The ETP Nanomedicine's contribution to the European Pilot action of an Innovation Partnership on Healthy Ageing

The European Technology Platform Nanomedicine was established in 2005 as a joint venture of the European Commission and CEOs of large industrial companies such as Philips, Siemens and UCB, SMEs and academic research institutions to investigate and advance joint activities in the area of nanotechnology in medicine. Since 2005 the ETPN published a number of strategic documents outlining the strategic needs and roadmaps for nanomedicine research in Europe. Influenced by these strategic documents, the NMP unit of the Directorate General for Research funded projects worth 265 Mio. Euros so far in FP 7 including projects such as the NanoMed Round Table and the EuroNanoBio project which provided a first impression of the needs and conditions for a suitable social and economic environment and the structural requirements for an efficient translation of R&D results into innovative Nanomedicines.

Based on this large body of information and the partnership covering the whole value chain the ETPN is prepared to contribute to the setup and implementation of a pilot action for an "Innovation Partnership" in the area of Healthy Ageing. This contribution is important, as Nanotechnology applied to medical applications – usually called **Nanomedicine** – will be one of the key enabling technologies for earlier diagnosis (the sooner, the better the treatment), better targeted therapies (less side effects) and better therapy monitoring (faster recovery). Beyond that, Nanomedicine is thought to be instrumental with regard to improved and cost effective healthcare, one of the key issues for the ageing population. Furthermore, the field of Nanomedicine will be an important contributor to European economic growth and employment if developed properly.

The ETPN implementation plan consists of **five fundamental steps,** namely:

1. **Analysing the future needs of stakeholders including patients, clinicians and industries and the contribution that Nanomedicine can bring,**

2. Improving translation in Nanomedicine by advancing project setup process,
3. Establishing sustainable infrastructures for translation of R&D towards industry,
4. Improving coordination with member states and regions,
5. Fostering European harmonisation for increasing European global competitiveness and industrial attractiveness.

Implementation Plan

The ETP Nanomedicine is proposing a multi year implementation plan to be established under the framework of the Innovation Partnership on Healthy Ageing and within the FP 8.

Step 1:
Analysing the future needs of stakeholders including patients, clinicians and industries and the contribution that nanomedicine can bring

Nanomedicine is expected to deliver key tools for tackling age related diseases such as Alzheimer or Parkinson. To find better diagnostic and therapeutic tools for neurodegenerative, cardiovascular and musculo-skeletal diseases, a multi-layer approach is needed addressing the clinical, regulatory, economic, as well as social, ethical and governance aspects.

It is obvious that many different stakeholders such as clinicians, academics, SMEs, industry, ICT specialists, health care economists, regulatory agencies, health insurance companies, social scientists and ethicists have to be involved in a comprehensive analysis of the current situation and the definition of needs, constrains and future actions in all the above interrelated areas. The analysis shall be based on contributions of relevant European and national projects, networks and societies and shall be aggregated to a comprehensive report on the status and future requirements for healthy ageing.

Step 2:
Improving translation in nanomedicine by advancing project setup process

The implementation of nanotechnology in new diagnostic tools and therapeutic concepts not only requires the collaboration of many academic disciplines as divers as physics and engineering vs. biology and medical science, but also a guidance by clinicians, who define realistic needs, and by industry who define realistic markets and products. On top of that SMEs and large industrial companies are ultimately needed to jointly fund, produce and market these nanomedical innovations. Therefore, one of the first steps in this implementation plan shall be to define measures that ensure that more research projects with involvement of clinicians and industry are funded and that a firm integration of the projects into value chain is guaranteed. At same time project proposals need to be evaluated by a panel which also consists of experts from these institutions to insure end to end translatability and guarantee the translation of research results from bench to bedside.

All these efforts shall ultimately be leading to a dedicated funding area / programme for "Nanomedicine for Healthy Aging" under the Framework Programme 8 or within a Public Private Partnership (PPP) (see step 5).

Step 3:
Establishing sustainable infrastructures for translation of R&D towards industry in

order to increase the attractiveness for the development of nanomedicine in Europe

The complexity of the communication and collaboration between the different stakeholders along the value chain requires an efficient organisation to achieve fast translation of R&D results into patient treatments and laboratory scale to industrial processes. Several studies such as the EuroNanoBio CSA have indicated that a close vicinity of technology developers, clinicians and SMEs in regional clusters supports translation most efficiently. Models such as Clinatec in Grenoble combining technologist and clinicians under one roof or the Nanobioanalytik Zentrum (NBZ) in Münster gathering SMEs and clinicians in one building are being set-up and will provide prototypes for professional structures to which industry can connect to.

Consequently, a major initiative under the ESFRI programme should be initiated to establish a network of such centres focussing on Nanomedicine, certain disease aspects and clinical treatments with a common coordination of developments at the European scale to avoid duplication of efforts. The ETPN has already taken the initiative in identifying all “bottlenecks” which block or slow down the development of this emerging market. It will pursue this analysis and synthesise the various actors' (public and private) needs to create the appropriate paradigm shift for a public private partnership.

Additionally, the set-up and provision of a European Characterisation Centre (ECC) for nanomaterials for medical applications has to be initiated. Such a centre does not exist in Europe and therefore researchers have to send their materials to the USA for characterisation. Together with standardisation bodies CEN, ISO, etc the Center could also promote the adoption of European standards at the global scale. This will again increase the European competitiveness and foster the independence from e.g. US based institutions in this area. As a first action the ETPN, together with the Member States, shall define the criteria and financial support needed for such an ECC to create the attractive substrate for the development of the nanomedicine industry in Europe.

Step 4:
Improving coordination with member states and regions

Health systems are the national responsibility of the Member States. However, the goal to ensure an active and healthy ageing for all European citizens is not disconnected form the Member states economic situation and can only be achieved if Europe is scientifically, technologically, and economically competitive at the global scale. Exploitation of innovations by European companies will provide the jobs and economic growth necessary to raise the money for paying the healthcare and social security systems. Such jobs cannot be relocated easily outside the EU as they are strongly tied to the regions. To achieve this goal and in view of the global competition and the special requirements of the European ageing population, the Member States have to commonly agree on technologies, infrastructures and medical needs to invest European money in.

Already today, Member States and Regions give high importance to the development of nanomedicine and they invest in research, research infrastructures, education and training. Within the Mirror Group of Public Authorities of the ETPN,18 European Member States, Associated States and Regions joined their forces to align their funding activities in Nanomedicine. Together, they initiated an ERANET for Nanomedicine called 'EuroNanoMed' and already publish three annual Joint Calls for Proposals based on the research priorities identified by the ETPN in the Strategic Research Agenda.

The established Mirror Group together with the ERANET structures provide a "ready-to-go" basis for coordination of national programmes, avoiding duplication of efforts. The continuation of the ERA NET EuroNanoMed beyond 2011 will enable the member states to further harmonize their efforts and start preparing for the next steps in consolidating nanomedicine research activities.

Step 5:
Fostering European harmonisation for increasing European global competitiveness and industrial attractiveness

Ultimately, creating a coherent funding and support programme for nano- and future medicine research in Europe in the framework of the Innovation Partnership on Health Ageing or under FP8 will be pivotal for alleviating the burdens of the ageing population in Europe. To do so, the established structures in the area of future medical technologies originating from the ETP Nanomedicine and the ERA Net EuroNanoMed as well as from other ETPs (EPoSS, IMI, Photonics, etc…) shall be transformed into a coherent large scale European programme following the recommendations for Public Private Partnerships currently under revision by the European Commission.

Such large scale programme established under the Framework Programme 8 will guarantee, under the guidance of industrial and clinical stakeholders, the speedy translation of research from the lab to the product and from bench to bedside. In particular it will guarantee that research projects are well embedded into the value chain of health related industries and research results are ultimately picked up by companies according to the stage of development and associated risk of attrition to SMEs &/or Large companies) for bringing them to market. This will not only help academia to target their research better but also increase European competitiveness in this area, secure highly qualified jobs and last but not least contribute to the ultimate goal of enabling the ageing society to live longer and healthier. Such a well organised and integrated environment can compete with Asia and limit the departure of the industry and research from Europe. Indeed, the European Union needs to reinforce European attractiveness for industry, in order to create growth and employment.

At the same time, it is most needed to harmonize the national and European regulatory governance structures and regimes to speed-up the regulatory processes for the benefit of patients and

to create a European market with a common regulatory approval system acting as counterpart to the regulatory systems in the US and Asia.

Conclusion

The ETPN believes that amongst others, Nanomedicine will be a, if not the, key enabling technology to achieve the envisioned benefits for the ageing population in Europe. Only by heavily investing in future medical innovations will Europe be able to keep up the race against the inflating costs and increasing demands by patients. Europe has the strength and capability to develop and master this important economic sector rather than being pushed into the role of being a nanomedicine "consumer".

The ETPN is ready to take a lead in this endeavour, since it already has established contacts to many major relevant stakeholders such as clinicians, industry, SMEs, academia and social and ethical scientists which are necessary to successfully implement Nanomedicines into the future healthcare of the ageing population.

Background

Nanomedicine Research in the Framework of the Flagship Innovation Partnership in the area of Healthy Ageing.

One of the major societal and economic challenges of the next 50 years is the continuous ageing of the European population. This trend is even exacerbated by the "baby-boom" generation reaching retirement age in the next 10 to 20 years. A growing elderly population generates new needs like improved home care concepts and related technologies, real time monitoring of chronic diseases and health conditions in general, or early diagnosis and more efficient treatment of diseases such as neurodegenerative and cardiovascular diseases or diabetes and cancer.

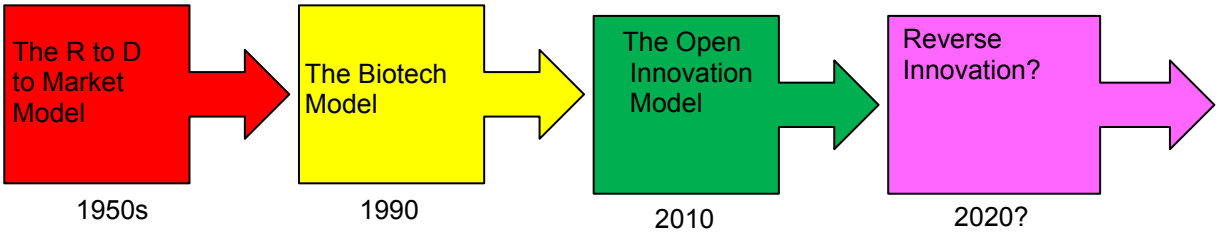
In the area of nanomedicine a set of unique challenges have been identified that need to be urgently addressed to overcome the issues addressed above.

New tools, novel diagnostics and targeted therapies

The ageing population expects to live in good healthy conditions, which contradicts the fact that illnesses such as Alzheimer, Parkinson, cancer or cardiovascular diseases increase with growing age. To meet the expectations of the ageing population and to successfully fight the diseases at reasonable costs early detection and innovative medicines are needed. Nanotechnology will enable many innovations by opening up new pathways for developing tools that lead to earlier diagnosis of potentially life threatening diseases. Nanotechnologies will only enable the development and design of revolutionary smart sensors & devices for detection of diseases or in or on body monitoring of chronic patients. In parallel such nanotechnologies are also prone to be key for making personalised and better targeted therapies possible. Here in particular novel tailor made nanoparticles for highly selective molecular imaging or specially engineered nano-coatings for precise drug delivery are envisioned. Beyond this functionalised nano-materials will be fundamental for the emergence of a true regenerative medicine where organs and tissues will be rather re-grown than replaced by technical systems.

Faster translation of research results from bench to bed

Time is pressing since the portion of elderly population is growing fast. Therefore, new innovations in nanomedicine need to be generated more rapidly, which will require a more efficient translation of R&D results into products. This translation process has changed significantly during the past 50 years for the pharmaceutical industry which has reduced its own in-house R&D capacities in favour of an open innovation. Differently, the semiconductor industry is looking for new markets in medicine using silicon based devices/sensors, mass produced, at very low costs per item and addressing a huge market.



In this new collaboration model industry is looking for key expertises and an appropriated environment to reduce risk of R&D by sharing expertise, finance, and infrastructures within a professional academic and industrial framework. This new mode of operation will speed up the development of new potential solution, regardless of where that they come.

However, the global approach of the open innovation model puts a lot of pressure on the European economy, because many well paid jobs in industrial R&D are lost to other countries such as China or India and because European academic institutions, the main source of new ideas and technologies, are not well adapted to this model for historical and organizational reasons. Furthermore, innovations in nanomedicine need highly interdisciplinary teams and new forms of collaboration between research teams and companies. Therefore, Europe needs new and more efficient and attractive translation structures that foster networking of academia, clinical research SMEs and Industry in a multi disciplinary way to stay competitive for the generation and exploitation of innovations in nanomedicine at the global scale. This is also a prerequisite for innovations to be exploited in Europe and to participate in the emerging industrial market of Nanomedicine with huge potential for profit, which in turn is essential for continued economic prosperity needed to keep the social security system alive.

Strengthening European competitiveness through standardisation and characterisation

Nanomedicine – the use of nano-materials and nanotechnology based devices in medical applications – will result in new and earlier diagnostic procedures, more targeted drug delivery with less side effects, and new innovative materials for regenerative medicine. In order to speed up industrialisation and regulatory approval, it seems necessary that the novelty of these materials requires a thorough characterisation and standard reference materials to be safely used in medical applications. So far only the National Cancer Institute in the US has set-up a central Nanotechnology Characterisation Laboratory (NCL), where academia and industry can send their material for characterisation in the perspective of regulatory approval, and which is used already by European groups and companies for the same purpose. For Europe to be involved in setting global standards for the characterisation of nanomaterials in medical applications as part of the whole value chain from early research up to industrialization, a similar initiative needs to be set-up in Europe. A central or distributed facility brought to ESFRI by Member States looks achievable in a reasonable

period of time. It would be based on the excellent and famous (nano)analytical expertise available in some leading European clusters.

Contacts

Bertrand Loubaton

Chairman ETPN, Director GE Healthcare,
Bertrand.Loubaton@ge.com

Dr. Sebastian Lange

Managing Director ETPN, Senior Consultant VDI/VDE-IT,
Sebastian.Lange@vdivde-it.de

Secretariat ETP Nanomedicine
c/o VDI/VDE Innovation + Technik GmbH
Steinplatz 1, 10623 Berlin, Germany
Fon: +4930310078155
Fax: +4930310078225
secretariat@etp-nanomedicine.eu
www.etp-nanomedicine.eu