

Innovation in Healthcare: From Research to Market – SMEs in Focus

Meeting Report

20-21 May 2010

The following report is a summary of the discussions and the presentations held at the “Innovation in Healthcare: From Research to March – SMEs in focus” jointly organized by DG RTD and DG ENTR in Brussels on 20-21 May 2010.

Conference report

Innovation in Healthcare: Bringing Research to Market – SMEs in focus

Organized by DG RTD and DG ENTR

20 - 21 May 2010

**Square-Brussels Meeting Centre
Mont des Arts, Brussels 1000**

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OVERVIEW OF THE EVENT

Fostering innovation in healthcare is a particularly difficult and articulated process, due to the escalating costs and the long time frame for healthcare product development and regulatory approval. There is an expensive (above €1 billion for a new drug) ten-fifteen, sometimes 20 years gap for a company from idea to a viable, marketable product and becoming profitable. This often represents a "valley of death" for an innovative Small and Medium Sized Enterprises (SMEs).

That is why the Health Directorate of DG RTD and the Competitiveness in the Pharmaceuticals Industry and Biotechnology Unit of DG ENTR have been working in synergy since a number of years to address all the elements affecting innovation in healthcare and decided to organize the conference: **"Innovation in Healthcare: From Research to Market – SMEs in focus"** in Brussels on 20-21 May 2010.

There were about 350 participants representing the relevant stakeholders, in particular SMEs, policy makers, including Members of the European Parliament and Member States Governments representatives, clinicians, representatives of universities and other research institutions, regulatory authorities, venture capitalists and bankers. In addition there were exhibitors of the "mini-fair", namely relevant industry and patients associations and support structures.

The event took a very broad approach to sustaining innovation from Research to Market. The opening plenary provided the policy context and was followed by the stakeholders' view session. The detail oriented examination of the elements and challenges to innovation were implemented in the parallel sessions, where speakers, panel discussion and debate with the audience highlighted respectively the current situation in EU funding, technology transfer, ingredients for innovation, access to finance and regulatory aspects. The closing plenary summed-up the event outcome.

The event highlighted key elements that will be provided to the Commissioner Geoghegan Quinn and to the innovation task force to help preparing the "Plan for Research & Innovation". This plan will be discussed by EU heads of state at the summit on research and innovation scheduled to take place in autumn 2010.

SCOPE OF THIS DOCUMENT

The following report is a summary of the discussions and presentations during the event.

This report does not endeavour to provide a word for word record or minutes of the meeting, but rather to summarize the key points discussed, to extract the key issues raised and challenges highlighted, and in particular to focus on the recommendations of the expert panels and on solutions proposed. In short, this report is intended to capture and crystallise the key outcomes of the meeting, the recommendations and proposals made so that these may be reviewed and taken into account in policy discussions within the European Commission and for future shaping of European Research.

METHOD

The method has been loosely based on the application of a basic SWOT (Strengths, Weaknesses, Opportunities, Threats) analysis applied to the various discussions, and then to the overall conclusions and outcomes. As the purpose of this initiative is to generate a clear picture of the major obstacles to innovation in healthcare in Europe and the development of a strong and competitive bio-economy in Europe, the primary emphasis was placed on weaknesses (or obstacles, challenges), threats, and opportunities to build on best practices, and to implement changes and solutions.

Moderators of each session were briefed in advance that a primary goal of each session in the programme was to draw out the opinions, experiences and insights of each of the assembled panels of stakeholders and experts, and to specifically ask them to identify their key problems, challenges and obstacles to innovation in healthcare in Europe as related to the topic of their session and their area of expertise, and more importantly the proposals and solutions for improvements.

Executive Summary & Conclusions

European Commissioner for Research, Science & Innovation Máire Geoghegan-Quinn opened the conference by stressing the importance of innovation in healthcare for Europe in terms of patients' health and well being, societal development, and economic growth and competitiveness, and furthermore emphasizing the key role of SMEs in innovation and bringing healthcare research to the market. At the same time, it was recognized that traditionally the focus of public funding in Europe has been on fundamental research, and this may well be one of the main reasons why Europe lags behind the US in terms of innovation and capturing the full value and potential of science and, by applying and commercializing it, ultimately bringing it to the patients. The Commissioner listed a number of specific objectives, but rather than simply proposing solutions called on the stakeholders present to actively present the problems as seen from their perspective, and proposals for solutions or changes.

The experts and stakeholder representatives applauded the Commission's call for input, and while recognizing a number of key European achievements and best practices which should be emulated and built upon further, also indicated a number of very serious, on-going challenges to healthcare innovation in Europe, and to SMEs in particular. They proposed a number of solutions. The specific comments and recommendations varied from session to session according to the topic, and are available within the section of the report on the programme sessions.

But a number of general, recurring comments emerge prominently from the panel discussions:

Knowledge foundation:

1. The focus of EU funding for research has traditionally been far too focused on fundamental research. Funding for fundamental research must be maintained, but funding for applied innovation, being disruptive innovation or even incremental innovation, can yield more value and must be increased.
2. In spite of many recent improvements, the application and management processes for Framework Programmes (FPs) is still too rigid and cumbersome. Simplification is beginning to occur, but more is needed. As well as increase the capability to finance riskier research.
3. FP programmes, while improving, are still not well suited to support SMEs driving healthcare research and innovation. More creative, industry oriented approaches, solving immediate research issues with potential for commercial exploitation, should be explored. In particular, the requirement for 3 consortium members from 3 EU countries greatly decreases both the appeal and the potential benefit (application and exploitation) of the project results.
4. Long time periods are also generally un-suited to the needs of SMEs, and guidelines for Intellectual Property consortium agreements should be further simplified and should prioritize approaches that will improve the prospects for eventual application of results.
5. Free movement of researchers is a must. Researchers have to be encouraged and supported in free movement not only among countries but also from academia to industry and vice versa.

Breakthrough ideas:

1. EU should help addressing the 'valley of death' by financing proof-of-concept schemes similar to the small business innovation research (SBIR) in the US, eventually with small early funding for proof of concept, followed by the second phase project funding.
2. Bringing the benefits of healthcare and biotechnology innovation to patients and to the market starts with good technology transfer.
3. Far more needs to be done to finance and support the best initiatives in Europe and develop the expertise and resources required, but these will only work if real experts in all development phases are involved, it is not a "Public Relation" exercise.
4. If public money is put to work supporting healthcare research and SMEs, we must learn from the failures of the past and use the money smartly, not spreading it around in small amounts to early stage companies, but leveraging the expertise of investors and allocating sufficient capital to the companies or projects with the most potential to be successful.
5. A few success stories can help drive the whole market, generating more institutional investment, creating jobs, developing management skills and serial entrepreneurs, providing benefits to patients, and leading to future spin-outs.

Access to finance:

1. There is a major structural funding gap in Europe, which is unique to the healthcare, biopharma, medical device and biotech sectors. Europe simply does not have the needed number of active institutional investor Limited Partners (LPs) for life sciences Venture Capital (VC) funds. The funds cannot attract sufficient money, and this can only be remedied through further direct public investment into life sciences VC funds (increasing the mandate of the EIF, or creating a new life sciences fund of funds), and encouraging and incentivising Europe's institutional investors to allocate a percentage of their investments to life sciences venture capital in Europe. The financial crisis is making things worse, but it is not the full cause, it is simply compounding an existing structural problem in Europe.
2. Venture Capital is an artisanal effort that requires lots of endurance and skills, and only yields returns when real value is created. It should not be treated punitively as an institutional asset class.

Innovation market:

1. The regulatory burden for healthcare products is very high and in spite of a number of good measures to support SMEs, more needs to be done to reduce costs, simplify the process and to assist SMEs in preparing effectively.
2. The level of fragmentation and disharmony in Europe between Member States policies creates an enormous burden for SMEs in everything from Health Technology Assessment (HTA) to Intellectual Property (IP). A single, harmonised European market for innovation is desperately needed, including a single Community patent.
3. Many of the access to finance supports for SMEs developed at EU level, both equity and debt, are not well suited to life sciences healthcare SMEs, and therefore very few biopharma, medical device and other healthcare SMEs have been able to qualify for this support, especially product companies that can generate the most long-term value for Europe. Changes are required to make it more accessible for them. The financial crisis is having an impact on the financing available for all sectors, however healthcare research is different and was already suffering from structural problems such as the lack of institutional investors.

PROGRAMME & SESSION REVIEW

Welcome Plenary Session

The meeting was opened at 9:00 AM on 20 May 2010 by Commissioner Máire Geoghegan-Quinn, European Commissioner for Research, Innovation & Science.

The Commissioner

- Recognized the importance of healthcare research in bringing novel drugs, therapies and medical technologies to patients while sustaining a key sector of the European economy.
- Stressed that while Europe has a strong scientific-base, this has not necessarily ensured that the best of healthcare research is brought to market.
- Emphasized the need to remove barriers to innovation and commercialization, which requires fostering technology transfer, a sense of entrepreneurship in researchers, and better academia-industry partnerships.
- Called for the broadest possible approach to sustaining innovation from research to market, with a specific focus on funding, regulation, technology transfer, industry-academia partnerships, and all with a focus on SMEs.
- Stated that the financial crisis has compounded the challenges already faced by biopharma and healthcare SMEs in terms of the rising costs of clinical trials and long development period for healthcare products.
- Called for an open dialogue and the support of stakeholders in identifying the strengths and weaknesses of current support measures and, where necessary, recommending improvements or changes.
- Confirmed the commitment of the new European Commission to drive a transformation of research funding policy with more co-funding in partnership with the Member States.
- Set as her objective delivering a single market for innovation and completing the European Research Area which would include:
A target for SMEs 15% of the €6 billion Euros allocated to health research in FP7. Simplification of participation in EU funded research projects.
Strengthening instruments supporting innovation, such as the Structural Funds, the Competitiveness and Innovation Programme, and the instruments of the EIB. Mobilization of cross-border venture capital. Creating a single Community patent in Europe. Finally she called for input from the stakeholders.

Paola Testori Coggi, Director General for Health & Consumers, DG Health & Consumers, European Commission

- Europe needs a better dialogue between research, markets, and policy makers.
- European Member States have common objectives in health policy, but there are 27 models.
- Europe's ageing population requires a greater focus on prevention, and therapies that do not simply extend life but which add quality of life so that ageing patients can live longer and healthier lives and to minimise hospitalisation and reduce the burden on healthcare.
- Medical devices can play a crucial role in the diagnosis, prevention, treatment and monitoring of disease. We therefore need adequate investment, a strong

RTD programme, and we need also to determine what is the best regulatory framework for medical devices.

- The Commission launched last year a joint initiative with the member states to develop a common methodology for Healthcare Technology Assessment that can be applied across the 27 Member States.

Françoise le Bail, Deputy Director General, Enterprise & Industry, Commissions SME Envoy, DG Enterprise & Industry, European Commission

- SMEs are crucial for innovation in the healthcare sector, and are a key source of innovation for the pipelines of larger firms.
- Lack of SME access to finance is a Europe-wide challenge and it is not specific to a state or sector.
- The gap in innovation between Europe and the US and Japan is narrowing in recent years.
- China's rate of investment in Research & Innovation may result in a rate of innovation equal to Europe's in 10 years.
- Access to finance remains the key driver of innovation, and investment in research and innovation influences the growth patterns for decades ahead.
- This is why the Commission has put together the Competitiveness and Innovation Framework Programme (CIP) to facilitate access to capital and loan financing for SMEs in Europe with €1 billion for 2007 - 2013, the venture capital instruments of which help narrow the equity gap in Europe, with investments made into 12 life sciences VC funds so far.
- Patents in the EU are far too expensive, and a Europe-wide patent can improve the patenting process for European companies.
- Public procurement should sustain fostering innovation and stimulating SMEs.
- We need to build on our experiences with the EIB and EIF to raise additional capital for innovative businesses, which will require working closely with private investors.

Cristina Gutiérrez-Cortines, Member of the European Parliament

- European policies are complicated by the various member state policies.
- In healthcare we cannot distinguish clearly between research and innovation, there can be no innovation without fundamental research.
- Hospitals should have a much more central role in the research and innovation system than they currently do.
- Research should tackle specific needs identified by medical doctors.
- We need to involve the high tech industry in the public system from the beginning to ensure critical mass and creativity.
- European funding should be refocused on smaller projects with fewer participants, which would be more relevant for SMEs.
- Europe needs more researchers.
- There is a lack of management skills and experienced managers.
- There is a need not only for a single European Patent, but also some distinction between SMEs and big pharma.

The Stakeholders view

Simon Philipp Hoerstrup, Head of Regenerative Medicine Programme, Professor of Biomedical Engineering, Zurich University

Dr. Hoerstrup presented the FP7 funded LifeValve project, which combines tissue engineering and minimally invasive implantation technology to replace heart valves in newborn babies with inborn malfunctioning hearts. The use of new biomaterials and the rapid prototyping of several innovations were realized in this project. Prenatal cells taken from their amniotic fluid will be treated in vitro and then implanted back into the newborns through a catheter (in animal models so far). This technique allowed the treated cells to grow into functioning new heart valves without the need for a large operation and minimising risk of reject.

The main challenge that came up in the Q&A session related to the management of intellectual property in such a project. The answer was that the cooperation in a consortium, as required in this case by FP7, forced the partners to discuss the terms early. In practise it is a matter of finding a balance among which IP to share and what to protect. Professional assistance is essential.

Anders Olauson, President, European Patients' Forum (EPFs)

He started by saying "If you take only one message away from this presentation, it should be that patients' involvement with healthcare research matters, and can lead to more patient-oriented policy and action." He explained the considerable benefits of patient involvement, and therefore

- Call for increased policy attention and investment into supporting patient involvement.
- 'Research with' rather than 'research on' patients is an imperative - patient involvement on equal terms.
- Project coordinators/officers have clear interest in developing patient involvement but have difficulty translating this into practice.
- Restructuring patient involvement in FP projects: Evidence from the FP6 and FP7 project 'Value+' highlighted that patient involvement was clearly weaker in EU-funded research projects than in other projects. It showed that there is limited patient involvement at the inception and planning stages, as well as in the governance structures of projects.
- Education of patients and the public about research concepts is essential. When patients are engaged from the onset they are more committed. Patients can share their real-world experiences, which can be an invaluable source of information for researchers.
- Need to balance scientific excellence with social and cultural relevance.
- Call for the European Commission to include explicit criterion on patient involvement in relevant Calls for Proposals
- A commitment on the part of DG Research plus partnership with EPF will mean greater awareness among patients on how to get involved as well as receptiveness on the part of project promoters and innovators on how to involve patients meaningfully.

The discussion evolved around how to motivate the EU funded consortia to put this into practice; especially for SME. Suggestions: to involve the 'learning' patients and to use the EPF handbook and toolkit as reference. Also medical devices came up in the discussion and EPF promised to look into that area to identify appropriate actions.

John O'Dea, CEO, Crospon; Board Member of Irish Medical Devices Association

John O'Dea argued that the Framework Programmes are not well structured to be suitable for SMEs and therefore are not nearly as effective at promoting innovation, especially in medical devices, as they could be. He noted significant improvements over the past years, but stressed that there is much more room for improvement. As the Eucomed study shows, the top 3 problems challenging SMEs are Access to Finance, Clinical Trials, and Reimbursement.

How can the EU help?

- Under FP7 most medical device research is not within the Health Theme. A stronger focus on medical devices is needed.
- The timeframes are too long and not conducive to the short-term results companies need to survive and attract funding.
- Too many "cooks" in EU funded projects? Why not one company/country? It is what works in the US.
- Most good ideas for medical devices come from medical practitioners (as the US example and benchmark shows). But they are not generally involved in EU projects.
- More funding needed for applied research.
- The best new products in medical devices usually come from more incremental innovation. This also needs to be funded, and being able to be commercialized should be a criterion for research funding - if it does not go to market, it will not benefit anyone.
- The FP7 application process is still too cumbersome.
- Proposal for a "small business innovation research" (SBIR) type scheme, like in US (NIH), that allows companies to engage in bolder visions for their projects. This plays a fundamental role in medical device start-ups in the US and such a scheme in Europe would be fabulous and have real impact.
- SBIR is a competitive scheme, but a doctor with a good idea may get a million for the early phases of development of his innovative idea. If one goes to venture capital meetings in the US it's obvious that many of the participants got where they are because of the SBIR process.
- The EU needs to remember that research doesn't have to happen only in universities - it can happen in companies.
- EU competition law constrains the way in which countries are able to support their startups. We need to consider some sort of minimal criteria for small companies.
- There is a need for a harmonized HTA in Europe. It is maddening that the review of the same clinical evidence needs to be repeated in 27 countries. Mutual recognition can't come quickly enough for the EU. It's harder to launch a new product here than in the US because of the US homogeneity.

- Further work is needed to finalize a European patent.
- FP7 should prioritize a) Clinician-directed, device-oriented research, and b) Clinical-need-directed, device-oriented research.

The time is right now. Medical devices are not only about some new gizmo, it's about doing something more effectively or cost-effectively and there is a need for such research.

Successful start-ups will need to demonstrate cost or clinical benefits.

Emmanuel Chantelot, Executive Director, European Biopharmaceutical Enterprises

Started by stressing that for Europe to be successful, what is needed is an adequate policy environment and adequate access to capital.

The EU can and should support adequate access to finance throughout the full lifecycle of innovation. European institutions should focus on funding research, but also on funding product development. It is important to ensure investors remain confident in the future of the healthcare market and the development of new healthcare technologies. We should encourage the EC to invest in new initiatives to support healthcare access to finance. Life sciences is the field with potentially the greatest value for society and the economy, yet so far very few life sciences and healthcare companies have been able to benefit from the EIF activities, they are designed for more traditional, less risky sectors.

- Called for a greater focus on developing the right environment for innovation, or "innovation ecosystem," involving universities, small biotech companies, large industry, patients, healthcare professionals, regulators and government agencies.
- Pointed to notable achievements such as the Innovative Medicines Initiative (IMI), and examples of good regulatory policy initiatives such as the Orphan Drug Designations and the Advanced Therapies Regulation.
- Outlined threats to a growing and successful ecosystem for biopharmaceutical innovation, including:
 - from some of the ways in which the clinical trials directive has been implemented,
 - the various constraints on the commercialisation of medicinal products in member state markets.

In short, there is real promise in many of the 'supply side' research initiatives, but there are continuing problems with regulation and the 'demand side' for innovation in Europe. Our common goal here is to identify and reduce remaining obstacles for the EU to unleash its full innovative potential, in particular through innovative SMEs. Successful outcomes from innovation policy also require consistency in the broader political context. For instance, protection of innovation IP is essential for investor confidence. This is why the biopharmaceutical industry along with other stakeholders supports the European Commission initiatives for the adoption of the Community Patent. Consistent respect for IP rights is the foundation of any future innovation policy, and stating the obvious, the medicines lifecycle is strongly reliant on the IP framework. Biomedical research is very strong in Europe. But the biopharmaceutical industry is a sector where specific conditions and policies are needed to ensure its continued success.

The most important ingredients for innovation in healthcare are an adequate policy

environment, fair rewards for innovation, and access to cash.

This requires:

- New funding initiatives that could share risks between private and government funds or increase public and private co-investment could bring back both institutional and private investors' confidence in the sector.
- EC engagement into new types of actions to address the increasingly serious problem of access to finance for biopharmaceutical SMEs in Europe.
- We have heard that all SMEs are affected, but we say here that biotech SMEs are affected even more. The European mechanisms that are in place for life sciences are extremely helpful but there are not so many companies in drug discovery that have benefited from support from the EIF and EBE and EFPIA will work with the institutions to see which mechanisms can be put in place. National competent authorities to match the joint IMI undertaking with rationalising and simplifying administrative process.

Research & Innovation stream - Silver Hall

The DG RTD organized the Research and Innovation stream in the Silver Hall and included 4 sessions on May 20 and 21, focusing on EU funded health research and opportunities for SMEs, technology transfer, open innovation, and research and entrepreneurship.

The 4 sessions were

EU funded health research: creating opportunities for SMEs & innovation

- Michael Goldman, Executive Director, IMI
- Luuk Borg, Director of EUREKA Secretariat
- David Sourdivé, Vice President of Corporate Development, Collectis
- Jacques Viseur, CEO, Eurotop
- Ruxandra Draghia-Alki, Director, Directorate Health, DG RTD, EC

(moderator)

Technology Transfer: bringing healthcare research to the market

- Claes Post, Senior Business Developer, Innovation Office, Linköping University
- Kari Paukkeri, CEP, Licentia
- Pedro de Noronha Pissarra, CEO, Biotechnol SA
- Manfred Horst, Licensing/Business Development, Merck & Co.
- Peter Ruile, COO, Ascenion
- Hicham Abghay, Chairperson Healthcare Sector Group, Enterprise Europe Group
- Christian Suojanen, Valor Management SA, & Co-Chairman, Tech Transfer Summit (moderator)

Is open innovation a solution for health care/ if e science?

- Paul Stoffels, Group Chairman of Pharmaceutical R&D, Johnson & Johnson
- J.W. (Hans) Hofstraat, VP Philips Research, Healthcare Strategic Partnerships
- Gunnar Muent, European Investment Bank
- Claire Skentelberry, Network Manager, Council of European Bioregions
- Frank Heemskerk, CEO, Research & Innovation Management Services

(moderator)

Ingredients for innovation: research & entrepreneurship

- Henriette Van Eijl, Policy Officer, Innovation Policy Development, DG ENTR, EC
- Cristina Glad, Executive VP, BioInvent International AB
- Ritchie Head, European Collaborations Manager, TrusTECH
- Dinah Weissmann, CEO, BioCortech
- Manuel Gea, Co-founder & CEO, Bio-Modelling Systems, VP Innovation Adebitech
- Frank Heemskerk, CEO, Research & Innovation Management Services

(moderator)

EU funded health research: creating opportunities for SMEs & innovation

Ruxandra Draghia Akli, EU funding:

FP7 collaborative projects in the Health theme represent a great opportunity to address long-term vision for Europe 2020, the building of ecosystems for innovation, and in particular creation of networks, international contacts, new collaboration with the development of new skills and knowledge, obviously all to be used for new products or services.

Nevertheless, a series of weaknesses have to be addressed such as fragmentation of research and knowledge, going from research to market, difficult impact assessment, cumbersome procedures. In the future, EC funding should address high-risk research, better support the entire continuum from basic research to market, to innovation; address specially the 'valley of death' by funding medium-stage development of SMEs, to support proof-of-concept schemes similar to the SBIR schemes in the US.

Michael Goldman, IMI:

Public private partnerships (PPPs) are really necessary, now more than ever: to create a balance between risk and benefits, to accelerate processes and to foster new business models of cooperation (Open Innovation). This is particularly suited for new fields like personalized medicine. IMI offers a unique and flexible approach for pre-competitive research with topics defined by a group of companies, to fight fragmentation in Europe and includes education/training elements. Opportunities: more effective processes, networking, access to patients groups, cost savings and to attract more private funds. Threats: some IP matters need clarification during the negotiation phase.

Luuk Borg, Eureka:

As SMEs are key to growth, Eureka is a program that funds projects closer to the market. It has a focus on the industry needs, not on the big challenges, is market oriented with a bottom-up approach. An overview was given of the Eurostars program, co-funded by the EC under art 169, to create maximum leverage with industry funds. About 25% of the projects are in Biomed/Health as these SMEs have more in-house R&D capacity and often work together with academia. The aim is to complement FP7 and CIP funding programs with funding for projects with a very high return on investment (ROI). Challenges recognized: synchronization of national funding, slow time to contract. Opportunities: achieves a new level of EU integration, simple concept and single entry point, which are well appreciated by SMEs, link to EIB initiatives to create support for SMEs across all phases of the innovation value chain.

David Sourdive, Collectis:

Sharing of his experience with EU programs he stated that FP7 is significantly better for SMEs than FP6. However it is better cut for research community building and programmed research rather than to bring products to the market. In Europe innovation is supported through co-funding with subsidies allowing SMEs to keep IP ownership. In the US innovation is supported through public procurement contracts that cover 100% of the costs, which is far more attractive to SMEs.

Opportunities: open calls with deadlines every 3 months would work better for SMEs. Threats: time to contract for EU funded research ('why not create a type of fast track call?'); pool of EU specialists too small ('many Europeans with real business skills reside in the US') which results in lower growth for SMEs in Europe ('glass ceiling for growth'); funding gap, it is in fact a catch 22: FP7 doesn't fund up to Proof of Concept and SMEs can't get through to sufficient private equity until they reach the Proof of Concept.

Jacques Viseur, EuroTop- Kappa Health:

The Kappa Health project is currently assessing the impact of 196 FP projects with SMEs, to identify ingredients of success and to help newcomers to learn how to commercialize and get access to finance. According to results to date, arguments favourable to SME participating in FP result from a mix of drivers: pure business factors, senior management issues and research arguments. Therefore, their decision-making is complex and not based only on research outcome. Small shorter projects (STREPs) are generally preferred and 83% of the SMEs that that have participated will continue with the collaborative partnerships developed during the project.

The funding gap is addressed by partnerships with large companies but SBIR type of projects could be very beneficial.

Discussion: during the discussion in addition to a number of smaller technical issues, one important general remark was made: 'not all SMEs are equal'. Focus should be on innovative research intensive SMEs. Synergies should be built with other programs, such as Eureka, that are designed to help bring products to the market. One part of the FP7 program, the Mobility-Peoples program, is greatly under-used by SMEs (industry in general).

Technology Transfer: bringing healthcare research to the market

The speakers on this session started by explicitly defining the technology transfer not as the simple act of signing a licensing or R&D agreement, but the entire process of bringing world class research to the market, which involves all stakeholders and stages of the process.

The focus was less on general presentations but rather on specific take away messages:

- Technology Transfer must be considered from the very earliest stages of research. Fundamental research is fine, but if it cannot be later applied, it will have no value for patients, society or the economy.
- The way a project and the IP are initially handled will have a long-term impact on the potential application of that research. A lot of the problems that VCs see in developing companies could have been avoided if they were not ingrained into the company DNA from the beginning. Retroactively correcting such problems is a lot harder and more expensive than getting it right in the first place, and results in a lot of wasted potential and opportunity, leaving good science undeveloped.
- Technology transfer is not just about licensing, it requires a strong understanding of the sector, the market, and who the eventual customers will be.
- In the end, it is about partnering, so dialogue is important, and you need a clear understanding of the interests and requirements of potential customers, to know who will buy the product and why, in order to be able to commercialize it.
- There are excellent models in several countries or regions such as Flanders, Finland and Germany about how to develop very professional, effective healthcare biotech technology transfer programmes with the depth of capacity and track records to have a real impact.
- Best practices should be highlighted and supported.
- VCs and industry are very willing to get involved in the process and contribute with their expertise, but there has been very limited reciprocation so far. European efforts have focused more on supporting regional interests with limited expertise rather than on supporting existing stakeholders' initiatives

and involving the key stakeholders and experts with the right track records and experience.

- Initiatives to finance better technology transfer practices, and funds, such as those supported by the EIF, can have a real impact, but only if they involve stakeholders with the needed expertise.
- In the end, it is about building competence, relationships, expertise, and understanding. No matter how important fundamental research is, it needs to be managed properly, to be later applied and generate real value, contributing to patients well being and to the BioEconomy.

There is a strong call for small FP project consortia, over shorter periods of time, with just one or two participants. FP projects should be asked to address technology transfer issues clearly and fully from the beginning of the process, not simply state that IP will be managed and someone will take care of commercialization. It is necessary to foster sensible "consortium agreements". The route to market is much clearer and shorter when IP ownership is clear. It may well mean allocating IPR to one or two specific partners from the beginning rather than sharing it. To foster innovation, SMEs must play a lead role. They cannot play this role, nor raise the needed capital, if they do not own IP that will enable a viable business model.

Is open innovation a solution for healthcare/life science?

Paul Stoffels, J&J:

He talked about how to move innovative products to the market with the real aim to provide solutions for patients. In drug development, because of its long time to market, you need to plan ahead up to 15 years in order to avoid that your product is not competitive anymore by the time it reaches the market. And if you want to address the big global challenges like HIV/AIDS, cancer, Alzheimer, you have to cooperate with a wide variety of partners and communities. The scientific challenge has shifted to include prevention and diagnostics, biomarkers etc.; it is not just the product that is at the centre, but also the entire knowledge that has to come from networks and be connected. Drug development programs are nowadays so expensive and complex that not even J&J can do that alone (about 50% of the R&D is done outside the organization), although pharma still has its own role in the final stages of bringing products to the market. Public Private Partnerships can be initiatives highly favourable to Open Innovation, pre-competitive, consortia working under the IMI program are such an example, although it is necessary to find a balance between sharing certain IP (cooperation) and keeping other IP to yourself (competition).

Hans Hofstraat, Philips:

The focus has to be on people and their needs and not on technology. Within the medical technology area Philips provides solutions to improve quality of life of people. Example: high tech medical imaging helps to target a cancer therapy on individual patients (personalized). To develop that kind of technology, you need intensive interaction between several players: companies, research institutes, patients and care providers. For Open Innovation it is essential to create a favourable environment for sharing knowledge: an ecosystem for Innovation in which it is vital to respect each other's strengths, work together openly, and develop a culture of trust. Example: ELAT triangle supported by the EIB under the RSFF: going from coordination to co-creation in a co-located ecosystem.

Moderators suggestion: consult 'Responsible partnering Guidelines': a handbook providing valuable guidance on effective collaborative research and open innovation between academia and industry.

Gunnar Münt, EIB:

He provided an overview on the characteristics of the available financial instruments linked to Innovation support and how the EIB puts these in practice. The EIB's strategic priorities are closely aligned to the EU's policy objectives, initial targets have been surpassed and the

total value is expected to exceed 100 billion by end of 2010. The RSFF is one of the new initiatives to support Innovation ecosystems. This tool may facilitate funding open innovation, allowing investors to share the risk with EIB and therefore addressing the funding gap for SMEs. This is particularly important, as precisely those companies that are highly innovative and R&D intensive, often have a weak balance sheet and are perceived too risky for investors. The benefits of Open Innovation are various: using each other's strengths, knowledge, experience and expensive research equipment will result in efficient and effective technology developments. Combining views and visions can create synergies, a win-win situation and make successful research accessible for all parties, including SMEs, large corporates, research institutes, etc. The success rate of new initiatives that emerge from open innovation is substantially higher than the success rate of closed research centres. Open innovation also creates space for specialist companies to develop their core business at a high level and to market new products effectively.

Claire Skentelbery, Council of European BioRegions (CEBR):

As both SMEs and Knowledge are scattered across Europe, and all regions claiming to be the best, there is a need to tear down border barriers and let knowledge and people flow. Bioregions, as knowledge communities, are another way to link SMEs and knowledge together in a flexible manner. They can connect and facilitate mobility of experts: employment law is currently one of the main obstacles standing in the way of effective technology development. A good example for enhancing mobility is provided by CEBR, which is creating a searchable pool of experts: a simple measure with a high potential value. Next step is to connect the different players to create shared value. We should move from the habit of "use it or lose it" to "share it". The European FPs, and now the new initiatives like IMI and RSFF, are great initiatives to encourage shared exploitation to create impact.

Conclusion of this session: we need to work with new business models, new workflows, new clinical practices, and new delivery modes. For Open Innovation environments it is "essential to work with a culture of trust to go from coordinated research to the creation of Innovation ecosystems that co-create value".

Ingredients for Innovation: research & entrepreneurship

Henriëtte van Eijl, DG Enterprise:

She gave a vivid example of what is important from a patient's perspective: while sufficient critical mass and networked cooperation are needed to achieve a more costs-effective system, equally important are good access to new therapies plus adequate delivery of local quality care. It is not only about investing more money into R&D, but we need to pay attention also to the implementation. She set the scene for this session with 3 policy challenges: a) innovation in public procurement, b) funding the right knowledge transfer activities (linear vs. collaborative models) and c) linking the various public funding streams (e.g. FP7, CIP, Cohesion and structural funds) towards reinforcement of common societal challenges such as healthcare from different angles. A public sector innovation scoreboard, with healthcare as one of the focal sectors, will be published later this year.

Cristina Glad, Bioinvent:

Due to difficulties in attracting VC investment, BioInvent re-invented itself by changing their business model from a drug discovery company to a company focused on diagnostics and out-licensing validated biomarkers. She stressed the importance of building a portfolio of products to balance risk, establishment of a cash flow cycle in which revenue can be re-invested in new activities and on the value of out-licensing to have additional funding. This case is an original way to circumvent the largest funding gap to bridge research up to achieving proof of concept (for which expensive clinical studies are needed).

Frédéric Allemand, Biocortech:

He explained how important it is to be able to navigate through the maze of business decisions, what to do when you encounter a real problem. Developing multiple options in parallel and timely responsiveness (not necessarily quick) on new opportunities are key elements. Biocortech started with drug discovery, but is focused now on biomarkers discovery and clinical validation of in vitro blood tests for psychiatric disorders. Navigating adaptively may allow the management to go around the revenue gap and offer something else, but still use the assets, knowledge and the expertise the company has built up before. This "corporate agility-based" business model is another way to grow a company without VC money. Unfortunately, most funding mechanisms do not leave room for this flexibility and SME financing policies fostering innovation have to be consistent with this requirement of corporate-agility. "We need more 'Ariane' helping young companies to find their way through the maze".

Manuel Gea, Bio-Modeling Systems:

A third case, about disruptive innovation, in the field of systems biology that already delivered operational results, showed an example of an innovative business model in which disruptive innovations are at the basis of creating growth without VC money. A major problem is the difficulty to find financing for disruptive innovation (conservatism in the funding schemes - both in programs and in the evaluation) as opposed to incremental innovations, which are more accepted. In this company all technologies are proprietary and they are never sold, which ensures complete technological independence, however almost everything is done in a collaborative mode. Individual innovations resulting from collaborations among companies are spun out or developed in joint ventures in return for shares, each company focused on its own market, while the original company retains its knowledge and people act as a hub to generate new avenues.

Ritchie Head, TrusTech-NHS:

This presentation demonstrated a collaborative model of a large healthcare network (15,4 Bn €) of hospitals, laboratories, care providers, etc. working together in innovative ways with the aim to make healthcare delivery more cost effective. This involves linking inventors and funders, providing shared infrastructure and an effective testing ground for innovative therapies and working with innovative procurement processes. Opportunities may be lost during the time in which partners address IP issues and secure funding. IP issues can act as barriers as well as facilitators. Often, being the first on the market and developing something that works is more effective than having patents. The innovation hub can also collect ideas and test innovative concepts from people outside the system. Early involvement of stakeholders in the market is key.

Conclusion of this session:

We have seen 3 examples of different innovations in business models, demonstrating that those new models and a variety of approaches are agile and successful in spite of the regular challenges of attracting VC money. In order for these companies to realize their high potential in creating leverage, we may need to pay more attention to innovation in the regulatory framework and in the funding landscape.

General comments: Biotech sector is still young, innovation models from other sectors like aerospace are sometimes more mature in their adoption and implementation. All players (industry, academia, funders, government and regulators and other stakeholder groups) need to learn (and training will be needed) how to innovate their activities, processes and rules in order to cooperate effectively with each other.

Recommendation: one key to success would be to *allow more flexibility* in certain parts of each of those systems: already this would take away a lot of frustration and allow new business models and collaborations to be tested out.

Regulatory and Access to Finance Stream - Copper Hall

The DG ENTR organized the regulatory and access to finance stream in the Copper Hall and included 4 sessions on May 20 and 21, focusing on marketing authorization from EMA, regulation of advanced therapies, access to finance, and use of public financing instruments for innovation. The two regulatory sessions were organized in close collaboration with DG SANCO.

The 4 sessions were

Instruments in place to support SMEs applying for a marketing authorization from the European Medicines Agency

- Melanie Carr, Head of SME Office, EMA
- Pavel Balabanow, Scientific Administrator, Scientific Advice section of the human medicines, Special areas sector, EMA
- Maria Pascual, VP Regulatory & Manufacturing, Cellnex
- Maria Figuerola, Pharmaceuticals Unit, DG Health & Consumers, EC (moderator)
- Ludovic Lacaine, Director, Healthcare Biotechnology, EuropaBio (moderator)

Experience of the centralized procedure, a case study on the regulation of advanced therapies

- Sol Ruiz, Committee for Human Medicinal Products/Committee for Advanced Therapies (AGEMED)
- Michelle Lipucci di Paola, Eurordis
- Janneke de Wal, director Clinical Development, Amsterdam Molecular Therapeutics
- Wilfried Dalemans, CTO & VP Regulatory Affairs, Tigenix
- Lucia D'Aporte, Member of the Secretariat for the Committee for Advanced Therapies, EMA
- Maria Figuerola, Pharmaceuticals Unit, DG Health & Consumers, EC (moderator)
- Maria Pascual, VP Regulatory & Manufacturing, Cellnex (moderator)

Access to finance for biopharmaceutical product development in Europe

- Tom Saylor, President & CEO, Arecor, and Chair of EuropaBio SME Platform
- Edwin Moses, CEO, Ablinix, and Board Member of European Biopharmaceutical Enterprises
- Michiel de Haan, General Partner, Aescap Venture
- Mark de Boer, Partner, Index Ventures
- Hakan Goker, Associate, Atlas Venture
- William Brooks, Investment Director Life Sciences, Quest Management
- Florent Gros, Managing Director, Novartis Venture Fund
- Giulia del Brenna, Head of Unit Competitiveness in the Pharmaceuticals Industry and Biotechnology, DG ENTR, EC (moderator)
- Emmanuel Chantelot, Executive Director, European Biopharmaceutical Enterprises (moderator)

The use of public financing instruments for innovation - at EU and national level

- Per-Ove Engelbrecht, Head of Unit Financing Innovation & SMEs, DG ENTR, EC
- Piyush Unalkat, Principal, EIF
- Michael Brandkamp, Managing Director, High-Tech Gruenderfonds
- Patrick Chatlin, Leuven University
- Miran Pleterski, Director Corporate Advisory, PEMicon
- Giulia del Brenna, Head of Unit Competitiveness in the Pharmaceuticals Industry and Biotechnology, DG ENTR, EC (moderator)
- Dirk Carrez, Director, EuropaBio (moderator)

Instruments in place to support SMEs applying for a marketing authorization from the European Medicines Agency

The theme of this session was instruments and procedures to support industry in general and more specifically SMEs in the development and registration of products at the European Medicines Agency. Focus was on advanced therapy medicinal products.

The regulatory framework in the EU includes measures to support small companies for development of medicinal products. Key successes include legislation on Orphan Medicinal Products (OMP) and Advanced Therapy Medicinal Products (ATMPs).

Yet weaknesses were identified with regard to harmonisation of EU regulation among 27 member states, particularly the tissue and cell directive and the clinical trials directive, which result in an increased burden on small companies.

The SME Office of the EMA has been successful in helping companies throughout the regulatory pathway from beginning to end, by offering regulatory assistance, fee incentives, organising workshops and training sessions for SMEs, and providing translation of product information required for the granting of an EU marketing authorisation. However, there is still a lot to do to help SMEs to improve the success rate at the stage of the application for marketing authorization. Experience to date with SMEs through the centralized marketing authorization procedure has shown that major objections run high on quality and clinical documentation – particularly in quality. When looking at clinical data there is an element of premature filing, with many companies completing development following negative opinion withdrawal & planning re-submission.

Companies need to be made more aware of the importance of seeking scientific advice proactively and comprehensively on key issues in development (quality, non-clinical, clinical) and seeking follow-up advice as development proceeds. The EMA could provide further support to them in the follow-up of the recommendations from this scientific advice e.g. by offering a de-briefing meeting for SMEs after scientific advice.

The EC and the SME office need to go out and engage more actively with the SMEs to make them aware of the tools and supports that are in place to assist them in getting regulatory marketing approval. Companies should be further encouraged to open up an EC-EMA-SME dialogue early on to ease the regulatory burden.

There is an abundance of regulatory guidance. The EC and EMA could further facilitate access to key information and documents, guidelines, and reinforce the need for SME incentives also at the national level.

Once companies have marketing approval there is lack of harmonization at national level about Health Technology Assessment (HTA) and also pricing and reimbursement which also needs to be addressed by the EC.

Finally, the EU regulatory framework should also be put in a broader political framework around innovation and achieving innovation in Europe.

Experience of the centralized procedure, a case study on the regulation of advanced therapies

Sol Ruiz, Agemed:

The huge diversity among Member State regulations regarding the regulatory framework, authorization and importation of cell therapy products was the basis to develop Regulation (EC) 1394/2007 on advanced therapy medicinal products (ATMP). This Regulation includes for the first time a definition of tissue engineered products. The Committee for Advanced Therapies (CAT) has been set up at the European Medicines Agency (EMA) with representation of a diverse expertise as required for this particular kind of products. Patient associations and clinicians are also represented in the CAT. One of the incentives in this Regulation is the Certification of quality and non-clinical data for small and medium size enterprises developing an ATMP. Certification does not equal market authorization; it is not legally binding, rather a quality mark.

Michelle Lipucci, Eurordis:

Opportunities: patient organizations can provide real added value to present incentives for product development from patient perspective, adapt regulations to the fast new scientific developments and ensure fast and early access for patients to therapies. This added value ranges from collecting data, disseminating information and provision of training to really engaging in content on technical issues such as ethics, pharmaco-vigilance

Threats: fragmentation of regulatory requirements, lack of funds - tax incentives are fragmented at national level and usually not enough - lack of international cooperation, difficulty of access to regulatory procedures by non-profit organizations.

Janneke de Wal, Molecular Therapeutics:

A case study from of a SME was presented with an example of a gene therapeutic intervention for a severe rare metabolic disease, lipoprotein lipase deficiency (LPLD) going through the centralized procedure. The centralization is of great benefit, although gene therapies are complex to position in the regulatory landscape. She explained the benefits of gene therapy as part of personalized medicine (short development cycles, lower costs). However there are still challenges at different levels (quality, non-clinical and clinical), hence the need for specialized training for all stakeholders and early communication with the regulators.

Wilfried Dalemans, Tigenix:

He presented a success story of an SME that had gone through the centralized procedure for the first cell-based product that obtained EU marketing authorization in Europe. Challenges need to be overcome at CMC (how to regulate cells, not single molecules), preclinical (which validation model to choose?) and clinical level (how to document and score clinical benefits?). Even during the entire procedure things were adapted (CAT came on board during the procedures for their product). Therefore this is a learning curve for the regulators too and one has to work together. Other challenges still exist: reimbursement issues (the SME has to go through this procedure once again 27 times across Europe), false expectations (measure benefits for quality of life during the studies, not just the pure clinical parameters count for reimbursement decisions) and to be realistic: it takes 15

years to get a product in the various markets, which may be beyond the financial capacity of the SME.

Discussion:

The discussion evolved around different aspects of added value in engaging patient associations (avoiding wrong expectations on novel therapies, patient perspective taken into account for which regulations, etc).

While there are grey areas in regulatory definitions for ATMPs it was realized that those rules would not change quickly (harmonization not only across Europe but also with FDA would be of interest to avoid the case to case decisions that create uncertainty and risk).

A call for more centralized analysis of data that are common in the national assessments (avoid duplication of analyses in 27 MS), length of procedures ("an SME can go out of business in the meantime..."). The European Commission (DG Sanco) should give guidance to the national agencies on who decides, on which issues, who sets the rules and who addresses which concerns with regards to ATMPs.

Also a discussion emerged around the observation that in the US there is unfair competition by hospitals that are exempt from FDA restrictions and can use (which can be dangerous for patient) homebrews test for non-routinely manufactured products. The important questions are to define what is 'non-routine' and to ensure that patients will get safe and effective products.

General: There is a clear need for more harmonization of the regulatory landscape for ATMPs across Europe. In particular SMEs are struggling with the burden of having to go through different procedures, interpretations of definitions and rules as applied by individual Member States.

Access to finance for biopharmaceutical product development in Europe

This session assembled a number of key life sciences venture capital investors, a corporate investor from a big pharma corporate VC fund, and two experienced biotech CEOs, in order to capture their insights and recommendations through a moderated discussion. There were therefore no presentations, and the following is a summary of key statements, problems identified, and recommendations and proposals.

The VCs on the panel made a very strong argument that Venture Capital is currently being confused by the public and policy makers with institutional investment private equity and hedge funds, and it is not at all the same. VCs work very closely with a few companies, taking high risk and making significant returns only after several years and only if they are able to finance and support the creation of real value for all concerned. It takes expertise and risk and creates a lot of value, and should not be hampered by EC regulations on institutional investors and private equity.

The CEOs stressed that drug development has nothing to do with cross border collaboration, and that the focus on collaborative research is far less effective than simply funding the best research within the best prepared SMEs.

The VCs agreed that in terms of public funding, the EC should not just focus on financing research, but on selectively financing the best companies and projects with the greatest potential to generate value. It is at most 1 out of 50 that can succeed, and the EC should support these through financial instruments, because if a few serious companies grow they will have an impact on spin-outs, job-creation, economic development etc. In order to do this, it is necessary to leverage the expertise of the people with the most experience at getting actively involved and building companies.

The panel was unanimously agreed that Europe does not have the institutional investors needed. In the US, some institutional investors can put 10 to 15% of their funds into VC. European investors do not do this and do not have the appetite for risk. We need to look at how to encourage state pension funds in Europe to increase their appetite for risk and invest into VC funds, otherwise the money will not be there in the overall chain, and a few gems will get funded but many very good companies will not.

The panelists also agreed that there is a funding gap for biotech companies at all stages of development, but that it is structural, and there is a priority. If late stage funding is secure, VCs will begin investing in an earlier stage. So, the early-stage financing gap is a result of the late-stage funding gap. The funding gap has to be addressed in terms of the overall funding structure. VCs are very good at investing in early stage so there should not be a gap there, but in fact there is a gap because the later stage money is not there, and therefore they cannot invest earlier because they will not have the money to support these companies until the moment they have a liquidity event or are profit making. So, if you solve the late-stage funding gap, the earlier stages will take care of themselves to some degree. The risk is that the focus of public money may be on the early stage because it is easy, and we do not want to see more funding for companies that have no potential for growth and should never have been created.

There was also extended debate on the timeframe that LPs allow VCs to return their investment. Ideally the current 10 years should be extended, for example, to 15 years as life sciences/biotechnology/drug development companies take considerably longer time to reach an exit for investors, compared to the historic exit times, due to longer trials/regulatory needs etc. But institutional investors or LPs will not take the lead in this and they would likely only accept it if the EIF leads the way.

The next point emphasized was that everything starts with good technology transfer, which is largely lacking. There was agreement that very often projects from academia approach investors prematurely. Perhaps the EC could provide means to ensure that the right projects get enough additional funding early on, before they are companies, to help get them to the point where VCs can invest. Not all projects should become companies; more proof of concept work is needed. The Flanders example of VIB was highlighted as a model, where there have been relatively few spin outs but a very high success rate in terms of value and job creation, and that VIB has one of the best tech transfer operations in Europe. Technology transfer is not just about setting up more offices or associations, nor is it just transactional; to be done well it requires deep expertise and market knowledge. Resources should be dedicated to recruiting professionals and to develop measures which have potential to build real expertise and capacity, not just administrative skills or networking.

The panel strongly endorsed the EU financing of clinical trials and stressed that this should be further emphasized, and move on later stage. In the US one company can get 15 to 20 million from US government agencies. Europe should at least offer the same.

The panel also explicitly called for the EU to recognize that there is a shortage of institutional investors in Europe for life sciences, and therefore the EU should increase the mechanisms and funding of the EIF for healthcare VC funds, and should also take active measure to stimulate institutional investment into biotech and healthcare VC funds. Additional resources for the EIF, or a new public fund-of-funds for life sciences and healthcare is needed, to leverage the expertise that already exists but which is financially under-resourced in Europe.

Public funding of research in companies should leverage the expertise of investors and help to make smart decisions about where to put the money in order to generate results which will have a real knock-on effect in building innovation in Europe and should also address the major structural challenges in access to finance. A Swiss model of using retired VCs and CEOs

to coach companies receiving grants was proposed as one possible model for replication at the European level.

Finally, VC funds create value, they should not be subject to the same regulations or tax treatment as hedge funds and private equity, which will further reduce the funds available to them to support innovation in healthcare in Europe – the exact opposite of what is needed.

The financial crisis and the currency/debt crisis are both aggravating existing structural problems that are holding Europe back from the Lisbon goals and the achievement of a strong, innovative society.

The use of public financing instruments for innovation – at EU and national level

This session focused primarily on public funding instruments that could complement the private ones, with the presentation of several models of public funding instruments. We have new funding instruments at the European, national, regional and local level. Some are very efficient, others are not. Public funding instruments are mainly focusing on early stage of business development and to date have been most effective at it. They play an important role, although more selectivity and focus on picking the winners is needed. What kind of invention should lead to a spin-off? What can really make a difference later on? What kind of business can mature and grow? To do this we need very efficient Technology Transfer agencies. Once again, skills, knowledge, application of business are important. Key message: not every invention is or should be a new business.

The presentations provided detail into a number of public funding schemes, but in the discussion emerged that the actual or potential role of public funding is not yet so clear at the later stages of a company's development. Instruments like RSFF should be well suited to healthcare and biotech SMEs because they are risky business. But SMEs cannot easily access these support mechanisms or sources of funding because of the selection criteria used. Therefore there is a strong recommendation to revise or develop a new tool enabling SMEs to access this kind of financial support at an affordable cost.

Additional recommendations called for legislation and fiscal incentives for investments into healthcare R&D and into VC funds, at both the European but especially at the Member State level, with tools having easy application and administration procedures. Additional EU funding for proof-of-concept studies focussing on SMEs are recommended, to support SMEs up to the point that they can attract private investors. This would allow to level the playing field vis-a-vis the US where companies can get direct funding from government agencies right up to proof of concept, without the need for a multi-partner cross-border collaborative research project.

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