Cancer Research UK response to the Department for Business, Innovation and Skills call for evidence on the EU Framework Programme

December 2010

Summary

The EU Framework Programme (FP) is a useful resource for British scientists which we believe could be more fully exploited. This is increasingly important in an era of financial austerity. To this end we recommend that:

1. BIS and the national contact points, supported by interested parties, should undertake a programme aimed at better promoting the availability of FP funding to UK researchers.
2. Sustained funding should be provided for key areas, such as the 'cooperation' programme (and specifically health), European Research Council (ERC) awards and the Marie Curie actions.
3. The current approach to funding should be continued, including the thematic approach and ERC and Marie Curie actions.
4. A new theme on medical research and biotechnology should be established, or combined with the health theme, rather than biotechnology continuing to be included in the same theme as food, agriculture and fisheries.
5. As part of the ongoing review of the EU Clinical Trials Directive, the UK Government should support measures to remove unnecessary barriers to the conduct of clinical research.
6. Information communication technologies (ICT), together with biomarkers and other key enabling technologies, which allow therapeutics to be appropriately targeted for patient benefit should be a key focus of FP8 funding, as should stratified medicine.
7. The Innovative Medicines Initiative (IMI) programme should include funding for overheads and allow longer timescales for applications.
8. In addition to inputting into discussions about changes for the FP8 programme, BIS should push for some changes to be made in the shorter term to FP7.
9. The arrangements for intellectual property rights need to be further clarified.
10. The Consortium Agreement template should be revised to reduce the number of amendments required for each new project.

Background

Cancer Research UK is leading the world in finding new ways to prevent, diagnose and treat cancer. We are the largest independent funder of cancer research in Europe, and over half of all cancer research in the UK is carried out by our doctors and scientists. Cancer Research UK's work is entirely funded by the public and we receive no Government funding for our research. In 2009/10 we spent £334 million on research, supporting the work of more than 4,000 scientists, doctors and nurses.

Thank you for the opportunity to provide comments on this area. In responding to this inquiry, we have answered the questions that we feel are most relevant to our experience. Our response has been collated following discussion with staff and researchers across Cancer Research UK.

Cancer Research UK's interest in the EU Framework Programme

Cancer Research UK funds research into all aspects of cancer from exploratory biology to clinical trials of novel and existing drugs as well as epidemiological studies and prevention research. We support research in a variety of different environments, including university research groups, core funded Institutes, and the Cancer Research UK Centres.

Our researchers have contributed to most of the world's top cancer drugs and we pioneered the use of radiotherapy to treat cancer.

These world-class scientists, doctors and nurses collaborate with other cancer experts in over 50 countries. For example, Cancer Research UK is part of the European Prospective Investigation into Cancer (EPIC), the largest-ever study of the links between diet and health. Important discoveries, such as the link between excessive red meat consumption and cancer, continue to flow from this work and will inform cancer prevention strategies that will save lives in the future. Cancer Research UK is also part of the International Cancer Genome Consortium (ICGC), which aims to obtain a comprehensive description of genomic, transcriptomic and epigenomic changes in 50 different tumour types and/or subtypes which are of clinical and societal importance across the globe. In particular, we are a significant contributor to the project on prostate cancer. We have also applied to participate in an Innovative Medicines Initiative (IMI) project that is being coordinated by the European Organisation for Research and Treatment in Cancer (EORTC) on imaging biomarkers and this project has been successful in the initial bid stage and is progressing well to the next stage of negotiations.

Researchers in our five institutes and in joint Department of Health/Cancer Research UK funded Experimental Cancer Medical Centres (ECMCs) receive core funding from Cancer Research UK in order to ensure that the necessary research infrastructure is in place to support world-class research. These researchers are also encouraged to apply for project grants from other funding bodies and several receive support from European funding.

For example, the London Research Institute (LRI) and Cambridge Research Institute (CRI) are experienced in successfully applying for EU funding. These institutions receive support through a number of streams including European Research Council (ERC) Starting and Advanced Grants; the Cooperation (Health) theme; Marie Curie Fellowships (Intra-European and International Reintegration); and Marie Curie Initial Training Networks funding. The LRI currently receives FP finance for 22 projects, with a further nine in negotiation or yet to commence, while the CRI have been awarded 11 projects, with two currently in negotiation. In addition, the Beatson Institute in Glasgow has been awarded two Marie Curie Fellowships so far under FP7, with a third fellowship at contract negotiation stage.

Question 1: What should the UK's high-level objectives be for FP8?

We believe that the UK's objectives should be to maximise funding opportunities, and in doing so, to foster innovation and cutting edge research across the UK. FP8 should aim to create efficiencies in research by leveraging the expertise and intellectual property of other European research institutions through collaboration. It is important that the terms of FP8 remain acceptable to research institutions in the UK so that they continue to utilise this important source of funding to achieve these objectives.

The UK is a centre of excellence for research within Europe. As the consultation documents outline, the UK's performance has been strong in FP7 – with researchers receiving €1.83 billion (£1.64 billion) of funding from the €12.7 billion (£11.37 billion) awarded to date. Nevertheless, we firmly believe there could be increased opportunities for academia and industry in the UK to benefit from EU funding.

Based on discussions with our researchers and grants staff, there appears to be a mixed picture of EU funding across the UK. While some research groups are familiar and comfortable with FP funding processes, others do not have such a good understanding and will actively choose not to apply for it. We would therefore strongly support further activities to encourage the involvement of UK organisations to better understand, and apply for funding under, the Framework Programmes.

Recommendation: BIS and the national contact points, supported by interested parties, should undertake a programme aimed at better promoting the availability of FP funding to UK researchers. This should include the production of a single clear and consistent guidance document, aimed specifically at UK-based researchers, which outlines who can apply for this funding and what this involves. This should be made available online and presented to interested researchers.

Question 6: How can FP8 support innovation in the UK?

FP8 must ensure that the terms and level of funding available are attractive to potential applicants, to encourage participation. This will inherently make a positive contribution to the UK economy, by supporting UK innovation and driving research.

We have found that the efficiencies created in terms of information and intellectual property sharing by 'cooperation' projects is of value to the EU. The balance of funding provided by the Framework Programme is also important. In particular, EU funding values mobility requirement for researchers, trains future research leaders and supports the creation of training networks across Europe.

Question 7: What are your views on the split of the FP7 budget between these specific programmes? Should this change in FP8?

We are keen to see existing levels of funding for key areas, such as the 'cooperation' theme and specifically for health, continue. The ERC awards and Marie Curie actions have been shown to be successful in supporting research and should also be retained.

Recommendation: Sustained funding should be provided for key areas, such as the 'cooperation' theme (and specifically health), ERC awards and the Marie Curie actions.

Question 10: What are the arguments for and against FP8 moving towards funding research and development which addresses grand challenges?

While an approach of funding research into 'grand challenges' is interesting, we believe that the thematic approach currently adopted should be retained, especially while the grand challenges projects are developed.

Recommendation: Cancer Research UK strongly believes that the current approach to funding should be continued, including the thematic approach and ERC and Marie Curie actions.

The thematic approach has been shown to work well in previous programmes. A thematic approach is also useful because it enables funding to be allocated based on the priority given to certain sectors. However, given the importance of medical research, we recommend that 'biotechnology and medical research' should be given a separate category, rather than included in the same class as food, agriculture and fisheries.

Recommendation: A new theme on medical research and biotechnology should be established, or combined with the health theme, rather than continuing to be included in the same theme as food, agriculture and fisheries.

However, in the medical research sector, projects that address larger issues, including grand challenges, usually carry a higher risk profile than projects aimed at making more incremental scientific developments. While these projects may result in significant scientific breakthroughs, it can be more difficult to secure funding for these higher risk projects from sources such as venture capital. We believe that the most useful approach would be to find a balance between 'grand challenges' research projects and research projects with more assured but incremental results.

Question 12: How should FP8 engage with countries outside the EU or associated to the Framework Programme in addressing global challenges?

For projects that relate to global challenges, including for example the health issues addressed by medical research, it may be useful to allow flexibility in allowing entities located in countries outside of the EU to be associated with Framework Programme projects.

Medical research is increasingly an international endeavour, and requires the cooperation of EU Member States with other countries, such as the United States and Japan. As befits Framework Programme funding, such cooperation enables the sharing of understanding, reduces duplication and pushes innovative research where leading scientists in related fields can work together. Cooperation with countries outside of the EU is particularly necessary in areas like clinical trials, where there is a need, for example in stratified medicine and rare cancers, to work internationally in order to achieve a sufficient patient population to produce tangible evidence.

In order for Framework Programme funding to be most effective, we must also address some of the regulatory hurdles which are currently impeding our ability to carry out multinational collaborative research across Europe. We are particularly concerned that the European Clinical Trials Directive 2001/20/EC[1] (CTD) has negatively impacted on large academic trials run by Clinical Trials Units (CTUs). There are concerns across the research community that this legislation and the way it is interpreted in the UK (and other Member States) is hampering our ability to conduct clinical research in the UK and internationally. We believe there should be clear and straightforward processes for applying for approval for, conducting, and monitoring of clinical trials.

[1] EU Clinical Trials Directive (2001/20/EC) and related guidelines: http://ec.europa.eu/health/human-use/clinical-trials/index_en.htm

Cancer Research UK believes the EU Clinical Trials Directive should be revised so that authorisation processes are streamlined, a risk-based approach to assessment of clinical trials is adopted and clear guidance is provided on issues such as substantial amendments.

Recommendation: As part of the ongoing review of the EU Clinical Trials Directive, the UK Government should support measures to remove unnecessary barriers to the conduct of clinical research.

Question 14: What should be the role of key enabling technologies e.g. ICT and nanotechnology in FP8?

Information communication technology (ICT) is important for furthering health research. We are concerned that projects involving the creation and development of databases are in danger of falling between the gaps of research grants. The development of enabling technologies in the medical research sector also plays a critical role in the preparation of new therapeutics. With this in mind, and as outlined in a case study below (Question 28), stratified medicine is an area of interest which is likely to benefit patients significantly in the future and should therefore also be a key focus for FP8 (under enabling technologies and within 'cooperation' more broadly).

Recommendation: We recommend that ICT, together with biomarkers and other key enabling technologies, which allow therapeutics to be appropriately targeted for patient benefit, should be a key focus of FP8 funding, as should stratified medicine.

Question 16: What are your views on how the Framework Programme allocation for collaborative research should be apportioned between themes; enabling technologies and underpinning areas of research e.g. social sciences and humanities?

Multidisciplinary collaboration should be readily supported. Given the importance of health and medical research, this sector should receive at least as much allocation for collaborative research as the ICT sector. This multidisciplinary approach should be focused on particular projects and themes in order to keep the work focused and effective.

Question 17: To what extent should ERC funding focus on supporting frontier research? Are there other areas in which ERC could add value?

Frontier research is an important area in which the ERC should focus funding. It is often difficult to secure funding for such research from other sources, given its higher risk profile. As mentioned above, funding should be balanced between high risk projects, and incremental developments, to ensure that both approaches are suitably supported.

We agree that applications should be assessed for their translational merit. This would incentivise applicants to put forward projects that linked with private sector translational interests, and could therefore stimulate greater industrial investment in research. However, this should only be one of a number of criteria. It is vital that funding is still made available for those projects without immediate translational potential. This more basic research makes an important contribution to scientific advancement.

Question 20: What priority should researcher mobility and skills development have in FP8? What is the best way to address this?

Researcher mobility and skills development are important parts of the Framework Programme, and should be continued in FP8. These can provide opportunities for researchers to gain experience in labs in other countries. The current 'People' Framework Programme grants that facilitate researcher secondments between the labs of participants are an effective way of achieving this.

Initiatives which enable skills sharing between labs and researchers in different countries promote the development of research efficiencies and best practice. This is one of the central benefits of the Framework Programme and should continue.

Question 28: What should be the role of public-private partnerships in FP8?

Cancer Research UK often works in collaboration with other funders, including other not-for-profit organisations, industry or Government bodies, in order to pool resources, share experience and prevent duplication. Given the importance of medical research, and the significant benefits that the range of pan-European initiatives, which draw on the expertise of specialist institutions in different countries, can have on this type of research, additional funding streams for this research would be useful.

There are several areas, however, that could be improved. Funding through the IMI scheme, for example, only provides a partial contribution to the direct costs of the research. This deters organisations from taking part. Cancer Research UK core-funded institutes are in a relatively strong financial position, compared to most higher education institutions (HEIs), but they are still discouraged from taking on funding which does not provide any overhead component.

In addition, the time allowed for preparation of the proposal, and for revisions during the negotiation process, are extremely short given the complexities of the project and partners involved. Longer lead in times for the planning stages, to ensure a high quality proposal can be put together, are essential. We welcome the improvements that have been provided, such as the second IP clarification note but we believe that the IP terms remain biased in favour of industry partners. Key issues such as who is granted access rights (affiliates, third parties etc), on what terms (fee bearing or royalty free) and for long (fixed term of indefinite still need to be addressed).

Recommendation: The Innovative Medicines Initiative (IMI) programme should be expanded to include funding for overheads and allow longer timescales for applications.

The IMI programme has proven to be an innovative approach to medical research through public-private partnerships. The difficulties encountered by this programme have demonstrated the importance of ensuring that the applicable commercial terms meet the needs of both industry and academic or charity participants. If the interests of industry participants are allowed to dominate, there is a risk that academic or charity institutions will not participate and the programme will therefore not achieve its objectives.

Case Study: Cancer Research UK and Technology Strategy Board project on stratified medicine

Cancer Research UK and its commercial partners recently launched a multimillion pound programme, alongside the Technology Strategy Board's Innovation Platform in stratified medicine, to make the UK a better place for stratified medicines research. Cancer Research UK will be running the Stratified Medicine programme from May 2011 to establish whether it is feasible to routinely carry out broad spectrum molecular diagnostic testing on NHS cancer patients at diagnosis and relapse. The charity will also collect and link clinical and genetic data from tumours and link this to clinical data on treatment and outcomes.

Alongside this project, the Technology Strategy Board (TSB, which is funded by BIS) will be investing up to £50 million in a new Stratified Medicines Innovation Platform. The TSB will offer grants to industry-led groups to develop a broad spectrum of molecular diagnostic tests that can cover many of the known mutations of the most common types of cancers, making genetic testing cheaper, more reliable, and improving their commercial availability. Companies will also be invited to pitch to develop IT systems that can link clinical and genetic data together. Effectively, the TSB is developing new commercial products that solve problems within the Cancer Research UK programme, while the Cancer Researc UK programme is developing a market for any successful TSB-funded innovations.

Cancer Research UK will be partnering with two pharmaceutical companies in this project. Tumour samples will be collected from lung, breast, colorectal, prostate, ovarian and skin cancer patients being treated in selected Cancer Research UK / Department of Health funded Experimental Cancer Medicine Centres (ECMCs). This programme will lead to the application of innovative technologies. It will help contribute to better patient outcomes in the future and enable cost savings in the NHS.

This opportunity to stimulate industrial involvement and multi-partner collaboration could provide useful lessons for FP8.

Question 31: Would any proactive effort to alter the current balance of funding between universities, research organisations and businesses be appropriate or effective? If so, what might be involved?

Reducing the bureaucracy of the Framework Programme through revisions to the Consortium Agreement, and making the process easier to understand, may encourage more organisations (including SMEs) to participate in the Programme.

Question 33: What could the Commission do to reduce bureaucracy of FP8 over and above the current simplification proposals (including changes to the Financial Regulations and Implementing Rules)?

While it is understood that a certain level of bureaucracy is required, there are several areas within the application process which could be improved. For example, there are currently too many forms to fill out at different stages and too many guidance documents. Furthermore, guidelines can be difficult to interpret, and sometimes give conflicting advice; they could be clearer and simpler.

A key difficulty is the time taken between stages in the application and award process, with a distinct lack of information regarding the stage an application has reached, and whether or not there are any outstanding issues that need to be resolved.

Once funding has been awarded, there are also a number of areas that could be improved within the processes to report progress. The requirement for timesheets to be completed by everyone working on an FP7 grant, even if all of their time is spent on the grant, is unnecessary.

The need for amendments to the grant agreement during the project to update changes in the contact person or a change in the budget profile also adds a needless level of bureaucracy. An additional issue for the UK is the influence of exchange rate fluctuation. It is often for institutions in the UK to give an accurate budget to researchers at the beginning of the project, because the exchange rate that has to be used in financial reports is the one at the end of the reporting period. This causes significant problems in terms of under and over-spending. The preferred approach would be where the exchange rate used for reporting matches the rate in effect when funds were received.

Our researchers on the whole have found the ERC Executive Agency to be efficient in grant agreement negotiations. However, the Research Executive Agency (REA) has been relatively slow in providing grant agreements for Marie Curie fellowships and we believe this should be improved.

Furthermore, there are a number of ambiguities within the current FP7 Consortium Agreement that consistently require amendment by participants when each new project arises. This adds to the time it takes to negotiate these agreements, and could be avoided if the template agreement was revised to resolve these ambiguities. Given the number of collaborating partners in Framework Programme projects, any steps that can be taken to reduce the number of amendments that need to be made to agreements will help minimise the time to complete contracts.

Since some FP7-funded projects still have several years to run, and in the context of the recent Expert Group Interim Evaluation of FP7, there are a number of improvements that could be made in the shorter term including:

- Reducing the number of forms to fill out at different stages and too many guidance documents.
- Guidelines can be difficult to interpret, and sometimes give conflicting advice, and verbal guidance from Commission officials is sometimes not written in the guidelines. Guidelines need to be clearer and simpler.
- Timesheets have to be filled out for everyone working on an FP7 grant even if they are working solely on the project. Staff working exclusively a project should not have to fill out timesheets. This could be achieved by the Commission relaxing how they interpret their guidance on timesheets without a legal change.

Recommendation: In addition to inputting into discussions about changes for the FP8 programme, BIS should push for some changes to be made in the shorter term to FP7.

Question 35: Should the programme move away from a cost/input-based funding model to one based more on results/outcomes/performance?

While results / outcome / performance based funding may be appropriate for some projects, for science projects, the uncertainties associated with scientific research often make it difficult to be as prescriptive in these areas as others in terms of specific outcomes. Similarly, projects should be flexible enough to enable performance to be modified during the course of the project, based on the results received to date. Research excellence should be the focus for support.

Question 36: Should the rules on intellectual property (IP) in FP7 be changed for FP8?

There appear to be sufficient obligations within the Framework Programme Consortium Agreement, as currently drafted, to ensure that knowledge gained from Framework Programme projects is disseminated, exploited and remains accessible to participants for a reasonable period of time.

However, there are a number of ways in which the IP terms in FP7 Consortium Agreements could be improved:

- Recognition within the Consortium Agreement that many universities and medical research charities assign the IP they develop to a Technology Transfer Office (TTO) or commercialisation company. There needs to be an exception to the normal notification of assignment provisions in the Consortium Agreement to provide for this as it is not feasible to provide notification when each piece of IP is created and assigned.
- It is important for universities and medical research charities to be able to sub-license the IP they develop to other academic / charity / not-for-profit entities to ensure that it is widely available for medical research. Provision needs to be made for this in relation to jointly owned IP.
- The extensive rights that are required under background IP (IP that exists before activity on a programme takes place) often makes participants reluctant to commit background IP to a project.
- A maximum time period should be introduced beyond which a party cannot delay another party's publication for the purpose of obtaining IP protection, to encourage rapid dissemination of results.
- Access rights granted to affiliates of participants should be limited to the affiliates listed in a schedule of the Consortium Agreement so that there is transparency regarding which entities are permitted to use their IP.
- Information which is disclosed orally should not be required to be reduced to writing to constitute confidential information. Given the level of interaction between researchers, it is generally not practical to confirm all oral disclosures in writing (and imposing such an administrative burden could negatively impact on the conduct of the research programme).

Recommendation: The arrangements for intellectual property rights need to be further clarified.

These issues are subject to negotiation between the partners. However, we believe that Framework Programme participation could be encouraged by ensuring that IP provisions are acceptable to all parties and that the process for negotiating the Consortium Agreement is streamlined as much as possible. Revision of the template Consortium Agreement to reduce the current ambiguities will in turn reduce the number of amendments that need to be made to the agreement for each project and will therefore be important in ensuring that time-to-contract is minimised.

If the bureaucracy of the Framework Programme was reduced through a revised Consortium Agreement, which addressed the current ambiguities and did not require as much amendment to be acceptable to all parties, then more businesses and other organisations may be encouraged to participate in the Program.

Recommendation: The Consortium Agreement template should be revised to reduce the number of amendments required for each new project.

Question 39: How effective are the current UK support services?

We have found the UK support services are effective and helpful but more could be done to encourage further participation in FP8**.** The organisations that are experienced in securing EU funding are successful in their applications, and suitably aware of the required process, but those that are not clear of the process are unnecessarily apprehensive. In particular, more activities should be undertaken across the UK (by a number of organisations including support services, industry groups and academic organisations) to increase awareness and understanding of opportunities for FP funding, how to apply and sharing examples of experience and best practice.

The Marie Curie and ERC application processes seem to be working well. From an administrative point of view a fair degree of bureaucracy is expected, but staff at the EU Research Executive Agency respond to queries helpfully, provided enough time is allowed for a response. Unfamiliarity with the bureaucracy is a key deterrent from seeking EU funding. It would also be useful for support services to better educate UK researchers on the wider European Community objectives that need to be addressed in scientific projects to qualify for FP finance, as UK scientists tend to apply for grants on scientific merit alone.

Question 41: Are there any lessons from other countries that could help raise UK participation?

Other countries have better involvement in FP7, and we should look to them to see how they support this. We have found that some of the most successful applicants for EU funding within the UK are scientists who come from elsewhere in the EU (e.g. Austrian, Italian). These researchers often have more diverse EU networks and are more familiar with EU administrative processes. The UK has a well established framework for research funding in comparison to many other EU countries but this should not mean that we do not suitably access EU funding to help further develop and retain an excellent research base which benefits the UK and EU.

If you have any queries or would like to discuss the comments raised in this response, please contact layla.theiner@cancer.org.uk.

Submission details

Name: Layla Theiner
Organisation: Cancer Research UK
Address: Angel Building, 407 St John Street, London EC1V 4AD
Affiliation: Major research charity

Please acknowledge this reply.

At BIS we carry out research on many different topics and consultations. As your views are valuable to us, would it be okay if we were to contact you again from time to time either for research or to send through consultation documents? Yes