

Nanomedicine in Europe: present and for the future

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Speakers' biographies and summaries

1. *Nanomedicine in the EC's Action Plans for Nanotechnology*

Christos Tokamanis trained as chemical, material engineer holds a degree in Business Administration. He has worked in the chemical and electrical engineering industries before joining the European Commission in 1987. Since then, he has been working in the Research field of advanced materials, new production systems and transport technologies. He has been, for 5 years, Head of Unit responsible for Sub-Priority 6.2 "Sustainable Surface Transport" in the FP6 Specific Programme "Integrating & Strengthening ERA".

Nanomedicine has great potential for breakthroughs in basic, applied and clinical sciences, leading to more efficient and targeted diagnosis, treatment, and monitoring of disease. It can moreover enhance competitiveness of healthcare industry and in the longer term reduce social care costs. In the Seventh Framework Programme the themes Industrial Technologies, ICT, Health are involved in the funding of nanomedicine projects. EU funding for nanomedicine was around EUR 330 million in FP6 (2002 – 2006) and EUR 280 million in the first two years of FP7 (2007-2008). European nanomedicine research is structured through the ERA-NET EuroNanoMed. Ethical, legal, social, and regulatory aspects, which are of particular importance for the successful development of nanomedicine, are also supported by EU-funded support actions.

Nanomedicine is part of an integrated safe and responsible strategy for the development of nanotechnology as expressed in the Nanotechnology Action Plan 2005-2009 which is under renewal for the next five years to address pressing socio-economic challenges, such as climate change, healthcare, energy, clean water, to consolidate social trust and ensure high level of safety and security to citizens for a smart and sustainable growth. Public engagement in the innovation process is a condition for the development of nanotechnology applications for a proper understanding of benefits and potential risks of nanotechnology. On the regulatory front, regulation needs to be reviewed, especially in light of the practical experience of REACH and various surveys (by 2011). On the research front, research needs to be consolidated, building on the results of the research already carried out, especially on human and eco- toxicology, exposure studies and life cycle assessment.

2. *Nanomedicine to 2020*

Patrick Boisseau has an education background in biological engineering. During his career, Patrick Boisseau gained experience in basic research in plant biology, project management, technology transfer, and science communication. More recently he coordinated the FP6 Network of Excellence Nano2Life from 2004 to 2008, and then the FP7 EuroNanoBio support action on EU nanobio infrastructures in nanobio. He is on board of the European Technology Platform on Nanomedicine since 2005. His current scientific and technical expertise is on organic nanocarriers for clinical diagnosis and therapy.

Most of the public investments in nanomedicine research in the last 6 years were directed toward fundamental research, exploring the potential of nanotechnologies applied to healthcare, and understanding the medical potential of the interface between inert matter and living organisms. After this period, companies, research centres, and academia are able now to move towards clinical applications in diagnostics and therapy, by prioritising the most promising and translatable technologies and products. The European Technology Platform on Nanomedicine on Nanomedicine has recently identified the industrial technology roadmaps with highest priority to offer better, faster, more reliable and more comfortable healthcare to EU citizens. The translation of knowledge from bench to bedside has never looked so close. Nevertheless, such technological developments, preclinical validation and clinical trials require the cooperation and the efficient interface among a wide panel of stakeholders. Therefore, it is as important as science and technology, to set up a suitable European framework and environment where all the necessary disciplines and experts, like scientists, engineers, manufacturers, hospitals, patients' associations, regulation authorities and politicians could cooperate towards the development of nanomedicine to the benefit of our citizens. Networks of dedicated infrastructures should facilitate the translation towards clinical implementation, as well as education, research, tech transfer and engagement with the public. Europe has a real potential which can be fully expressed only if strong political support is backing it.

3. *Changing academia/industry relations for nanomedicine*

Mike Eaton worked in research in the Pharma industry for more than 35 years. He was a founding member of Celltech in 1980; later acquired by UCB. He has worked on a number of marketed drugs - Mylotarg in 2000, the first Antibody drug conjugate and certolizumab pegol in 2009, the first PEGylated antibody. Unusually he has worked with both small molecules and large molecules including DNA. He built the first automated DNA synthesiser in Europe; it now is owned by the Science Museum London. Mike is a special professor at Nottingham and an executive board member of the European Technology Platform for Nanomedicine, since its inception in 2005. He left UCB in February 2010.

Nanomedicine will improve healthcare; albeit in a tightly regulated sector the market will take the same timescale as for Biologicals. Nanomedicine research is taking place when "Big Pharma" is losing significant jobs and skills to lower cost economies. In addition Open Innovation is creating a true global competition for all aspects of the pharma business. Despite significant funding, nanomedicine progress is impeded in Europe by the lack of knowledge in academia and SMEs of how to translate research from the lab to the clinic. All at a time when such knowledge is being lost from industry, we are continuing to fund and research public sector failures. This is not what patients across Europe are expecting and it is unsustainable with intensified global competition for R & D. Some solutions are suggested for what are both a serious problem and an opportunity for Europe.

4. *The view from a small nanomed company – MagForce Nanotechnologies AG*

Dr. Andreas Jordan studied biology at the Free University of Berlin, followed by further studies in biochemistry at the Technical University of Berlin. Since receiving his doctoral degree in 1993, he has dedicated his work to basic research and product development in the area of nano-cancer therapy.

MagForce Nanotechnologies AG is focused on using nanotechnology to fight cancer. Its proprietary system of therapy is based on injecting aminosilane-coated iron oxide nanoparticles into a tumor which has already been localized. These nanoparticles are then subjected to a high-frequency alternating magnetic field, causing them to vibrate and produce heat which then damages or destroys the tumor cells. Depending on the temperature attained within the tumor, the method may be used either as hyperthermia therapy in support of conventional forms of treatment (such as radiation and chemotherapy) or by itself as thermo-ablation for the direct destruction of tumor cells. This approach, now in the phase of European regulatory approval, may be used for many different types of solid tumors, as fundamentally all tumor cells may be damaged or destroyed at a certain temperature. MagForce's current product range includes the iron oxide nanoparticles (Magnetofluid NanoTherm®) for injection into tumor tissue, the magnetic field applicator (NanoActivator®) for warming the nanoparticle-laden tumor tissue, and specialized software for thermal treatment planning (NanoPlan®).

5. *Nanomedicine in the broader field of nanotechnology's present and future*

Dr Steffi Friedrichs is the Director-General of the Nanotechnology Industries Association (NIA), globally the only industries-focused trade association in nanotechnology with registered companies in the UK (NIA Ltd) and in Belgium (international level, NIA AISBL). Based on business-strategies and policies developed by Dr Friedrichs, the NIA provides a sector-independent, responsible voice for the industrial nanotechnologies supply chains. In this capacity, she has represented the nanotechnology industries through provision of expert advice and evidence to numerous national and international expert committees and regulatory organizations on topics ranging from regulatory-/safety-issues to environmental and societal benefits of nanotechnologies, educational-/skills-requirements for nanotechnologies to commercialization-/business-issues related to the advancement of nanotechnologies to general policy considerations for emerging technologies. She initiated several in-depth programmes in support of the ongoing advancement of nanotechnologies and participated in many stakeholder debates and citizen's engagement panels.

Dr Friedrichs will give an insight into the wide number of benefits provided to the medical sector by nanotechnology-enabled innovations. She will also highlight the current challenges faced by the industries in implementing and harvesting these benefits and invite discussions on a way to overcome those challenges as a fully-inclusive stakeholder approach.

6. Patients' views and needs

Alastair Kent is the Director of the Genetic Interest Group (GIG) - the UK alliance of charities and support groups for people affected by genetic disorders. GIG's mission is to promote the development of the scientific understanding of genetics and the part that genetic factors play in health and disease, and to see the speedy transfer of this new knowledge into improved services and support for the treatment of currently incurable conditions. Prior to joining GIG Alastair worked for a number of voluntary organisations on issues concerning policy, service development and disabled people.

1. Nanotechnology remains a closed book to most patients. While many have heard of nanotechnology, few have any idea of its application in (or potential application) in "their" disease area.
2. When current ideas in nanotechnology in medical research were explained, patients were interested but cautious with regard to the claims for this field of research. For many patients this is early days and it is too soon to rush to judgement.
3. Safety concerns were, by at large, no different from nanotechnology than for other areas of innovation in R&D. The key issue for patients is the potential to deliver health gain. It is not the route by which this is achieved.
4. Nanotechnology in medicine is seen as an area where there is significant potential for delivering health gain, but it is an immature technology that warrants a sustained programme of investment in order to either establish its potential or disprove the claims that are being made for it.
5. Patients and patient support organisations want to play a part in strategic programmes to explore this potential. They need a structured programme through which accessible information is provided in order for them to be able to interact with other vested interests and have a say in the future direction of research and development of this promising area of biomedical research.

7. The regulatory framework

Prof Julian Kinderlerer

8. Safety aspects and risk assessment issues

Robert Geertsma, Senior Scientist at the Centre for Biological Medicines and Medical Technology, National Institute for Public Health and the Environment (RIVM) in The Netherlands, provides scientific advice to regulators on quality and safety of medical technology, sits on international Standards Committees, EC working groups (co-Chair of New & Emerging Technologies WG), FP7 projects ObservatoryNANO and NanoMed Round Table and on the Advisory Board of NanoMedNet, European platform on Nanomedicine.

While product development in the field of nanomedicine is progressing rapidly, knowledge on the associated risks is still in an early phase. At the current state of knowledge about the risk profile of nanomaterials, hazard identification and risk assessment needs to be conducted on a case-by-case basis. Hazards indicating potential toxic effects were demonstrated for a variety of, but not all manufactured nanomaterials. Furthermore, it is important to realise that there are great differences in risk profile between different applications of the same nanomaterial, depending on the potential of exposure to the nanomaterial. Testing and risk assessment should always be performed on the actual product, and not by extrapolation of data from other products. The risk assessment should pay special attention to the physico-chemical characteristics, the pharmacokinetic and the toxicological properties. Test methods that are relevant and suitable for the nanomaterials have to be carefully selected, adapted or developed. The presentation will

discuss current perspectives on relevant safety aspects and risk assessment issues for nanomedicine products.

9. Ethical and societal considerations

Alfred Nordmann, Department of Philosophy, nanoOffice and NanoCenter at Darmstadt Technical University and the University of South Carolina. Since 2000, Nordmann has been studying the philosophical foundations of nanotechnology and the convergence of enabling technologies. He was rapporteur of the 2004 expert group "Converging Technologies - Shaping the Future of European Societies", partner in the EC-funded projects DEEPEN, NanoCap, EthicSchool, ObservatoryNano, and NanoMed Roundtable."

According to the findings of the group on ethical and societal aspects of nanomedical research, it is paramount that one does not overstate the radical novelty of nanomedicine. It is equally unhelpful to consider a pipeline of nanomedical innovations that will deliver its goods to those who are best prepared to receive them. As the March 2010 PCAST review of the US National Nanotechnology Initiative makes clear, one can only take competitive advantage of nanomedical research by grounding it in a clear understanding of needs and capabilities. In order to achieve such understanding, we need to know where nanomedicine is coming from: It continues social as well as scientific trends that started in the 20th century and are becoming intensified in the 21st. The trend to address diseases at deeper and deeper levels and now at the level of molecules is only one of these. Some of those trends were not very productive in the 20th century and need to be closely monitored in the 21st. Other trends were deeply unsettling to many patients and physicians in the 20th century and are likely to raise eyebrows in the 21st. Accordingly, the group on ethical and societal aspects recommends explicit agenda-setting for nanomedicine that begins with a clear understanding of achievable benefits and the ways in which it is, indeed, novel. Such a need-based approach needs to consider the UN's millennium goals. Among the societal trends that may well become intensified by nanomedicine, the group draws attention to the possible devaluation of medical expertise through the commercialization of medicine in the wellness-market.

10. Engaging the public

Wolfgang M. Heckl is Director General of the Deutsches Museum in Germany and professor of Science Communication at the Technische Universität München (TUM). As a dynamic and charismatic science communicator he received the Communicator Prize in 2002 from the German Science Foundation and was awarded the first European Descartes Prize for Science Communication in 2004.

Public engagement and deliberation about nanomedicine at all levels is fundamental if we as a society want to profit from the hopes and promises invested in nanomedicine. The findings and recommendations of the Communication Working Group that will be presented here reflect this need. The desired outcome of nanomedicine communication should not simply be one of maximising the benefits to society whilst minimising the risks. Rather it is also one of reconfiguring the debate so that it better characterises what it at stake. Public responses to technology, or even to particular applications, are not simply either positive or negative; rather, pros and cons are seen as intermingled and often inseparable. In order to involve and engage as wide and varied an audience as possible in a public debate and deliberation on nanomedicine, it is vital to be continuously innovative in communication practices. A selection of such novel approaches were integrated into the recently opened Centre of New Technologies of the Deutsches Museum and will be given as examples in case.