pushing back the frontiers of science is that you can't predict in which direction it is going to go. Programme grants need to be very flexible and cover broad domains, and they need to be driven from the bottom up."

Defining research topics narrowly is a particular problem because bureaucratic organisations like the Commission are slow to respond to events. "You need to be able to react very quickly when somebody says, 'this is hot, it needs to be done in the next few months and it will revolutionise this area of work.' You are always guessing the future."

You will collaborate with Y

Researchers responding to a call are obliged to form a consortium to meet strict guidelines about involving a number of countries, particularly those with a poorer research base.

The theory is that the EU can make the value of research in Member States greater than the sum of its parts through promoting collaboration and minimising fragmentation and duplication of research.

But here too, Sullivan argues, the EU has got it wrong. "There is little evidence to show European cancer research is fragmented."

Indeed, while the ECRM survey identified 138 major funders of cancer research in Europe, more than 80% of that funding came from only 25 organisations. What is needed says Sullivan is more communication and collaboration between these bodies to support transnational research.

European cancer also has a highly developed system of international cooperative groups – lymphoma groups, breast groups, groups for paediatric oncologists, groups for radiotherapists. European clinical researchers have worked together in EORTC for decades.

Sullivan says, "Everybody knows who everybody else is. You know who your competitors are. You are either cooperating with them because it is mutually beneficial, or you are in ruthless competition with them, because you are working in the same area."

He says that forcing people to collaborate as a condition of funding is counterproductive since true scientific collaboration cannot be imposed.

One scientist, who had benefited from an FP6 Network grant, put it this way: "We collaborate with who we want to collaborate with, and we don't collaborate with who we don't want to collaborate with." He said that the rules create sham partnerships where partners do not really work with one another. "It's just a way of getting the money."

You will involve the private sector

Another irritation has been the frequent requirement to include at least one small or medium enterprise (SME). The rationale is to speed up the translation of research into marketable results, by narrowing the gap between scientists and private enterprise.

However, the questions that academic researchers want answered do not always coincide with the priorities of profit-driven companies.

The experience of TRANSBIG is revealing. Despite reservations, they agreed to include Agendia, the company that developed the microarray platform used in Amsterdam to generate the '70-gene signature', within the consortium. Meanwhile, a group in Rotterdam conducted a similar study using a different company and a different platform. Their study identified a 76-gene signature, which seems equally effective at differentiating tumours, but has only three genes in common with its Amsterdam rival.

Naturally TRANSBIG scientists are eager to compare the Rotterdam and Amsterdam platforms and signatures. Equally naturally, Agendia would prefer their platform to be the only one validated. As part of the consortium, Agendia has a say in how MINDACT proceeds. The trial steering committee think they have found a way to resolve the problem, but they are strongly urging the Commission to drop the requirement to include SMEs in future.

Red tape

The biggest complaint is about red tape. To comply with EU requirements, consortia are required to fill in a level of paperwork before, during and after a project that beggars belief, and is entirely inappropriate for academics and small businesses that have no civil service and very little administrative support.

After applying for his first EU grant, Steve West, a leading scientist studying DNA repair mechanisms, says, "never again". Sitting on his desk is the completed application – a pile of paper 10-cm thick. West estimates that only 20 pages of this are relevant to the science.

Although the grant is large, it has to be spread across 15 labs. When he compares this with the nine- or ten-page research proposals required by other bodies, West concludes that it is not worth the hassle.

He is not alone. In a consultation on the future of European research carried out by the Commission in 2004, the anger and frustration at red tape was identified as the "single most recurrent message of the consultation".

Lisbon relaunched

There are encouraging signs that the Commission is trying to take on board many of these complaints. Publishing its proposals for FP7 in April, it said, "The expansion of the scope, span and volume of EU action in research requires, as a condition sine qua non, a substantial simplification and rationalisation of the way the Framework Programme Works."

It talks of "reducing the burden of administrative and financial rules and procedures," judging value on results rather than by controls, and says that their general approach "will be one of trust towards the researchers." Recognising that projects have been too tightly defined, it talks of "focusing more on themes than on instruments" and promises sufficient flexibility to accommodate emerging topics. It even talks about "investigator-driven research", and proposes the creation of a European Research Council, led by leading members of

Consortia are required to fill in a level of paperwork that beggars belief

Some governments may cut their domestic research budget to offset higher contributions to the EU

the scientific community, which would control 15% of the research budget.

"The new 7th Framework Programme," says the Commission in a tacit admission of the level of disillusionment, "will not be 'just another Framework Programme'. In its content, organisation, implementation modes and management tools, it is designed as a key contribution to the re-launched Lisbon strategy."

To support this, the Commission proposes doubling the FP7 budget to 67.8 billion euros over a longer timeframe of seven years. It predicts that this will lever 93 eurocents of private investment in research and development for each extra 1 euro of public funding, which "will boost business confidence that Europe delivers on its commitments and offers an attractive future."

It is easy to be sceptical. But it would be churlish not to recognise the real effort the Commission is making to move European research up a gear, and members of the cancer research community now need to ensure that their own governments back this effort with political support and hard cash.

Over the next two years, the FP7 proposals will be debated by the European Parliament and in the Council of Ministers. This is where the cancer research community has a chance to lobby for improvements – for instance to allow non-commercial clinical trials to apply for EU funding, or to relax the requirements on forced collaboration or the involvement of SMEs. This is also traditionally where national governments and powerful vested interests indulge in the sort of tit for tat horse-trading that so often reduces initially coherent proposals to ineffective and unworkable legislation – for which they then turn round and blame the Commission.

Some governments, including Germany, are threatening to cut back their domestic research budget to finance the increased contributions being requested by the EU – in fact so far only the UK has given a commitment that it will not do this. Governments may also not be very open to suggestions that researchers should be freed from their onerous reporting requirements and the relationship should be one based on "trust" – in fact many have spent recent years insisting the Commission tighten up its accounting and reporting requirements, following accusations of massive waste. There are also plenty of vested interests who may not be keen to see a strong European Research Council with the authority and independence to follow a purely research-driven agenda.

The cancer research community will need to make its voice heard.

The home front

It is, however, at national level that the future of European cancer research will be decided. The contribution made via the EU research programme, after all, accounts for only around 6% of the total spending on cancer research in Europe, although this proportion will increase in 2007.

More importantly, it is within national academic and health systems that Europe's young researchers are nurtured. The career prospects, research opportunities and general culture within these systems are key determinants of whether scientists stay or head for the US, and whether clinicians get involved in clinical and translational research. One consistent complaint from cancer doctors throughout Europe is how few incentives there are for clinicians to do research, particularly outside the top research institutes and teaching hospitals.

Cardoso fears, for instance, that many centres will not be able to participate in MINDACT because of lack of back up, and that there will be some European countries with no centre taking part. "Research should not be looked at as something of a luxury that smaller hospitals shouldn't even think about it. Most important is a change of mentality among the people who decide where the money goes and those who run the hospitals. In almost all centres, doctors and nurses who want to do research have to do it in their spare time. There is no time dedicated to research within your working hours, so you have to work double for the same pay."

Sullivan, of Cancer Research UK, calls for the promotion of a "research culture". "You have to have the same pro-research message at every level, from the funders and government all the way through to the front-line of cancer healthcare delivery and universities. It's not something you do for a couple of weeks and hang it up. You have to carve out extra time and offer

real career pathways that reward clinicians and scientists for their research work. The funding environment needs to foster a research oligopoly where there is both competition and cooperation. It also needs to support research that challenges prevailing dogma."

He hopes that European governments will follow the UK and France and set up bodies that can take a strategic approach to national cancer research. The creation of the UK National Cancer Research Institute in 2001 opened the way for joint initiatives by the main non-commercial funders, which can address the research infrastructure, clinical research and basic cancer research in a coordinated manner. Over the past few years, the proportion of UK patients enrolled in clinical trials has increased from around 3% to 11%. A similar approach in France led to the creation of the Institut National de Cancer (INCa) as part of the French Cancer Plan of 2003. While Germany and the Netherlands have excellent cooperative groups and some outstanding research institutes, there are no other national strategic cancer research bodies. This not only hampers the organisation of cancer research at a national level, but deprives researchers of the voice they need to get governments and the EU to take cancer research more seriously.

LISBON TRIUMPHANT?

There is more at stake here than who will lead the world in genomics and biotechnology for health. Investing – or failing to invest – in research has a direct effect on standards of care and the survival of Europe's cancer patients. For instance, one consequence of pharmaceutical investment moving to the US is that Europe's patients have to wait up to three years for new cancer drugs to clear regulatory hurdles. Conversely, European patients have benefited from early access to groundbreaking techniques pioneered in European treatment centres, including adjuvant chemotherapy, breast conserving surgery, conformal radiotherapy and meso-rectal excision in colon cancer.

More generally, studies have shown time and again that patients treated within clinical trials do better – whether they are in the experimental or the control arm. Participating in clinical trials is also good for hospitals. It encourages clinical staff to take a more critical approach to their work, and it promotes multidisciplinary working and teamwork.

The logistical demands can lead to lasting improvements in the way service delivery is organised. Indeed, joining an international clinical trial can be a very effective way to raise standards.

However, arguments about the quality of patient care may not be enough to win debates over research budgets, because Europe's research agenda is driven by economic rather than healthcare considerations. And traditionally, it is basic research that has been relied upon to fuel European growth, as biotechnology SMEs take discoveries made in the labs and develop them into marketable applications.

However, as the MINDACT trial demonstrates, developing applications for all the '-omics' requires work with patients, and that requires collaboration with hospitals and clinicians who recruit, enrol and follow-up the patients, and provide tissue and blood.

This is research that Europe is uniquely equipped to undertake. Not only is Europe strong in biomedical research – the European Molecular Biology Laboratories in Heidelberg, Germany, and Cancer Research UK have been rated two of the three top centres in the world – but its public health systems offer an environment supportive of collaborative work that is unparalleled anywhere in the world.

The capacity of Europe's medical researchers to communicate and collaborate between hospital departments, between treatment centres, and most challenging of all, between hospitals and laboratories is widely recognised and is a huge strength. It explains in part why, despite poor funding and heavy regulation, the MINDACT trial is happening in Europe and not in the US. This capacity gives Europe the potential to lead the world in developing applications from the rapid advances in molecular biology.

By raising investment in cancer research closer to US levels, and above all by supporting clinical cancer researchers, the EU and national governments would be playing to Europe's strengths, which will be essential if the EU is to stand a chance of winning the global race to become "the most competitive and dynamic knowledge-based economy in the world." They would also ensure that Europe's patients gained access to the best quality treatment in the world.

Failing to fund research directly affects standards of care and survival of Europe's cancer patients