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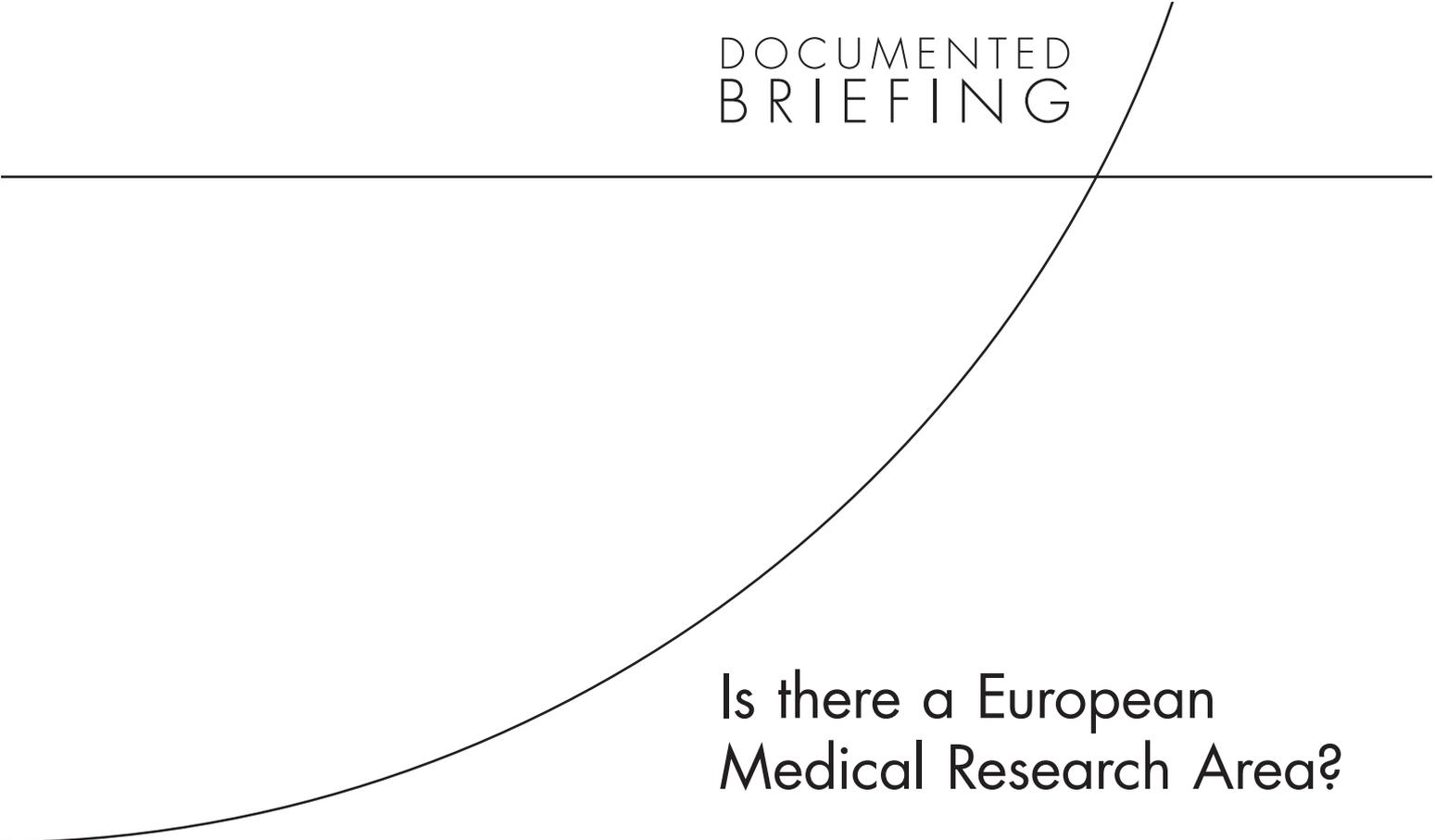
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BRIEFING



Is there a European Medical Research Area?

Observatory on
Health Research Systems

Emmanuel Hassan, Susan Ella Kirk

Prepared as part of
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Preface

This documented briefing provides an overview of the European Research Area and explores whether such an integrated research area exists in health and biomedical research. The report is published as part of RAND Europe's Observatory on Health Research Systems, supported by the Department of Health (England).

The report is divided into four parts. The first part, 'The European Research Area at a glance', outlines the principle of a European Research Area and measures which have been introduced to encourage this to develop. The second part, 'Funding and performance of European medical research', outlines the current status of medical research in Europe in comparison to other regions, particularly the USA. The third part, 'National and institutional barriers in European medical research', looks at the key challenges to the development of a European Research Area in biomedical research. The fourth part, 'Strengthening European medical research', explores measures which have been taken already to begin to break down some of these barriers as well as what still needs to be done to realise a European Research Area.

The report is based on desk-based document review and does not attempt to discuss current policy options or make recommendations for future strategy. The report will be of interest to government officials dealing with health and medical research policy, medical research councils, health and medical research charities, public and private institutions engaged in health research and researchers.

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Summary

Summary: Key Points

- A European Research Area is a unified area which allows increased collaboration across countries and better use of resources
- The concept was developed by the European Commission, but most progress towards its realisation has been made since the programme was relaunched in 2007
- Public funding for medical research is lower in Europe than in the USA
- The scientific impact of European medical research is low
- A number of barriers to the progress of medical research in Europe have been identified:
 - research infrastructure;
 - unattractive working conditions;
 - inflexible and fragmented funding provision;
 - complex and varied regulatory environment.
- Programmes such as Joint technology initiatives and Joint Programming have been introduced and these schemes have begun to tackle some of these issues
- However, more work needs to be done to establish a European Research Area in biomedicine, focusing on the barriers identified

This documented briefing outlines the principle of a European Research Area (ERA) and analyses the medical research field in Europe to see if this has been established. It explores the main challenges to forming such a unified research area in Europe, and outlines the measures that have been taken to address these issues.

An ERA is a unified research area across the European Union (EU) that enables:

- mobility of and collaboration between researchers;
- knowledge-sharing; and
- optimal use of available resources through effective use of infrastructure and coordinated national and regional research programmes.

In addition, an ERA acts as a major player on the world stage, interacting with other research centres and influencing the international agenda.

The idea was introduced originally by the European Commission (EC) in 2000, but was relaunched in 2007 due to changes in the broader international context and in order to boost progress towards its aims. Since this time, a number of initiatives have been developed to move towards these goals, particularly in terms of developing financial and research collaboration across Member States and between the public and private sectors.

In comparison to research undertaken internationally, and particularly in the USA,¹ European research receives significantly lower levels of funding, investing only 1.8 percent of gross domestic product (GDP) in research compared to 2.7 percent in the USA in 2007. This R&D funding gap between the USA and the EU did not decrease since 2000.

This R&D funding gap between the USA and the EU is also apparent in biomedical research. Moreover, the scientific impact of the EU in biomedical research is low at the world level. Finally, there are also signs of a growing innovation gap between the USA and the EU.

A number of key barriers to strengthening biomedical research in Europe have been identified:

- **research infrastructure** – the current system does not facilitate collaboration and multidisciplinary work or translation of research from bench to bedside;
- **working conditions** – conditions are not as attractive as conditions in the USA, largely due to significantly lower levels of pay, but also due to more limited opportunities for young researchers to progress and lower levels of mobility both within the EU and between the public and private sectors;
- **funding** – funding tends to be dispersed and uncoordinated in the EU. Centralised funding from the EU is not significant, with most Member States preferring to distribute funding on the national level to meet their own research priorities. In addition, levels of funding are lower than that of competitors such as the USA;
- **regulation** – regulation of clinical trials in the EU is complex and differs between Member States. A more unified, streamlined approach would facilitate research progress.

A number of measures have been introduced to target these issues and overcome barriers to research, which include the following.

- **Seventh Framework Programme** – the EC's current funding programme for research. Health research forms a significant portion of this, under the 'cooperation' element of the programme.
- **Joint Technology Initiatives (JTIs)** – these provide a new mechanism for public-private partnerships in areas of strategic importance. One initial example is the Innovative Medicines Initiative to facilitate cooperation between industry and academia on work related to biopharmaceuticals.
- **Joint Programming** – this facilitates multinational collaboration in areas where this approach could provide significant additional benefit. One such example which has been initiated is neurodegenerative diseases.

¹ Throughout the document, we compare the EU to the USA not only because they have comparable size in terms of inhabitants but also because the USA is recognised often as the world-leading nation in medical research and drug development.

Despite this progress, much still needs to be done in order to build an ERA in the biomedical sciences. A recent White Paper published by the European Science Foundation (2007), reflecting the view of European medical research councils, outlines some measures which could be taken to achieve this, focusing on measures to leverage assets in four key areas:

1. **people** – recommendations reflect the need to attract the best researchers to European institutions and provide strong career opportunities for them within Europe. Appropriate career progression and training, together with the highest standards for the way in which research is conducted, are suggested to help to achieve this;
2. **research infrastructure** – the need to avoid duplication is considered to be critical, as well as standardisation in order to facilitate collaboration and avoid bureaucratic and procedural issues which could slow the progress of scientific discovery;
3. **research funding** – the key suggestion is to make sure that sufficient funding is distributed to the right people, and to ensure that researchers are operating on a level playing field by establishing standards for what constitutes good-quality research;
4. **society** – engaging society as a whole in medical research and being aware of the wider context in which research is conducted is considered to be essential for the progression of medical research in the EU.

List of abbreviations

EC	European Commission
EU	European Union
ERA	European Research Area
ERA-NET	Scheme to develop and strengthen the coordination of national and regional research programmes, as part of the EU's Seventh Research Framework Programme
GDP	Gross domestic product
GBAORD	Government budget appropriations or outlays for R&D – A measure of central government support for R&D
JP	Joint Programming – initiative to coordinate research between member states
JTI	Joint Technology Initiative
NIH	National Institutes of Health (USA)
OECD	Organisation for Economic Co-operation and Development
R&D	Research and Development

Introduction

Is there a European Medical Research Area?

Observatory on Health Research Systems



Emmanuel Hassan and Sue Kirk

September 2009

This documented briefing aims to give an overview of the present status and outlook of medical research in the context of a European Research Area (ERA). The first part explains the concept of an ERA, describing its objectives and the initiatives taken by the European Commission and European Union Member States towards its development. The second part describes the present status of medical research in the European Union, comparing medical research funding and performance in the European Union to global levels, with particular reference to the USA. The third part describes national and institutional barriers to the development of an ERA in the field of medical research. The final part outlines initiatives that have been taken by the European Commission and European Union Member States to strengthen European medical research. The briefing concludes by highlighting the recommendations formulated by the European Medical Research Councils for measures that should be taken in order to make the European Medical Research Area a reality.

The European Research Area at a glance

What is the European Research Area?

A unified area all across Europe:

- enabling researchers to move and interact seamlessly, benefit from world-class infrastructures and work with excellent networks of research institutions;
- where European citizens share, teach, value and use knowledge effectively for social, business and policy purposes;
- optimising and opening European, national and regional research programmes in order to support the best research throughout Europe and coordinate these programmes to address major challenges together;
- enabling the development of strong links with partners around the world so that Europe benefits from the worldwide progress of knowledge, contributes to global development and takes a leading role in international initiatives to solve global issues.

Traditionally, research has been funded and managed on a national level. This leads to divisions between research communities within Europe on a number of levels. Therefore, the European Commission (EC) has developed the concept of a European Research Area (ERA), which consists of a unified area across the whole of Europe in which research can take place. There are a number of key features which would be expected of an effective ERA.

First is the mobility and interaction of researchers across the research area. This allows researchers to benefit fully from the infrastructures and facilities which are available across Europe, many of which are world class, and allow researchers to work with a wide network of research institutions. This leads to cross-pollination of ideas from experts across the ERA and the best utilisation of the equipment and infrastructure available, minimising duplication.

Second is the unification of the use of knowledge generated across Europe. This includes findings which could have implications for society, business and policy. This requires effective communication of findings and knowledge transfer across the ERA.

Third is coordination between national and regional research programmes in order to minimise duplication and bring together researchers working in different areas, allowing cross-regional funding to take place.

Finally, an ERA would be expected to build strong links with partners in a broader international context, strengthening the position of Europe in research and allowing transfer of knowledge so that Europe can benefit from knowledge developed elsewhere and contribute to issues of global significance.

What is the European Research Area for?

- The creation of a European Research Area was proposed by the European Commission in its Communication *Towards a European Research Area* of January 2000
- The European Research Area should inspire the best talents to enter research careers in Europe
- The objective of creating the European Research Area was endorsed by the European Union shortly afterwards at the March 2000 Lisbon European Council
- The European Research Area should incite industry to invest more in European research – contributing to the EU objective to devote 3 percent of GDP to research, and strongly contribute to the creation of sustainable growth and jobs

The creation of an ERA was first proposed by the European Commission (2000) in its Communication *Towards a European Research Area*, published in January of that year. The Communication took stock of the level of funding of research in the European Union (EU) compared to its main competitors, namely the USA and Japan. In particular, the average research effort in the EU was only 1.8 percent of Europe's gross domestic product (GDP), as opposed to 2.8 percent in the USA and 2.9 percent in Japan, and this gap was increasing.

The purpose of an ERA is to improve organisation of research in Europe. The EC suggests that an ERA should:

- strengthen the network of existing centres of excellence across Europe;
- lead to a more coherent implementation of national and EU research activities;
- make better use of instruments and resources to boost investment in research and development (R&D);
- increase the stock of researchers and their mobility within Europe;
- improve the attractiveness of Europe for research; and
- promote common social and ethical values in scientific and technological matters.

The objective of creating an ERA was endorsed by the EU shortly afterwards at the March 2000 Lisbon European Council. Its creation was a key component of the Lisbon Strategy set by heads of state and government, making Europe the most competitive and dynamic knowledge-based economy in the world.

The ERA initiative has since been a central pillar of research policy in the EU, complementing the objective set by the March 2002 Barcelona European Council to increase R&D investment in the EU to 3 percent of GDP by 2010 (European Commission, 2002a).

What progress has been made so far?

- The EU Research Framework Programme is explicitly designed to support the creation of the European Research Area
- Initiatives such as European Technology Platforms, Joint Technology Initiatives and ERA-NET have been launched to improve the coordination of research activities and programmes
- Policy coordination in R&D is addressed through the Open Method of Coordination and the use of voluntary guidelines and recommendations
- The EU has adopted a broad-based innovation strategy, whose purpose is to improve the framework conditions for research and innovation
- EU cohesion policy and its financial instruments – the Structural Funds – give strong priority to the development of research and innovation capacities, particularly in less developed regions

Since 2000, several important measures have been introduced at EU level in order to aid development of an ERA.

The EU Framework Programme for research and technological development is designed explicitly to support the creation of the ERA. Framework Programmes have been the main financial instruments through which the EU supports R&D activities, particularly through cross-country scientific collaborations in almost all scientific disciplines. Framework Programmes can be proposed by the EC and are then adopted by the Council and European Parliament.

New initiatives launched in conjunction with the Seventh Research Framework Programme (2007–2013) are expected to have an important impact on the European research landscape. Created in 2007, the European Research Council is the first European funding body set up to support investigator-driven frontier research in the EU and stimulate excellence through competition. Endorsed in 2008, the European Institute of Innovation and Technology is an EU initiative whose mission is to stimulate innovation through the creation of integrated ‘Knowledge and Innovation Communities’, partnerships between universities, research organisations, companies and other innovation stakeholders.

First introduced in a Commission Communication of December 2002, *Industrial Policy in an Enlarged Europe* (European Commission, 2002b), European Technology Platforms concentrate on key issues where achieving Europe’s future competitiveness depends upon major technological advances (e.g. aeronautics, nano-medicine, road transport, chemistry, nano-electronics). These platforms bring together stakeholders, led by industry, to set medium to long-term R&D objectives and develop an action plan. They play a key role in

ensuring adequate research funding on areas of industrial relevance, by covering the whole economic value chain and mobilising public authorities at national and regional levels. In fostering public–private partnerships, European Technology Platforms contribute significantly to the development of a European Research Area. Arising from the work of European Technology Platforms, Joint Technology Initiatives (JTIs) (European Commission, 2005a) are initiatives to support transnational cooperation in key areas where R&D can contribute to European competitiveness and quality of life. In a small number of cases, European Technology Platforms have achieved such an ambitious scale and scope that they require the mobilisation of high levels of public and private investment as well as substantial research resources to implement important elements of their research action plans. JTIs can receive additional funding from the EU’s Research Framework Programme, and possibly loan finance from the European Investment Bank. Identified by the EU’s Seventh Research Framework Programme, JTIs have been proposed as an effective means of meeting the needs of this small number of European Technology Platforms.

The ERA-NET scheme aims to develop and strengthen the coordination of national and regional research programmes and thereby reduce fragmentation across the ERA. Under the ERA-NET scheme, national and regional authorities identify the research programmes that they wish to coordinate or open up mutually. The scheme also enables national systems to take on tasks collectively that they would not have been able to tackle independently. In a limited number of cases with high European added value, additional EU financial support is made available to aid joint calls for proposals between national and/or regional programmes.

Policy coordination in R&D is realised by the Open Method of Coordination. This method rests on soft law mechanisms such as guidelines, benchmarking and mutual learning, and enables policymakers to exchange ideas on ways to improve their innovation systems.

The EC (2005c) adopted an integrated innovation and research action plan in its 2005 Communication *More Research and Innovation: A Common Approach*, which calls for a major upgrade of the conditions for research and innovation in Europe. The plan launches ambitious initiatives to promote innovation and research, such as:

- redeployment of state aid;
- improved efficiency of intellectual property protection;
- mobilisation of additional funds for research;
- creation of innovation clusters; and
- improvement of university–industry partnerships.

EU cohesion policy and its financial instrument, namely the Structural Funds, give strong priority to the development of R&D, particularly in less developed regions. During the period 2000–2006, Structural Funds support for research, technology, development and innovation amounted to €10.7 billion. For the current 2007–2013 cycle, the amount of Structural Funds allocated for research, technology, development and innovation in the EU is €49.8 billion – i.e. more than €7 billion per annum (European Commission, 2008a).

What remains to be done to build the European Research Area?

- Researchers still see career opportunities curtailed by legal and practical barriers hampering their mobility across institutions, sectors and countries
- Businesses often find it difficult to cooperate and enter into partnerships with research institutions in Europe, particularly across countries
- National and regional research funding remains largely uncoordinated
- Reforms undertaken at national level often lack a true European perspective and transnational coherence

Despite the initiatives taken by the EC and EU Member States since 2000, much work remains to be done to build the ERA.

Researchers still see career opportunities curtailed by legal and practical barriers hampering their mobility across institutions, sectors and countries, despite the initiatives taken by the EC since 2000. The EC (2001, 2003) proposed measures to increase their mobility across the ERA and improve their career development. In 2005 the Commission adopted the European Charter for Researchers and a Code of Conduct for the Recruitment of Researchers (European Commission, 2005b), setting out the roles and responsibilities of researchers and their employers and funders, and ways to make recruitment fairer and more transparent. The 'scientific visa' package adopted in 2005 aimed to allow fast-track admission and residence of Third Country researchers. Researchers' mobility and careers were supported by funding from the Sixth Research Framework Programme. These initiatives have yielded results, but progress remains slow. Take-up of the voluntary charter and code has been limited and several Member States still have not implemented the directive of the scientific visa package. Existing policies tend to address issues in relative isolation, or take a narrow national perspective.

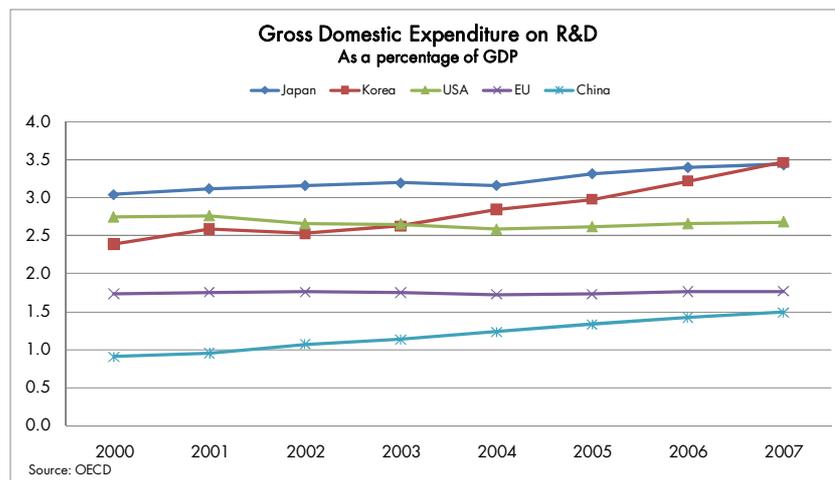
Firms often find it difficult to cooperate and enter into partnerships with research institutions in the EU, particularly across countries (European Commission, 2007).

National and regional research funding remains largely uncoordinated. Despite the introduction of the ERA-NET scheme, EU Member States have remained reluctant to restructure their R&D programmes to allow Joint Programming, leading to national and Community policies being developed in relative isolation from each other. Member States

do not appear to feel a sense of ownership of the ERA initiative and attribute its ownership largely at Community level. As such, the ambition of restructuring the European research fabric – of which national policies are the main components – with a view to addressing fragmentation and avoiding costly duplication of efforts, remains far from being achieved. The overwhelming majority of national policy efforts (and national funding) in all Member States remain driven mostly by national considerations, with the ultimate aim of making the national R&D system competitive on the international scale in its own right.

A new international context for the European Research Area

- Globalisation of research and technology is accelerating and new scientific and technological powers – China, Korea and other emerging economies – are attracting considerable and increasing amounts of R&D investments



Since 2002, the international environment for science and technology has changed dramatically. Emerging scientific and technological players such as China, India and Korea have increased their relative financial efforts devoted to R&D continuously.

In 2007, R&D intensity – that is, R&D investment as a percentage of GDP – amounted to 1.5 percent and 3.5 percent in China and Korea, compared to 0.8 percent and 2.4 percent respectively at the beginning of the decade. During that period, R&D intensity in the EU remained almost unchanged, averaging 1.8 percent in 2007.

The 2007 vision of the European Research Area

- Realising a single labour market for researchers to enable an adequate flow of competent researchers across countries
- Developing world-class research infrastructures to perform excellent research
- Strengthening research institutions to stimulate business R&D investment in Europe
- Sharing knowledge in order to improve knowledge transfer between public research and industry
- Optimising research programmes and priorities to increase the efficiency and impact of public funding
- Opening the European Research Area to the world in order to foster international cooperation in science and technology

Given the slow progress made towards implementation of the ERA and the new international context for research in science and technology, the EC decided to relaunch its initiative, giving it a new vision. In 2007, the EC published a Green Paper, *The ERA: New Perspectives* (European Commission, 2007), which proposed directions to deepen and widen the ERA so that it fully contributes to the Lisbon Strategy.

According to the EC, the ERA should have the following features:

- an adequate flow of researchers who can enter, with attractive working conditions, and move easily across institutional sectors and scientific disciplines;
- world-class research infrastructures that are open to EU and non-EU researchers and integrated through new generations of electronic communication infrastructures;
- excellent research institutions involved in durable public–private partnerships and linked into clusters through ‘virtual research communities’;
- effective knowledge-sharing, making public knowledge accessible to researchers, industry and society as a whole with an effective intellectual property regime;
- well-coordinated research programmes and priorities, avoiding research fragmentation and allowing knowledge transfer between EU countries; and
- a wider international perspective.

The European Research Area Partnership: 2008 initiatives

- The Ljubljana Process and 2020 ERA Vision aim to enhance the governance of the European Research Area
- The initiative on the management of intellectual property in knowledge transfer has the objective of facilitating and promoting the use of intellectual property created in universities and public research organisations
- The European Partnership for researchers constitutes a common framework and timeframe for improving both researcher career prospects and mobility
- The proposed Regulation for a legal framework for European research infrastructures intends to facilitate the establishment of large-scale research infrastructures
- Joint Programming is an initiative to tackle common European challenges in a few key areas by pooling national research efforts
- The Strategic European Framework for International for Science and Technology Cooperation proposes a new partnership to strengthen the international dimension of the European Research Area

Since the publication of the Green Paper, the EC and the European Council have taken several initiatives aimed at realising an ERA (European Commission, 2009a). These initiatives address:

- researchers' careers and mobility;
- research infrastructures;
- knowledge-sharing; Joint Programming; and
- international science and technology cooperation.

They aim to establish durable partnerships with Member States and stakeholders – including business, universities and research organisations – to develop the ERA jointly in their specific areas of focus.

The European Council and the EC have decided to enhance the overall governance of the ERA based on a partnership between the EC and Member States, entitled the Ljubljana Process. It was formally launched by a Council Conclusion adopted in May 2008 (Council of the European Union, 2008a). The enhanced governance of ERA is based on a shared 2020 ERA vision (Council of the European Union, 2008b) which the EC and Member States agreed in December 2008, and which strikes a balance between ambition and pragmatism. It includes a clear mission statement for establishing the Fifth Freedom across the ERA: free circulation of researchers, knowledge and technology.

In April 2008, the EC adopted a recommendation (European Commission 2008b) concerning policy guidelines for Member States on the development or updating of

national guidelines and frameworks, and a code of practice for universities and other public research organisations on improving the way that they manage intellectual property and promote knowledge transfer.

The European Partnership for Researchers constitutes a common framework and timeframe for improving both researcher career prospects and mobility. The EC adopted a Communication to launch the initiative in May 2008 (European Commission, 2008c). Improving the mobility of researchers should enhance diffusion of knowledge throughout Europe, balance demand and supply for researchers at European level, help to create centres of excellence and improve the skills of researchers in Europe. Improving career prospects for researchers in Europe can help to stimulate more young people to embark on a research career, retain researchers in Europe and attract more talented non-European researchers. The partnership will aim to accelerate progress in key areas including social security, competition-based transnational recruitment and portability of funding, employment and working conditions and training and skills.

The Regulation for a legal framework for European research infrastructures proposed by the EC in June 2008 (European Commission, 2008d) intends to assist EU Member States in developing and funding pan-European infrastructures, since the available national and international legal forms are not adequate for rapidly establishing the increasingly complex and expensive infrastructures required for European research.

In July 2008, the European Communication proposed a new approach, namely Joint Programming, to tackle more effectively common European challenges in a few key areas. Joint Programming is a structured and strategic process whereby Member States will agree, through a voluntary and 'à la carte' process, common visions and strategic research agendas to addressing major societal challenges. The aim is to foster a structuring effect so as to increase the efficiency and impact of public research funding.

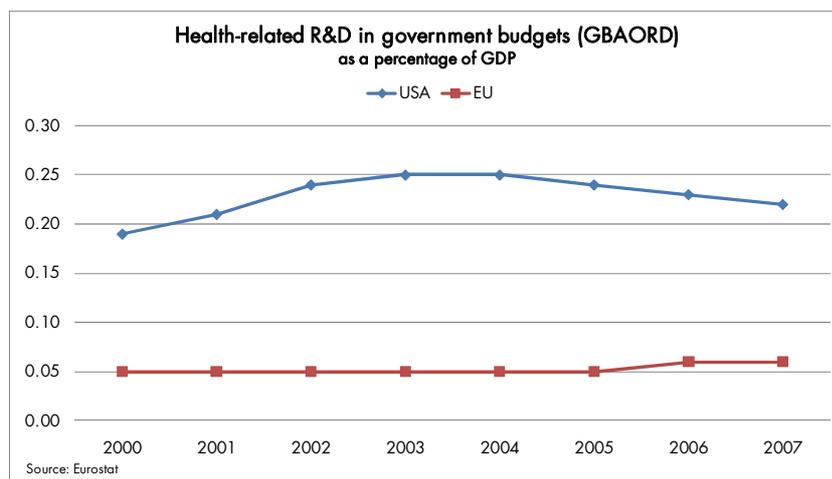
In September 2008, the EC proposed a Strategic European Framework for International Science and Technology Cooperation (European Commission, 2008e), which is a new partnership to strengthen the international dimension of the ERA in order to improve the framework conditions for international science and technology cooperation and promote European technologies in the world. International cooperation in science and technology embodies the Fifth Freedom: the free circulation of knowledge at a global level. It also promotes political cooperation, dialogue and trust.

Funding and performance of European medical research

This briefing has outlined the basic principles of an ERA and initiatives which have been introduced in order to facilitate its development. This section explores the current state of research in the biomedical field in Europe, in terms of both its performance and funding support, in order to establish the extent to which an ERA exists in this field at present as well as any areas where work is needed to develop the research field.

Direct government support for medical research in Europe

- Direct government support for health-related R&D is substantially lower in the European Union than in the United States



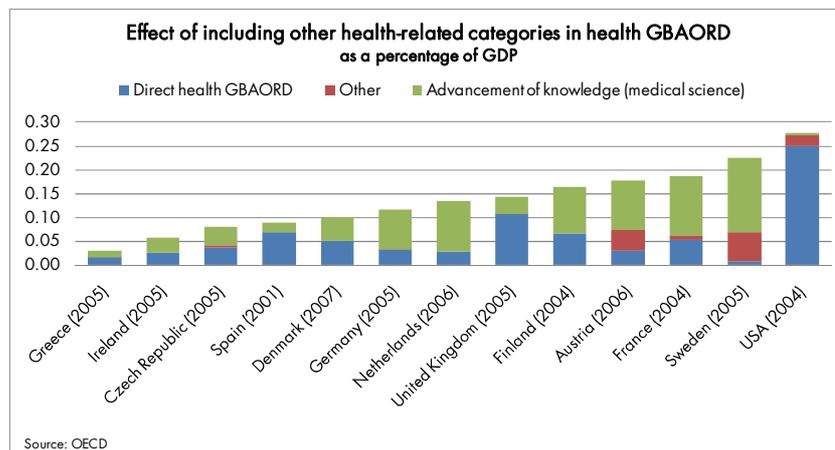
There are no official international comparable data on medical research funding. One way to proxy medical research funding is to measure health-related R&D. The data on central government support for R&D are derived from budgets and are referred to as government budget appropriations or outlays for R&D (GBAORD). GBAORD can be broken down by socio-economic objectives, such as the protection and improvement of public health, which is defined as follows:

This category covers research aimed at protecting, promoting and restoring human health broadly interpreted to include health aspects of nutrition and food hygiene. It ranges from preventative medicine, including all aspects of medical and surgical treatment both for individuals and groups and provision of hospital and home care to social medicine and paediatric and geriatric research. (Organisation for Economic Co-operation and Development (OECD), 2002)

The GBAORD health category is used here as a proxy for total central government funding of health-related R&D. In 2007, direct support for health-related R&D represented more than 0.22 percent of GDP in the USA, compared to 0.06 percent in the EU. This funding gap for health-related R&D between the USA and the EU has remained relatively stable since 2000.

Other government support for medical research in Europe

- The funding gap between the United States and the European Union is less dramatic when adjusting for institutional differences in the funding of health-related R&D



Although the data on direct government support to health-related R&D reveals a substantial funding gap between the USA and the EU, it should be noted that such data only cover programmes for which health is the primary objective. Furthermore, the classification of programme and institutional funding depends on how governments present their R&D priorities as well as the formal mandate of the institutions concerned. For example, long-term research may be the responsibility of a medical research body classified in health objectives (e.g. the National Institutes of Health (NIH) in the USA) or of a general research council whose funds are awarded mainly for non-oriented research (e.g. the National Council for Scientific Research in France). Arrangements for funding R&D in hospitals also vary between countries (OECD, 2007).

To address some of these limitations and build a more complete picture of health-related R&D, funding via non-oriented research and general university funds are included in the chart above where available, as are other relevant funds (e.g. R&D support in hospitals).

When data from additional GBAORD categories are used to adjust for institutional differences in the funding of health R&D, a different picture emerges. The USA is no longer an outlier: health-related R&D budgets relative to GDP approach that of the USA in a number of European countries, owing to the important contribution of funding of medical science through general university funds and non-oriented research. With one of the smallest direct government budgets for health-related R&D as a percentage of GDP, Sweden is a case in point.

However, even taking this into account, investment in research is still higher in the USA than in any individual EU country or the EU as a whole.

European medical research output

- The scientific contribution of the European Union in medical research is declining rapidly although it remains higher than that of the United States
- The scientific impact of the European Union in medical research is low despite some improvement over the years
- The United States is increasingly specialised in medical research compared to the European Union

	Scientific publications					
	World share (%)		Relative citation index		Scientific specialisation index	
	2006	Change 06/01 (%)	2006	Change 06/01 (%)	2006	Change 06/01 (%)
EU	36.8	-6	0.96	6	1.10	1
USA	32.0	-3	1.33	-2	1.22	5

Source: OST (2009)

In order to examine medical research output in the EU and compare it with its main competitor, namely the USA, the results of bibliometric indicators are presented here, based on the scientific publications indexed in the Web of Science.

The scientific contribution of the EU in medical research, as measured by its world share in scientific publications, amounted to 36.8 percent in 2006, higher than that of the USA which averaged 32 percent. Despite this good performance in terms of scientific output, particularly given that funding is lower than that in the USA, it is notable that the EU's world share of scientific publications in medical research declined more rapidly than that of the USA between 2001 and 2006.

Moreover, the EU's scientific contribution should be viewed in relation to its scientific impact, which can be measured by its relative impact index.² In 2006, the relative citation index of EU publications in medical research was slightly lower than 1 (0.96). This means

² The relative impact index of an actor (institution, country, etc.) in a given period of time and within a given frame of reference (world, for example) proportional to the actor's expected impact index for the same period and within the same frame of reference. It expresses the individual impact of publications compared to the average impact of the journals where the publications appeared. For a given actor, it shows whether they are cited more or less than the average of the journals in which the actor's publications appear. It is an indicator that takes into specific account the choice of journals by the actor for its publications, and it enables an actor to identify possible overvisibility or undervisibility of its publications compared to the journal overall. When the index is greater than 1, the actor enjoys a greater visibility than the average of all articles published in the journals in which its articles appear.

that the EU publications in medical research had a lower visibility than the average of all publications in the journals in which its publications appear. During the same period, the relative citation index of American publications in the field was higher than 1 (1.33), indicating that its publications had a greater impact than all the publications in the same journals.

In addition, the USA is specialised increasingly in medical research compared to the EU, as measured by the ratio of its world share of publications in this field to its world share in publications in all fields. In 2006, the scientific specialisation index of the USA in medical research was 1.22, compared to 1.10 for the EU.

R&D investment in the European pharmaceutical industry

- R&D investment by the top 20 EU R&D pharmaceutical investors represents less than half of the R&D investment by the top 20 non-EU investors
- Although the top 20 EU and non-EU pharmaceutical investors show comparable R&D intensities, there are sharp differences when considering the top 50 EU and non-EU pharmaceutical investors

No	Company	Top EU R&D investors				Top non-EU R&D investors					
		Country	R&D Investment		R&D/Net Sales		Country	R&D Investment		R&D/Net Sales	
			2007	2007	2007	2007		2007	2007		
			€m	%			€m	%			
1	Sanofi-Aventis	France	4,563.0	16.3	Pfizer	USA	5,532.6	16.7			
2	GlaxoSmithKline	UK	4,419.4	14.3	Johnson & Johnson	USA	5,252.9	12.6			
3	AstraZeneca	UK	3,448.6	17.1	Roche	Switzerland	5,010.2	18.0			
4	Boehringer Ingelheim	Germany	1,730.0	15.8	Novartis	Switzerland	4,387.0	16.1			
5	Merck	Germany	1,123.0	13.3	Merck	USA	3,339.7	20.2			
6	Novo Nordisk	Denmark	996.4	17.8	Eli Lilly	USA	2,384.8	18.7			
7	UCB	Belgium	781.0	21.5	Bristol-Myers Squibb	USA	2,244.8	16.4			
8	Shire	UK	354.8	21.3	Wyeth	USA	2,227.5	14.5			
9	Lundbeck	Denmark	293.3	19.9	Schering-Plough	USA	2,001.3	23.1			
10	Nycomed	Luxembourg	264.8	7.6	Abbott Laboratories	USA	1,713.8	9.7			
11	Ipsen	France	174.9	17.6	Takeda Pharmaceutical	Japan	1,183.5	14.8			
12	Elan	Ireland	155.7	44.1	Daiichi Sankyo	Japan	1,044.6	18.4			
13	Almirall	Spain	101.4	12.8	Astellas Pharma	Japan	1,028.2	18.2			
14	Gedeon Richter	Hungary	71.5	8.1	Eisai	Japan	663.0	16.1			
15	Krka	Slovenia	59.1	7.6	Allergan	USA	491.2	18.1			
16	Zeltra	Spain	51.7	60.8	Forest Laboratories	USA	458.9	19.2			
17	Stada Arzneimittel	Germany	49.2	3.1	Teva Pharmaceutical Industries	Israel	397.4	6.2			
18	Recordati	Italy	49.1	7.8	Cephalon	USA	252.5	20.8			
19	Mundipharma Research	UK	47.2	78.6	Dainippon Sumitomo Pharma	Japan	250.2	15.6			
20	NicOx	France	46.1	219.6	Shionogi	Japan	229.3	18.8			

Source: European Commission (2008f)

Not only is the EU lagging behind the USA in terms of public funding for medical research, but R&D investment made by the private sector, especially the pharmaceutical industry, is also significantly lower.

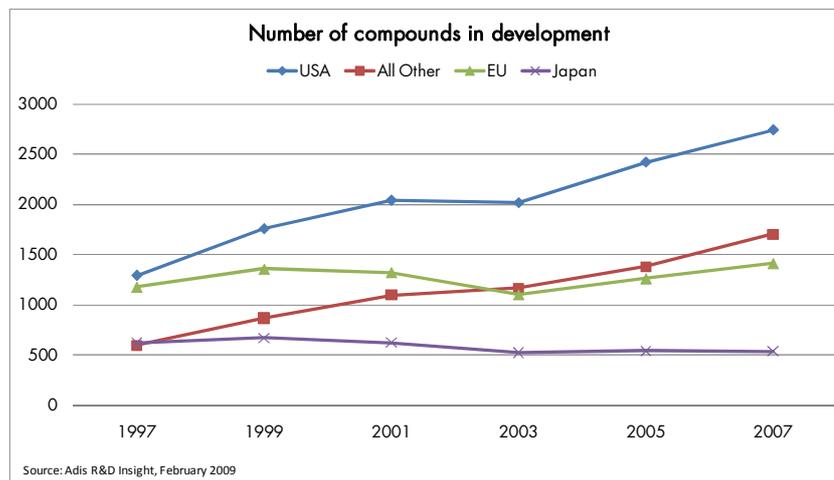
Because official internationally comparable statistics on business R&D in the pharmaceutical industry are not systematically available across the EU, R&D statistics are presented here, extracted from the 2008 EU Industrial R&D Investment Scoreboard (European Commission, 2008f). This presents information on 2,000 companies from around the world, reporting major investments in R&D. The set of companies that it covers comprises the top 1,000 R&D investors whose registered offices are in the EU and the top 1,000 registered elsewhere. The figures are derived from company accounts and indicate the R&D invested by companies' own funds, independent of the location of the R&D activity. Therefore this can be considered only a rough proxy for R&D spent in any particular location.

R&D investment made by the top 20 EU R&D pharmaceutical investors totalled €18,780 million in 2007 compared to €40,093 million for the 20 non-EU R&D pharmaceutical investors.

While the top 20 EU and non-EU R&D pharmaceutical investors showed a comparable R&D intensity in 2007 averaging 15.5 percent, there were sharp differences when considering the top 50 EU and non-EU R&D pharmaceutical investors. The R&D intensity of the top 50 EU R&D investors was only 8 percent in 2007, compared to 15.4 percent for the top 50 non-EU R&D pharmaceutical investors.

Innovative performance of the European pharmaceutical industry

- EU pharmaceutical companies are increasingly lagging behind the US in terms of innovative performance, as shown by the number of compounds in development



In addition to the R&D funding gap between the USA and EU in medical research, there is a growing innovation gap. American pharmaceutical companies outpace EU companies in terms of innovative performance, as shown by the number of compounds in clinical trials or awaiting approval. In 2007, American pharmaceutical firms had more than 2,700 such medicines, while in the EU there were only around 1,400 compounds in development.

These findings support the established viewpoint that the USA outperforms Europe in drug discovery and pharmaceutical research (European Federation of Pharmaceutical Industries and Associations, 2009; Grabowski and Wang, 2006). However, a recent publication disputes this, suggesting that the USA never overtook Europe in research productivity, and that Europe actually is outstripping the USA when comparing the number of new chemical entities approved for use (Light, 2009).

The conflict between these conclusions arises from a different measure being used for performance. In fact, when considering either of these measures, it is important to take time lag into account. There is an average time lag of 17 years for research to be translated into treatments (Buxton et al., 2009). Therefore, the measure used by Light, of treatments approved for use, may reflect the performance of research almost two decades ago. Moreover, looking at medicines in clinical trials or awaiting approval will reflect research done significantly earlier. It is notable that it is only in recent times that the USA has overtaken the EU in terms of research funding. Therefore, it is likely that neither of these measures give an accurate picture of current research performance.

National and institutional barriers in European medical research

The previous section described the current state of biomedical research in Europe, highlighting the underfunding and arguable underperformance of research according to some measures in comparison to international competitors, particularly the USA. This section outlines some of the national and institutional barriers that exist, which may block the development of a ERA and lead to some of the limitations described previously.

Research infrastructure

- The research infrastructure for medical research in the European Union does not facilitate collaborative and multidisciplinary research and its translation from the bench to bedside

USA	European Research Area
Decentralised universities. Multidisciplinary and extensive collaboration among the various parties already routinely embedded and represent an asset in moving biomedical research from discovery to commercial development and developing integrative ('bench to bedside' and vice versa) and relational capacity (public/private partnerships).	Centralised with hierarchical control and mainly public universities. Single field orientation and need for multi-sites collaboration to integrate all competencies required to develop new medicines. Reliance on scientific programming to create an adequate environment for translational research.

Source: European Science Foundation (2007)

As a specialist in biomedical research, the USA is ahead of the EU in terms of practice and methodologies in the field of biomedical science (European Science Foundation, 2007). Furthermore, the USA has adopted a decentralised research system with a wide range of funding sources, in contrast with the tightly administered European system, which limits the flexibility often crucial to effective research (Chu, 2004; Riccaboni et al., 2004). However, it is also worth noting that this may differ at the national level within the EU, as there are some countries that fall within the world-leading category, which could be used as models of best practice to stimulate developments in the European research system.

Moreover, the USA is more effective in transferring research developments into commercial products. The EU is less effective in the commercial exploitation of its research findings. Part of this may be due to the way in which the USA has generated clusters of excellence around universities and other public research institutions which integrate research with innovation and development. High-tech companies use such clusters to build on that knowledge environment and utilise the profusion of highly-qualified researchers and students. This is reflected in a higher number of research outcomes such as patents and publications in the USA. Indeed, it is notable that American companies not only take out more patents than EU companies in the USA, they also dominate the European patenting process, taking out more European patents than European companies.

The key barriers to investment in research by industry in Europe are issues over the ownership of intellectual property, for which there are well-defined protocols in the USA, and a lower level of spending on healthcare in general (Sheridan, 2006).

People

- Biomedical researchers in the European Union are not sufficiently autonomous and mobile and their working conditions are not attractive

USA	European Research Area
More research independence and mobility of faculty members at early career stage. High salaries for scientists. Incentives to increase the physician-scientists population. Promotion of entrepreneurship early in the education system.	Limited autonomy and mobility for younger researchers. Low salaries. Limited examples of initiatives to increase the physician-scientists population.

Source: European Science Foundation (2007)

The number of physician-scientists has been dwindling in both the EU and USA and this is a recognised issue which has been targeted through a number of schemes in both regions. The USA developed a number of schemes during the period 1998–2002, largely through the NIH, in order to attract more students to medical research, utilising financial stimuli such as grants and loan reductions. Europe’s efforts to tackle this issue began around five years later, and generally were introduced at Member State level. These programmes generally have a more theoretical rather than financial approach. Due to their later introduction, it is hard to quantify the success of EU programmes; however, in the USA the measures seem to have had some impact and now the number of scientists is beginning to increase.

At present, salaries are significantly higher in the USA (up to three times that for a similar position in the EU), which has led to a ‘brain drain’ in which many qualified European scientists move to America to continue their research career after their doctorates, with many never returning home (Chu, 2004). Furthermore, opportunities are generally more limited in the EU, with young scientists being less mobile and taking longer to reach senior academic positions where they can develop their own research programmes (Riccaboni et al., 2004; Sheridan, 2006).

Attitudes towards industry differ between the EU and USA. American scientists are more eager to patent findings and collaborate with industry. American scientists are also more likely to form spin-out companies, and this greater entrepreneurial spirit is thought to be a result of cultural differences. The European research field would benefit from an increase in innovation and a higher level of collaboration between the public and private sectors in R&D.

Funding

- Funding for biomedical research in the European Union is dispersed and uncoordinated, reinforcing research fragmentation

USA	European Research Area
Diverse sources (public/private): I) Substantial public R&D funds administered through the NIH (\$28.4 billion 2007) supports basic (60%) and translational & clinical (40%) research and allocated through a stringent peer review based on excellence; II) Alternative and complementary sources.	National and European public sources: I) Nationally-dispersed funding (data not available); II) EC funding by DG Research for cooperation in health priority (€6.1 billion for the period 2007–2013).

Source: European Science Foundation (2007)

Compared to the USA, European biomedical research is underfunded, particularly in the field of clinical research. The EU15 spend 1.99 percent of GDP on clinical research, compared to 2.76 percent in the USA (Sheridan, 2006), and investment has seen an overall shift towards non-clinical research. It is unlikely that the EU will meet its target of spending 3 percent of GDP on research and development; at present only Finland and Sweden have met these targets, and annual increases in spending will have to double across the EU if this target is to be achieved (Chu, 2004; Soteriades and Falagas, 2005). The difference in research spending with the USA is even starker in real terms, and the EU lags behind in terms of the number of researchers and PhD graduates in the workforce.

In addition, approaches to funding are markedly different. EU funding tends to be centralised, although approaches differ significantly between countries. However, one clear trend is the tendency of American programmes to foster interaction between basic and clinical researchers, which is not as common in the EU. For example, institutions such as the NIH in the USA provide significant funding to support the interaction of clinical and basic biomedical researchers (Riccaboni et al., 2004). This can improve research translation from bench to bedside, and help improve the targeting of research towards issues of clinical relevance.

Regulation

- Regulation of medical research is important for the protection of both researchers and patients. However, this regulation differs substantially between member states, which is a blocker to a unified research area.

USA	European Research Area
One unified system of regulation.	Different regulations between countries. Additional regulation at the EC level. High level of bureaucracy.

Source: European Science Foundation (2007)

The complexity of EC and national regulations regarding investigator-driven clinical trials inhibit the progress of medical research in the EU. Investigator-driven clinical trials include a range of trials such as proof of concept studies, comparison of diagnostic and therapeutic interventions and surgical therapies, thereby spanning a much broader scope than industry-driven clinical trials.

Legislation regarding clinical trials is often complex and differs between Member States, which is a particular challenge in the case of multi-centre trials. These regulations are necessary to protect both patients and researchers, but simplification and streamlining could further the progress of research and make the EU a more attractive prospect for conducting such work. By comparison, the USA is subject to one common set of regulations for investigator-driven clinical trials which simplifies the research process, and there is no additional level of bureaucracy created by the division between the Commission and national governments.

The EC could improve this by assessing the impact of existing directives related to medical research, with the aim of improving ease of collaboration while maintaining patient safety. Some work has been done in this area, but a lot more is needed. Many of the limitations of the current EC legislation are due to the EU's origins as an economic community. Much of the legislation in place was drawn up from an economic perspective, without the input of non-commercial organisations such as medical research councils, hospitals and universities. This is in contrast to Member State-level legislation, which generally was drawn up with health and research concerns in mind.

Following a series of workshops, and a consensus conference in 2008 at which national research councils established common ground, the European Science Foundation

developed a set of 26 recommendations for the further development of clinical trials in Europe. The top five of these, as ranked by the consensus conference, and hence approved by national funding councils, were as follows:

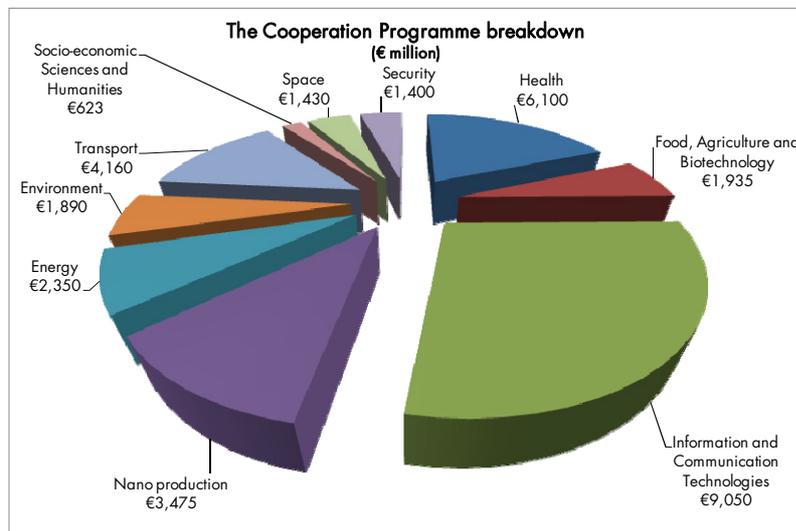
1. to improve the education, training, career structure and opportunities for scientists involved in patient-oriented clinical research;
2. to increase levels of funding for investigator-driven clinical trials;
3. to adopt a risk-based approach to the regulation of investigator-driven clinical trials;
4. to streamline procedures for obtaining authorisation for investigator-driven clinical trials;
5. to ensure that investigator-driven clinical trials are carried out with an appropriate number of patients to produce statistically reliable results, so that the trials are correctly powered.

Strengthening European medical research

The previous section outlined some of the existing barriers to the development of a biomedical research area in Europe. As a part of the development of an ERA, the EC has suggested a range of initiatives which can be applied to improve collaboration and performance of research. This section outlines where these measures have been applied in the field of biomedical research, and the current progress which has been made as a result. It also discusses further measures that need to be taken to further the development of an ERA in the biomedical sciences.

Health research under the Seventh Framework Programme

- The allocation of funds to health research under the EU Seventh Research Framework Programme, a key pillar for the European Research Area, amounts to €6,100 million



Several efforts have been undertaken by the EU, together with EU Member States, to overcome the aforementioned national and institutional barriers and to strengthen European medical research.

As a key pillar for the ERA, the Seventh Research Framework Programme (2007–2013) can play a crucial role in strengthening European medical research. Its broad objectives have been grouped into four categories: cooperation, ideas, people and capacities. For each objective there is a specific programme corresponding to the main areas of EU research policy. All of these programmes work together to promote and encourage the creation of European areas of scientific excellence.

Health research is a major theme of the Cooperation programme and the EU has earmarked a total of €6,100 million for funding this theme over the duration of Seventh Research Framework Programme. However, this should be compared to USA federal funding for biomedical research, which is significantly larger, amounting to \$28.4 billion in 2007. This is largely because EU Member States prefer to fund research at Member State level and are reluctant to relinquish control of their national research programmes.

The specific programme on Cooperation supports all types of research activities carried out by different research bodies in transnational cooperation and aims to achieve or consolidate leadership in key scientific and technology areas.

Under the Cooperation programme, funding for health research is given to the following activities:

- biotechnology, generic tools and technologies for human health, producing knowledge that will be applied in the area of health and medicine;
- translating research for human health, making sure that basic discoveries have practical benefits and improve quality of life;
- optimising the delivery of health care to European citizens, ensuring that the results of biomedical research ultimately will reach citizens.

The Innovative Medicines Initiative

- In 2007, the European Commission proposes the Innovation Medicines Initiative to reinvigorate the pharmaceutical sector in Europe by boosting investment in R&D and overcoming research obstacles in the development of innovative medicines
- The initiative comprises an original approach to support R&D at the European level, bringing together public and private funds and involving different stakeholders
- The initiative is one of the first Joint Technology Initiatives that have been launched
- Joint Technology Initiatives support collaborative research across Europe in fields of key importance for industrial research, where there are clearly identified common technological and economic objectives
- Joint Technology Initiatives contribute to strengthen the European Research Area by raising European, Member State and private R&D investment in these fields and by avoiding research fragmentation

Proposed by the EC in 2007, the Innovative Medicines Initiative aims to strengthen the innovative performance of the pharmaceutical sector in Europe by increasing R&D investment and overcoming barriers such as research fragmentation in the development of innovative medicines.

The Innovative Medicine Initiative comprises an original approach to support R&D in the EU that brings together public and private funds and involves various stakeholders such as large firms, small and medium-sized enterprises, academia, clinical centres, regulators and patients. The programme will be open to all researchers, provided that they are located within Europe.

By harnessing this range of expertise and experience, the initiative aims to make Europe a more attractive location for industrial investment in biopharmaceutical R&D investment and increase the competitiveness of European research in this field. It also aims to address a range of other issues identified previously, such as the 'brain drain' effect and fragmentation of research expertise in the EU.

This is one of the first JTIs launched in the EU.

A pilot joint programming initiative for neurodegenerative diseases

- In 2008, EU Member States identified neurodegenerative diseases and Alzheimer's, in particular, as an area where a common initiative, using Joint Programming, would offer major added value compared with the fragmented efforts in the European Research Area
- The Council invited the Commission to submit a proposal to prepare the launch of this pilot Joint Programming initiative in 2009
- Countries interested in participating in the pilot Joint Programming initiative would develop a shared vision of research coordination in this area and establish a Strategic Research Agenda
- In December 2008, 10 Member States and one associated country to the EU's Seventh Research Framework Programme have signed a declaration of intent showing their willingness to participate in this pilot initiative
- Since then, 20 other countries have also shown their interest and representatives from 20 countries are currently involved in the setting up of a management structure for implementing this Joint Programming initiative

Neurodegenerative diseases and Alzheimer's in particular, were identified in 2008 as an area where a common initiative, using Joint Programming, would offer significant added value compared with the current efforts in the ERA. This is partly due to the significant burden that these conditions place on health service provision across Europe, which is likely to increase as the population ages. It is also because there has been relatively slow progress in terms of the development of new treatments for these conditions despite significant research investment, largely due to fragmentation of the research effort both between countries and basic, clinical and transitional research and health service providers. The Commission submitted a proposal for a Council Recommendation to prepare the launch of this pilot Joint Programming initiative in 2009, which is expected to be adopted shortly (European Commission, 2009b).

Countries willing to participate in the pilot Joint Programming initiative will work towards developing a shared vision of research coordination in the field of neurodegenerative diseases, and establish a strategic research agenda with an implementation plan. Actions to be undertaken within the Joint Programming framework may include:

- exchanging information on national programmes, research activities and health care systems;
- identifying areas which could benefit from coordination;
- issuing joint calls for proposal;
- pooling resources;
- facilitating transdisciplinarity and cross-sectoral mobility and training;

- exploring the joint exploitation of research infrastructures;
- networking of research centres.

In December 2008, 10 Member States and one associated country to the EU's Seventh Research Framework Programme (Switzerland) signed a declaration of intent showing their willingness to tackle the challenge of neurodegenerative diseases, in particular Alzheimer's, through Joint Programming. Since then, other countries have shown their interest, and currently representatives from 20 countries are involved in the establishment of a management structure for implementing this Joint Programming initiative. More countries will be able to join the initiative later, in accordance with the participation rules of Joint Programming.

The Commission will act mainly as a facilitator and coordinator of activities. Together with Member States, it will explore possible Commission initiatives to assist with the development and implementation of a common research agenda. The Commission can take other initiatives to promote joint programming in this area, such as providing *ad hoc* and complementary measures to support such a pilot Joint Programming initiative. Finally, the Commission will contribute to the implementation of this initiative using existing financial instruments such as the Framework Programme for Research.

The future: what still needs to be done to build a biomedical ERA?

- Progress has been made, but more needs to be done to create a fully unified European Research Area in the biomedical sciences
 - In a White Paper published by the European Science foundation, key goals for the European Research Area were identified.
 - These were:
 - strong basic research
 - strong clinical research
 - strong translational research: bringing basic research knowledge into clinical practice, and vice versa
- With all three of the above being facilitated by interdisciplinary research and public-private partnerships
- To achieve this, they suggest a number of changes should be made to leverage assets in the following key areas:
 - people
 - research infrastructure
 - research funding
 - societal means

As described previously, progress has been made towards the development of an ERA in biomedical science. However, as shown in this report, many areas remain where work needs to be done to establish a fully functioning unified research area. Recently, Member State medical research councils approved a common set of goals and methods of achieving them in order to improve the integration of European medical research. This was published in a White Paper by the European Science Foundation (2007), which identified the following goals for an ERA:

- strong basic biomedical research;
- strong clinical research;
- strong translational research, bringing innovative ideas into clinical practice.

All of these can be facilitated by the development of interdisciplinary research and public-private partnerships.

In order to achieve these goals the Foundation identifies four key assets which can be leveraged, in each case providing a set of possible measures to improve performance and move towards the aforementioned goals.

The first is people, with a range of measures being recommended. One of these is career track schemes: a strategic career development path for academics, with attractive possibilities for researchers taking full advantage of co-funding strategies to improve their career prospects, particularly in terms of mobility across Europe. Also recommended is the development of a European medical scientific training programme for physicians and scientists, scaling up existing successful initiatives in this area. The Foundation stresses the

need for the highest level of research ethics, with no scientific misconduct. These recommendations reflect the need to attract the best researchers to European institutions and provide strong career opportunities for researchers within Europe. Appropriate career progression and training, together with the highest standards for research conducted, will help to achieve this.

The second is research infrastructure, with a number of recommendations made. This includes investment in national and European research infrastructure, covering the whole range from laboratory equipment in basic science laboratories and research facilities in hospitals to the largest pan-European infrastructures, as outlined in the European Strategy Forum on Research Infrastructures road map. The Foundation suggests that the EC should launch a call for proposals to support directly on a highly competitive basis a league of top performing biomedical research centres of excellence, integrated into regional clusters. Further, the Foundation suggests that investment is needed in post-genomic clinical medicine and in the intelligent and coordinated use of information technology. Finally, it identifies a need to address EC and national regulatory issues for clinical research, which need to be adapted to facilitate research. Here, the need to avoid duplication is clearly critical, as well as standardisation in order to facilitate collaboration and avoid bureaucratic and procedural issues which could slow the progress of scientific discovery.

The third is research funding, with two key measures identified. The first is the need for adequate research funding distributed on the basis of scientific excellence and through peer review. The second is an emphasis on the need for this to be supported by a set of common criteria and methods for the evaluation of research outcomes. Here, the key is to make sure that sufficient funding is distributed to the right people, and to ensure that researchers are operating on a level playing field by establishing standards for what constitutes good-quality research.

Finally, societal means could be leveraged to move towards an ERA in medical research through increased globalisation and collaboration, with the sharing of research and results. This could be supported by increased public engagement with medical research and its possible impacts, and would help to ensure that Europe is adequately prepared for the scientific issues of the future. Engaging society as a whole in medical research and being aware of the wider context in which research is conducted is essential for the progression of medical research in the EU.

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