

Article

Research Choices: Time for Europe to Decide

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Abstract

Taking real advantage of Europe's excellence in research to improve citizens' lives presents challenges that Europe's policymakers have not yet fully met. The EU has shown some clarity of assessment in recognising the needs, and some laudable determination to improve the situation, and it has intermittently taken some real steps to deliver on its ambitions to turn its research into valuable innovations. But Europe still faces harsh choices about whether it is actually going to do what it has so often discussed. The EU has to make some firm decisions about what research deserves support – and where. It must turn words into deeds to promote effective links between research and innovation. That requires a sharper focus on developing and retaining the right skill sets in Europe, on funding innovation, on creating an encouraging regulatory environment, and on building greater public understanding and engagement. Here, among other issues, the authors discuss where resources should be deployed, how to maximise the potential of personalised medicine, the time it takes for search to be turned into products ready for market, education, and the EU's regulatory role.

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The Who-Gets-What Dilemma

Should resources be focused on the best research centres, or should the pie be shared equally among EU member states? Any attempt at coordinating European research policy runs straight into an acute dilemma over resources. In a community that places a high value on equality, how legitimate is it to concentrate scarce funding on high-performance institutions that will drive research and ensure efficient management and exploitation of results?

It's a problem as old as the concept of solidarity. Should elite expertise trump egalitarianism? And it is a problem that has challenged even avowed communists: the iconic playwright Bertolt Brecht concluded his *Caucasian Chalk Circle* play about allocation of resources with the words "Children to the motherly, that they prosper, Carts to good drivers, that they be driven well, The valley to the irrigators, that it yield fruit."

For the EU, any discussion of this issue is charged with all the tensions that flow from the wide divisions among member states big and small, old and new, rich and poor... with deeply differing histories and backgrounds in research [2]. If the carts are to be given only to the good drivers, is that fair to the rest? And how will the bad drivers ever learn to get better? Or are they to be condemned to perpetual second-class status?

The EU has a treaty-based obligation and a publicly avowed mission to aim at reducing inequalities not only between individual citizens and the regions they live in, but between member states too. A more equitable distribution of research resources seems an inevitable consequence. The EU's current innovation agenda also brings further complexities to the discussion, with its attempts to build in a "public good" element, rather than solely "commercial good"; it includes "societal challenges" as legitimate targets, even though these may not produce a market return on investment. On top of those complexities, it is obvious that in times of austerity, the problem is exacerbated by even tighter limits on resources [3].

Whatever the rhetoric, the current reality is that the bulk of EU science funding goes to the richer countries and the older institutions. The concentration of academic and scientific institutions maintaining their leading position is confirmed by the Top 50 lists of EU funding. There is a clear gap between Western member states and the others, with inequalities in both the funding and the amount of research being undertaken across the EU [4].

From the time of its launch in 2010, the European Research Council (ERC) reinforced this trend, with researchers working in the 12 member states that joined the EU only since 2004 featuring in only 3% of all the successful proposals that resulted in ERC's Starter and Advanced grants. And researchers in eight of those 12 states received no grants at all [5].

All individual higher education institutions with more than 10 grantees were located in only 8 of the 27 member states, and all of them were in Western Europe.

This does not mean that no money at all went to the more recent member states, but the disproportion persists.

One policy response to ease the imbalance is a proposal that the CSF should be linked to future Cohesion Policy funding, especially its Structural Fund for enhancing the capacity of regional economies to change and innovate. Its EUR 86 billion accounts for nearly a quarter of the EU budget, and one of the components of that budget allocation is R&D and innovation [6].

Maximising the Potential

In any case, wherever the pursuit of innovation is conducted, the potential benefits will be derived where technical advances are effectively translated into commercial successes. The essence of successful innovation is translating research outcomes into a product that can

be brought to the marketplace. And the chances are maximised in geographies where there is the best integration of science and business, and adequate funding mechanisms for development.

Against the background of today's rapid technological and societal changes, the competitiveness of the European economy and the well-being of European citizens depend heavily on the ability of its researchers and businesses to develop and successfully commercialise innovative solutions.

The EU openly acknowledges what needs to be done. On the one hand, the European Commission says, Europe has world-class researchers, entrepreneurs and companies, as well as the unique strength of its values, creativity and diversity. But on the other hand, it adds, Europe's research and innovation performance needs to be boosted to master the challenges ahead and to keep its place in a fast-changing world.

The knowledge output from scientific research is the foundation upon which the objectives of an innovation strategy can be built. But it is not enough just to fund and manage research activity rationally. Other policies are needed too: encouragement to technology start-ups, support focused on SMEs, promotion of the innovative capacity of established companies, and encouragement for the emergence of novel business sectors based on new technologies.

Research-to-Market Gap

There is a wide research-to-market gap in Europe. The latest EU innovation scoreboard, published in June 2017, noted that although the innovation performance of the EU is improving, progress is too slow. Many of our global competitors are increasing their innovation performance faster pace, and performance gaps remain wide within the EU itself. Europe's comparative advantages in education, research, broadband infrastructure and ICT training are not matched by venture capital investments and the number of SMEs introducing innovations, both of which are declining strongly.

At the global level, the EU is less innovative than Australia, Canada, Japan, South Korea, and the United States. Performance differences with Canada and the United States have become smaller compared to 2010, but those with Japan and South Korea have increased. Japan has improved its performance more than three times as much as the EU, and South Korea has improved its performance more than four times as much as the EU. And while the EU still maintains a performance lead over China, this lead is decreasing rapidly with China having improved more than seven times faster than the EU.

Investment, Finance and a Trained Workforce

There is a lack of investment. The EU set a target in its 2010 agenda of devoting 3% of its GDP to research. But by 2012 it was still only 2.06%, and limited progress since then means the 3% target for 2020 is unlikely to be met. Investment in R&D is currently forecast to increase to 2.2% by 2020 – and could perhaps amount to 2.6% if all member states meet their national targets.

There is an acute shortage of private sector capital, especially in the current economic climate, available for research. It is failing to fill the need for funding is also required for the proof of concept stage of research – which is an earlier phase than most EU research funding supports. And although there is some EU funding for SMEs' R&D, there is an over emphasis on collaborative research at the expense of single SME company research. Given the reluctance of the private sector to invest since 2008, public funding of research is necessary if the EU is to reach the 3% objective for R&D spend.

Innovation needs the right finance. Publicly funded research programmes are important, but they must be organised to assist, not to hinder, innovators. SMEs and academic institu-

tions are often deterred from joining EU research programmes by the growing complexity of the submissions and validation processes and the costs involved. So much so that SMEs have spoken of a “valley of death” in seeking to advance their proposals through the application process. There is some prospect of a dedicated EU investment SME bank to enable streamlined marketing of its SME dedicated portfolio under a single brand name and as a means of simplifying the application process, but this remains at present merely a proposal.

Innovation also needs the right workforce. Access to a skilled and mobile workforce is a necessary factor. This requires the right sort of training for EU researchers and businessmen, and for officials and regulators. It means ensuring retention of talented researchers within EU, by offering attractive working environments that dissuade them from moving to other parts of the world. And it needs programmes to attract non-EU citizens who are researchers to institutions located in the EU, as well as encouraging EU citizens working beyond the EU to return. In addition there is a lack of technology transfer professionals who combine an understanding of science with business skills and acumen that allows them to support the research-to-market process.

Convincing the Public

Public support is needed for science. The strongly supportive enterprise culture of the USA, with its wide public endorsement of the merits of innovation, is only thinly echoed in Europe, where hesitancy is often the ruling sentiment in public discourse on science. This has its consequences in a less adventurous approach to funding, shortages of venture capital... But it has its roots in a discernible public scepticism about science, often articulated and promoted by influential agenda-driven activist organisations.

Public scepticism about biotechnology over the last two decades translated into such timidity among many member state governments that European policy – and consequently European innovation – in this field has been severely handicapped. More recent controversies over glyphosate confirm that scepticism remains vigorous. Despite scientific studies demonstrating the lack of hazard, re-authorization of the product is proving difficult in the face of NGO convictions that it is carcinogenic – driving the EU commissioner for health to publicly criticise the invasion of politics into science.

The continued prominence of such opposition risks deterring policymakers, nervous about public opinion, to err on the side of caution when contemplating whether they should promote science, research and innovation. The situation could be improved with better public understanding – in a context where, as Richard Dawkins has suggested, “We can learn to appreciate Science just as we appreciate a great work of Art.”

Regulation and the Role of the EU

Innovation needs the right regulation. Ideas need an innovation-friendly environment to grow and become products or services that will benefit Europe’s citizens and its economies. This can be handicapped by outdated regulations and procedures, slow standard-setting, fragmented or incoherent rules in member states and regions, failure to use public procurement imaginatively and strategically. The environment can also be improved by overcoming weaknesses in public education and innovation systems, or making patenting systems less costly and less slow.

Amid so many identified opportunities and requirements, the European Union has an obvious role in helping fill the needs, and thereby making sure the opportunities can be

seized. The EU role is as a funder, facilitator, forum and framework provider – an enabler at a European level.

Right now, the EU still lacks the market-creating innovation that is needed to turn its best ideas into new businesses and high quality jobs. At local, regional, national and EU level innovative companies – established ones and start-ups alike – have to have access to the right employees with the right skills, to academic communities, other innovators and business partners, to the right investors and finance, and to the right political support. And this is something that the EU is perfectly placed to drive.

Innovation also needs the right regulation – and by definition this is something the EU can facilitate, and can promote via common legislation, or by shared actions among member states or groups or regions.

It is the EU that can encourage the constructive pooling of resources in research. It is the EU that can remove bottlenecks by creating an internal market for skills, patents, venture capital, innovation procurement and standard setting, to foster ideas being quickly implemented on the market. Within a strategic framework, the EU can provide the coordination, via policy interventions and instruments, that permits more efficient and beneficial research activity to take place at an EU level, to make sure things dovetail well.

The EU's impact has been beneficial, even if not yet sufficient. The European Innovation Scoreboard 2017 concludes that EU innovation performance continues to increase, especially due to improvements in human resources, the innovation-friendly environment, own-resource investments, and attractive research systems. Sweden remains the EU innovation leader, followed by Denmark, Finland, the Netherlands, the UK, and Germany. Lithuania, Malta, the UK, the Netherlands, and Austria are the fastest growing innovators. And in a global comparison, the EU is catching up with Canada and the US, although South Korea and Japan are pulling ahead [7].

Part of the improvement is due to the EU's extensive engagement in research. It put EUR 55 billion into its last research framework programme in 2007–2013, backing 25,000 projects – including providing EUR 6.4 billion to SMEs. Many of these projects are still ongoing, and meanwhile its successor, the current Horizon 2020 programme, is providing around EUR 80 billion in support of research [8].

The European Institute of Technology (EIT) has been set up to develop a new generation of scientifically literate entrepreneurs and innovators. Its three Knowledge & Innovation Communities (KIC) are partnerships with members drawn from diverse scientific backgrounds united in developing ideas through to products. It provides a training emphasis on converting the science students involved in a partnership into entrepreneurs. The European Research Area (ERA) includes research infrastructures, Joint Programme Initiatives, Joint Technology Initiatives and Regional Partner Facilities. And the European Research Council (ERC) focuses on "*frontier research*" in an attempt to avoid the division into basic & applied research in the sciences [9].

There are also EU funds available specifically to assist SMEs' R&D; some 100,000 SMEs have received loan guarantees through one of the EUR 3.6 billion Competitiveness & Innovation Framework Programmes (CIP), the Entrepreneurship & Innovation Programme (EIP). Implementation is via the European Investment Bank (EIB) which also operates a popular Risk Sharing Finance Facility (RSFF) for research intensive SMEs and others seeking investment capital [10].

Simplification has become the mantra for reform of application processes and the subsequent management of successful applications in EU research support programmes [11].

What We Have – And What We Need

There is a sharp focus on health. Among the mechanisms and structures the EU has created to promote research and innovation, many are directed at stimulating and supporting life-science-based developments, and particularly at health. There are 19,434 health and medicine projects on the EU research database [12].

The Innovative Medicines Initiative (IMI), the world's largest public-private partnership in life sciences, supports collaborative research projects and builds networks of industrial and academic experts to boost pharmaceutical innovation in Europe. The Active and Assisted Living Programme (AAL) supports market-oriented research and SMEs, in tandem with the European Innovation Partnership on Active and Healthy Ageing to ensure the wider dissemination of best practices [13].

There are Joint Programming Initiatives on Antimicrobial Resistance and on Demographic Change, and a European and Developing Countries Clinical Trials Partnership. Three research infrastructures have direct relevance for health and for personalised medicine.

BBMRI (Biobanking & Biomolecular Resources) brings together 53 partners in 33 countries to bring greater harmonisation to biobanks. EATRIS (European Advanced Translational Research Infrastructure in Medicine) involves 10 countries in creating innovation clusters to drive the delivery of research to the clinic.

And ECRIN (European Clinical Research Infrastructures Network) engages 14 countries in linking joint work in this field. The structures also include the Scientific Panel for Health, a science-led expert panel charged with analysing and proposing solutions to bottlenecks to improvements, identifying influential long-term trends and recommending responses, and assisting the translation of innovation into practice [14].

But the need for further effort is graphically demonstrated by the difference between the % GDP R&D expenditure of the EU and its major global competitors in medical research, where the funding gap, both relative and absolute, is clear between the EU and USA & Asia [15].

Making It Work for Personalised Medicine

The EU has increasingly acknowledged the importance of personalised medicine over recent years. Within the EU's support for health research and development, personalised medicine is receiving increasing attention. During the first four years of Horizon 2020 (Work Programmes for 2014/15 and 2016/2017), the EU is investing more than EUR 2 billion in personalising health and care. In the first two years and a half of the programme, 167 personalised medicine R&I projects were selected for funding for a total of EUR 872 million. The EU is convinced that research & innovation supported here will improve understanding of the causes and mechanisms underlying health, healthy ageing and disease, and improve the ability to monitor health and to prevent, detect, treat and manage disease. It will also help older persons to remain active and healthy, and test and demonstrate new models and tools for health and care delivery. Two pilot projects with a combined budget of around EUR 30 million are aiming to trial personalised medicine approaches in existing healthcare settings. The projects will also evaluate how these new approaches bring value to healthcare systems and patients [16].

The research agenda of the Innovative Medicines Initiative rests on the fundamentals of personalised treatments. One example is EU AIMS, a EUR 37 million project aiming to explore the biological causes of autism, with a view to developing personalised treatments.

The Luxembourg EU Presidency made personalised medicine a priority area in 2015. The Council conclusions it secured agreement on urged member states to act effectively in pursuit of developing “personalised medicine for patients” [17].

The EU is also one of the principal promoters of ICPeMed, officially launched in November 2016, which aims to establish Europe as a global leader in personalised medicine research, and support the personalised medicine science base through a coordinated approach to research. Part of its task will be to provide evidence to demonstrate the benefit of personalised medicine to citizens and healthcare systems, and to pave the way for personalised medicine approaches for citizens. It has developed an action plan with central research and research-supporting activities in all areas relevant to personalised medicine [18].

The EU research commissioner, Carlos Moedas, is convinced that personalised medicine is a vanguard area of healthcare and health research, and he has given his public personal backing to the initiative. He has also spelled out what will be needed to allow Europe to exploit the opportunities. These “go beyond medicines and diagnostic devices, and include demand for high-tech storage and data-sharing, and for low-tech devices and services to heighten awareness of personal health risks,” he said at the IC PerMed launch [19].

But significant shifts are still needed in medical research and healthcare for personalised medicine to be fully exploited. Beyond Europe, both China and the USA are launching ambitious programmes. Prioritising a cutting-edge field like personalised medicine can help policymakers to design the right framework conditions for innovation. It is necessary to ensure that regulation is up to speed with the advances in this area, so that no unnecessary barriers block its development – and this has implications for clinical trials, health technology assessments, and reimbursement. The infrastructure that will be required to deliver this innovation is multinational and involves many disciplines – molecular genetics, epigenetics, biomarkers, pharmacogenomics and pharmacogenomics [20].

Personalised medicine requires a new mindset, putting the patient at the center of healthcare – and demanding innovation in the way medicines are developed and healthcare systems are structured to deliver care. The patient ceases to be the subject of research or treatment and instead becomes an active partner. Nascent civil society questioning of how progress will impact patient and citizens will have to be effectively answered. This needs sound policies on informed consent and the use of personal data, and concrete steps like electronic patient records, integrated into a system that has practical benefits for people. Europe needs to create a new ecosystem among research institutions, patients, healthcare practitioners and governments to exploit the growing range of data resources to prevent disease, or when disease does strike, to manage it better. Patients and their advocates will have a growing role in these debates if policy is correctly managed. And personalised medicine has to attract venture capital funds and philanthropic foundations to invest long term in healthcare R&D [21].

Optimistic Signals Are Emerging

Personalised medicine has real prominence now within the major national and international research framework programmes [22]. And in regional strategies, personalised medicine has captured the political agendas of several European regions. European regions hold a huge potential in terms of implementation of personalised medicine, since they can mobilise more than EUR 41 billion on research and innovation through the European Structural and Investment Funds up to 2020 – although coordination of regions still needs to be improved. A DG RTD survey of 129 European regions (NUTS II) shows that 45 have selected personalised medicine as a focus for their strategic regional growth. Seventy regions have desig-

nated diagnostics – key enablers of personalised medicines approaches – a strategic area. In Italy, the Lombardy regional government and its regional foundation for biomedical research in February 2017 launched a consultation on personalised medicine, to create a regional action plan that can channel EU regional funding resources into cooperation projects. The Lombardy region is a partner in IC PerMed and biomedical research foundation participates in an ERA-NET translational cancer research project and will lead activities in the upcoming ERA-NET on personalised medicine. The Campania region has launched a cancer programme designed to develop oncology research infrastructures and boost interregional competence centres, with personalised medicine as a core element [23].

And in Spain, Galicia is running a pre-commercial public procurement to incorporate elements of personalised medicine, i.e. diagnostic and prognostic biomarkers for colon, lung and prostate cancers, into the hospital oncology protocols.

On the other hand, Brexit is creating turbulence for EU policymaking in general and for research strategy in particular, and consequently has disconcerting resonances for healthcare innovation. The eligibility of UK participants for future EU research projects is under threat, with negative implications that extend to the EU too, since UK engagement in EU projects has until now been a significant contributor to research design and to positive results. The discordant debate over the future of the European Medicines Agency is one of the most conspicuous examples of how healthcare innovation is being impacted already, as its management openly acknowledge the damage being done to workflows, recruitment and staff morale. But other EU initiatives with a strong connection to healthcare innovation are also prejudiced by the current uncertainty over UK engagement, and the prospect of its eventual withdrawal – ranging from the Innovative Medicines Initiative to ICPerMed, and from the European Research Council to the attempts to combat antimicrobial resistance. Venture capital funding for the UK has already faltered. And above all, the sense of common purpose that the EU has represented in healthcare innovation is inevitably weakened by the defection of one of the most important players in this field.

So that personalised medicine becomes widely perceived as a legitimate and desirable innovation, there is a need now for reassurance of the healthcare sector as to its merits – and the best way to do that is to ensure that innovation is brought more effectively and more rapidly into healthcare systems, so the patients and citizens can see the benefit.

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