Concept for a European Infrastructure in Nanobiotechnology

Final report of the FP7 Support Action EuroNanoBio
January 2010

EuroNanoBio

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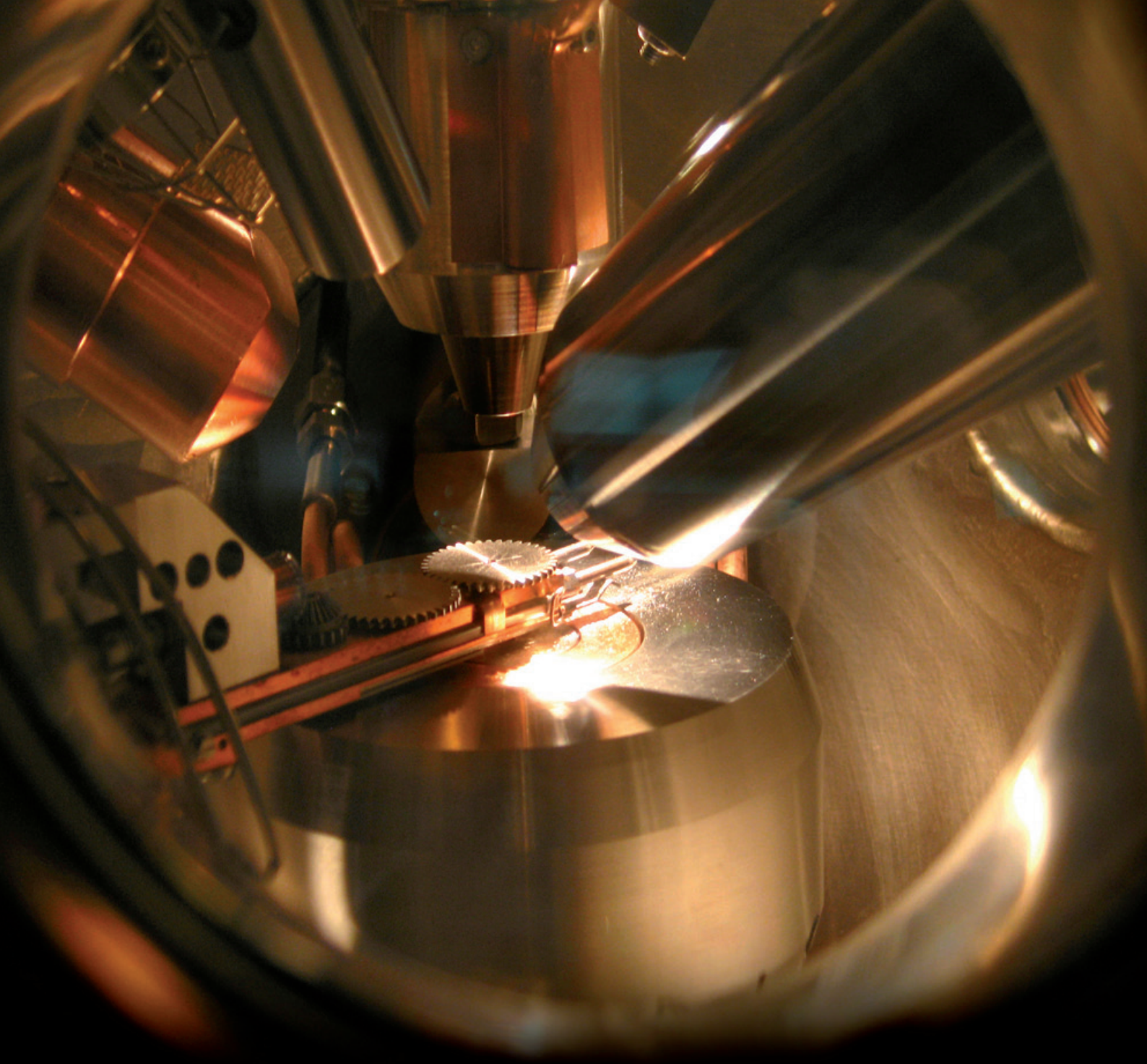
Content



Introduction

Nanobiotechnology is essentially different in many aspects from other areas of nanotechnology such as nano-electronics or nano-materials. It is certainly the most complex sub-area of nanotechnology, because it simultaneously involves very distant scientific disciplines such as physics and clinical research, biology and mathematics, or engineering and immunology. From the industrial perspective, nanobiotechnology does not yet represent an industry by itself or an existing market, but more a manifold of enabling technologies to aid existing sectors, such as medical technologies, pharma, biotech, food, cosmetics or water management and environmental applications. To promote successful research and translate it efficiently into economic applications in such an inherently complex environment requires a structured and efficient sharing of both knowledge and equipment among stakeholders from many academic disciplines and industries. This calls for an integration of people from different backgrounds, who had little or no previous contact or knowledge of each other. The best way to achieve this integration and to accommodate the complexity of nanobiotechnology is to set up a coordinated distributed European infrastructure of regional competence clusters.

The following recommendations are the result of intensive consultations and discussions with experts from academia, industry and local and national authorities. They provide a realistic conceptual framework and a tool box to structure the European capacity in nanobiotechnology.

Recommendations for a European Infrastructure in nanobiotechnology

A distributed infrastructure

1. To cover the large range of scientific disciplines involved in nanobiotechnology and the diversity of application areas, a European infrastructure has to be built on regional nanobio clusters, which have world-class facilities and expertise with high levels of engagement between industry and academia.
2. The nanobio clusters need to be connected and coordinated to share knowledge and equipment and to cover the whole value chain in specific application areas of nanobiotechnology such as environment or medicine, for example.
3. A dedicated infrastructure management should improve the engagement between academic disciplines, research centres and companies inside and between the involved clusters.
4. Clear technical roadmaps for each of the application areas within nanobio should be defined to provide a catalyst for collaboration between industry and academia within the infrastructure.
5. ELSA experts should be encouraged to work collaboratively with science departments, research institutes and industry to help explore ethical, legal and social aspects (ELSA) of developing nanobiotechnology thereby enabling early decision making about the probability of commercialisation in a socially and ethically responsible manner.
6. Set-up and upgrading of clusters will require local, national and European political support and funding supplemented by private investments at a later more mature stage.

Central services

7. A European reference centre is needed for characterization and toxicology studies of nanoobjects, which can be accessed by all nanoobject producers and users from academia and companies similar to the Nanotechnology Characterization Lab at NCI/USA.
8. A European Centre for Risk and Safety Management should be established, which provides information and advice about handling of nanoobjects and protection measures to SMEs and universities, which cannot afford expensive risk assessment.
9. Clusters should help especially SMEs to articulate their needs and interests to regulatory and standardisation bodies.

Communication and public engagement

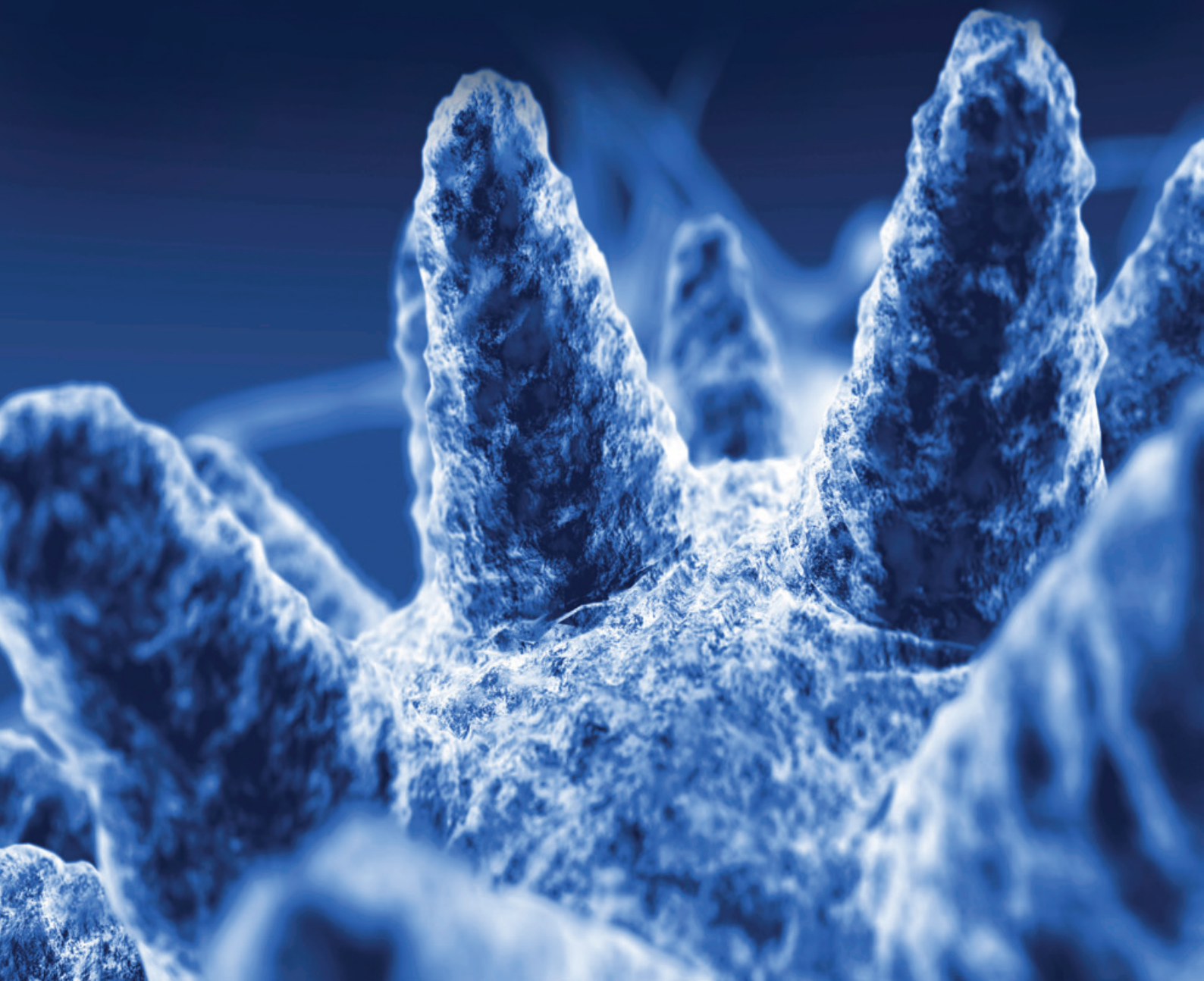
10. The infrastructure should provide pools of experts and professional communication tools necessary for engagement with the public.
11. Promotion of the capabilities of nanobiotechnology to SMEs and clinicians should be facilitated by showcasing examples of successful exploitation of nanobiotechnology.
12. Engagement of the European infrastructure with nanobio clusters and research centres outside Europe should be encouraged.

Education and training

13. The highly interdisciplinary nature of nanobiotechnology requires the integration of dedicated nanobio modules preferably at the MSc or PhD level.
14. Because nanobiotechnology touches on many important wider issues, teaching an understanding of ethical and social aspects and training in science communication and public engagement should be included at the MSc and PhD level.
15. Due to the rapid development in nanobiotechnology, targeted education and training programmes for in-career training need to be developed.

Concept for building a European Capacity in nanobiotechnology

The project has examined the state of the art and future requirements of the nanobiotechnology capacity in Europe with regard to infrastructure needs, communication management, education and training, and the political and social environment. In four work packages the concept of a decentralized infrastructure based on distributed European competence clusters was evaluated by expert interviews, analysis of existing or emerging clusters and intensive discussions at two stakeholders meetings. The results have corroborated the concept of a distributed infrastructure and substantiated the ideal conditions for efficient communication, education and technology transfer in nanobiotechnology.



A distributed infrastructure

The application of nanotechnologies to different biological or medical applications does not require the creation of large facilities like synchrotrons or heavy and expensive equipment such as super computers. Instead, it will completely depend on the generation and efficient exchange of knowledge between scientific disciplines, and transfer of knowledge between academia, SMEs and large companies, because it is a knowledge driven development. Therefore, the biggest challenge is the creation of an environment, where people with different background can meet and work together to develop a common understanding of each other's expertise and how to use it to develop new products for nanobiological applications. For example, to develop new nanoparticles for molecular imaging one needs at least chemists to produce them, physicists to develop the detectors, toxicologists to analyse their safety, and clinicians to validate and implement them in clinical use. Furthermore, this process needs academic labs for basic research, SMEs for development of prototypes and transfer to large companies, which validate, distribute and commercialize the whole system consisting of nanoparticles and detectors.

It is obvious that efficient transfer of knowledge required for such complex value chains needs a close cooperation between experts. This study has confirmed that the speed of development is best achieved by clusters having all necessary experts and facilities in close vicinity. Existing clusters are often located around leading research centres with core nanotechnology facilities, plus spin off ventures. They have a sufficient critical mass of scientists originally coming from diverse disciplines with ongoing collaborations with industry and hospitals.

These Nanobio clusters offer greater opportunities for SMEs and multi national companies (MNCs) to engage in mutually beneficial collaborations and to maximise the synergy from interactions of MNCs, SMEs and academic researchers. The SMEs can leverage IP opportunities from the MNC as well as gaining insights into new R&D opportunities, management practices, innovation implementation and greater access to external knowledge and advice.

Through the added value of close links of MNCs with local companies and the facilities and expertise from academic research infrastructures, a basis can be formed for MNCs to leverage new investment from parent companies, and it can also lead to more commercially focussed researchers. This in turn creates an environment with potential for MNCs to become more embedded in EC countries through local interactions with nanobiotech supply chain and multidisciplinary R&D collaborations. While such clusters already exist, the above definition provides for the inclusion of any new nanobio clusters from any EU region which fulfils the criteria.

Recommendation 1:
To cover the large range of scientific disciplines involved in nanobiotechnology and the diversity of application areas, a European infrastructure has to be built on regional nanobio clusters, which have world-class facilities and expertise with high levels of engagement between industry and academia.

The analysis of existing clusters in this study has shown that none of them covers so far the whole development process in a given nanobio application area. Instead, all of them focus on a certain sub-area based on their historical scientific strength and development. Furthermore, as an example, nanoobjects such as nanoparticles might not only be used as imaging probes but also for targeted drug delivery. This would involve two very different industries namely diagnostics and pharmaceutical companies with very different regulatory frameworks and value chains. A single cluster would not have the human and financial resources and facilities to cover both development processes.

Opportunities for leveraging cross-disciplinary IP opportunities can be optimised by facilitating closer links between well organized clusters and European companies as well as existing national and EU projects and frameworks involved in Nanobio research. Furthermore, exchange of insights among pharma, biotech, ICT and medical devices industries will lead to new R&D opportunities, management practices, and greater access to external knowledge and advice in an open innovation approach.

Recommendation 2:
The nanobio clusters need to be connected and coordinated to share knowledge and equipment and to cover the whole value chain in specific application areas of nanobiotechnology such as environment or medicine, for example.

The cooperation between different disciplines, academia and industry, and local authorities and financial services requires a structured and dedicated information and communication platform. Many clusters analysed in this study had established a cluster management team or organisation, which mediates between stakeholders, organises strategic

meetings, and promotes the cluster to the outside. It also serves as a central node for getting information about all partners, their projects, papers and patents, and R&D funding levels. Another important objective of the management agency is the communication and coordination with other clusters inside the European infrastructure.

The implementation of managing agencies to facilitate the cooperation of stakeholders inside and between the clusters will greatly support the innovation processes so that translation of innovation to market and clinics becomes more efficient.

Recommendation 3:
A dedicated infrastructure management should improve the engagement between academic disciplines, research centres and companies inside and between the involved clusters.

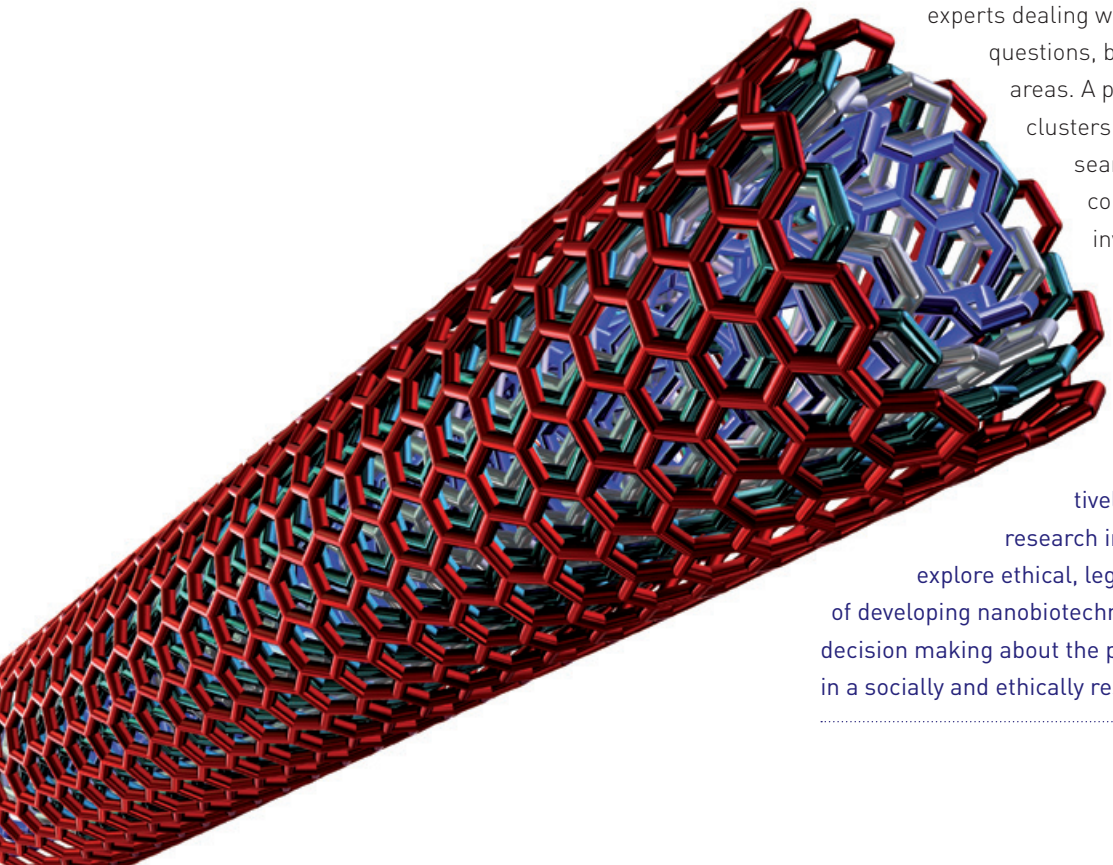
The often quite diverging agendas between different application fields of the nanobio industry call for a clear and defined roadmap for each nanobiotechnology application area like environment, medicine, life sciences, agro-food, and energy. In contrast to roadmaps for the electronic industry for example, the nanobio roadmaps have to include fundamental research targets which still represent major roadblocks for anticipated future products in this young technology. Such roadmaps have been defined for example by the ETP Nanomedicine for Drug delivery, Diagnostics and Regenerative Medicine.

Due to the embryonic stage of industrial markets in the field, such roadmaps will foster collaboration not only among related companies within sectors of the nanobio industry along the value chain, but by complementing industry requirements could also facilitate collaboration between industry and academia. Through the creation of a critical mass of expertise and facilities within a nanobio cluster, industry and academia can be more efficiently linked to implement the roadmaps leading to developments of innovative and converging technologies. Innovations could be brought to the markets much faster by such concentrated centres.

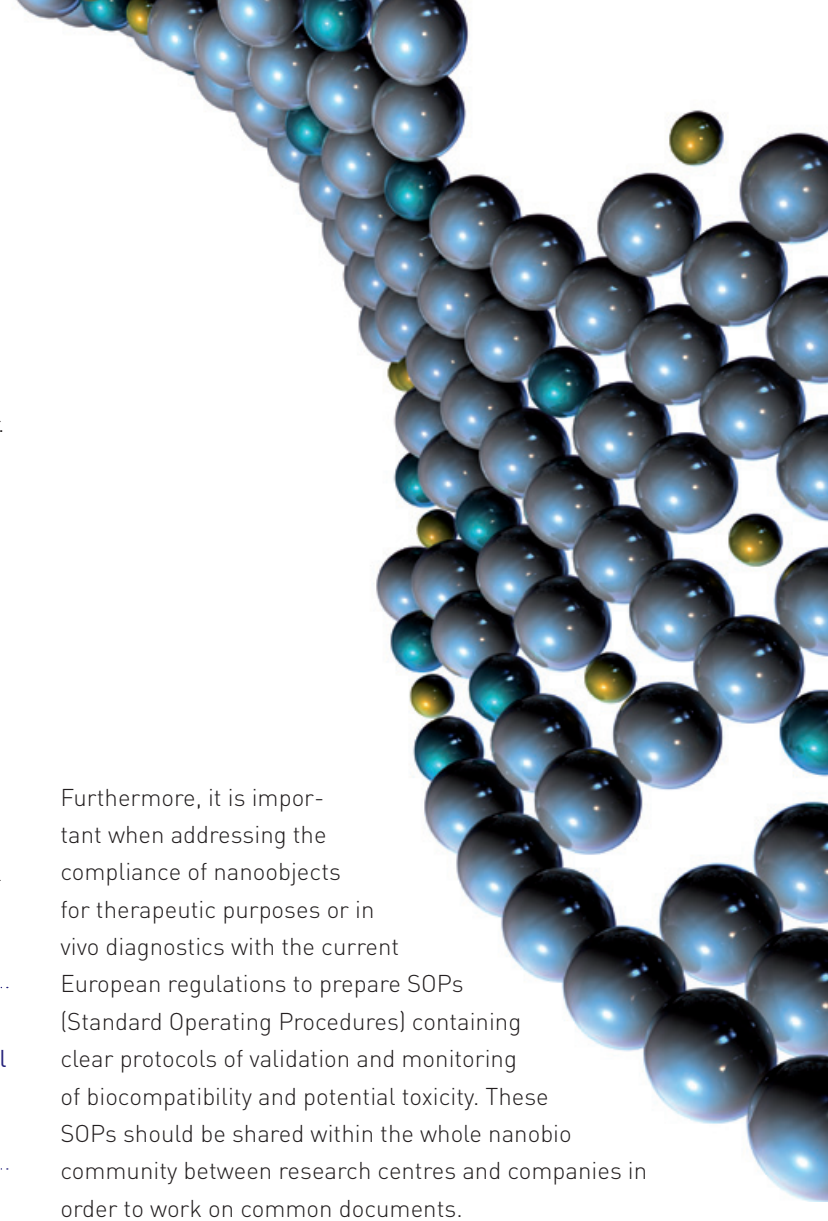
Recommendation 4:
Clear technical roadmaps for each of the application areas within nanobio should be defined to provide a catalyst for collaboration between industry and academia within the infrastructure.

The application of nanotechnology to biological or medical applications will raise social and ethical questions. Unfortunately, ethical and social thinking and the further development of technology and science are not connected anymore because the current qualification system for scientists does not leave room for such considerations in most countries. Therefore, advice on ethical, social and legal aspects of research projects needs to be made available for science and industry.

Many clusters analysed in this study have pools of experts dealing with ethical, or social or legal questions, but none of them covers all areas. A pan-European infrastructure of clusters can provide the platform for researchers, SME and multinational companies to get advice on and involve ELSA experts in nanobio developments right from the beginning.



Recommendation 5:
ELSA experts should be encouraged to work collaboratively with science departments, research institutes and industry to help explore ethical, legal and social aspects (ELSA) of developing nanobiotechnology thereby enabling early decision making about the probability of commercialisation in a socially and ethically responsible manner.



The analysis of existing clusters in this study not only revealed the need for state of the art expertise and facilities in nano and bio research in close vicinity to companies, but also highlighted that major regional political and financial support is necessary for setting-up and upgrading a cluster. This support by local authorities is crucial for creating the suitable infrastructural and financial environment for transfer of knowledge from research centres to industry. The regional commitment also provides the basis for a sustainable development and distinguishes a cluster from a large but isolated research centre. Once the cluster has reached a critical size and mass the initial public investment is complemented by private investments from large or multi national companies, which want to leverage from the R&D potential of the local research centres and SMEs. To attract the investment of such large companies, the connection of clusters into a complementary infrastructure will be a crucial step, because it will facilitate the recognition of nanobiotechnology in Europe at the global scale.

Recommendation 6:
Set-up and upgrading of clusters will require local, national and European political support and funding supplemented by private investments at a later more mature stage.

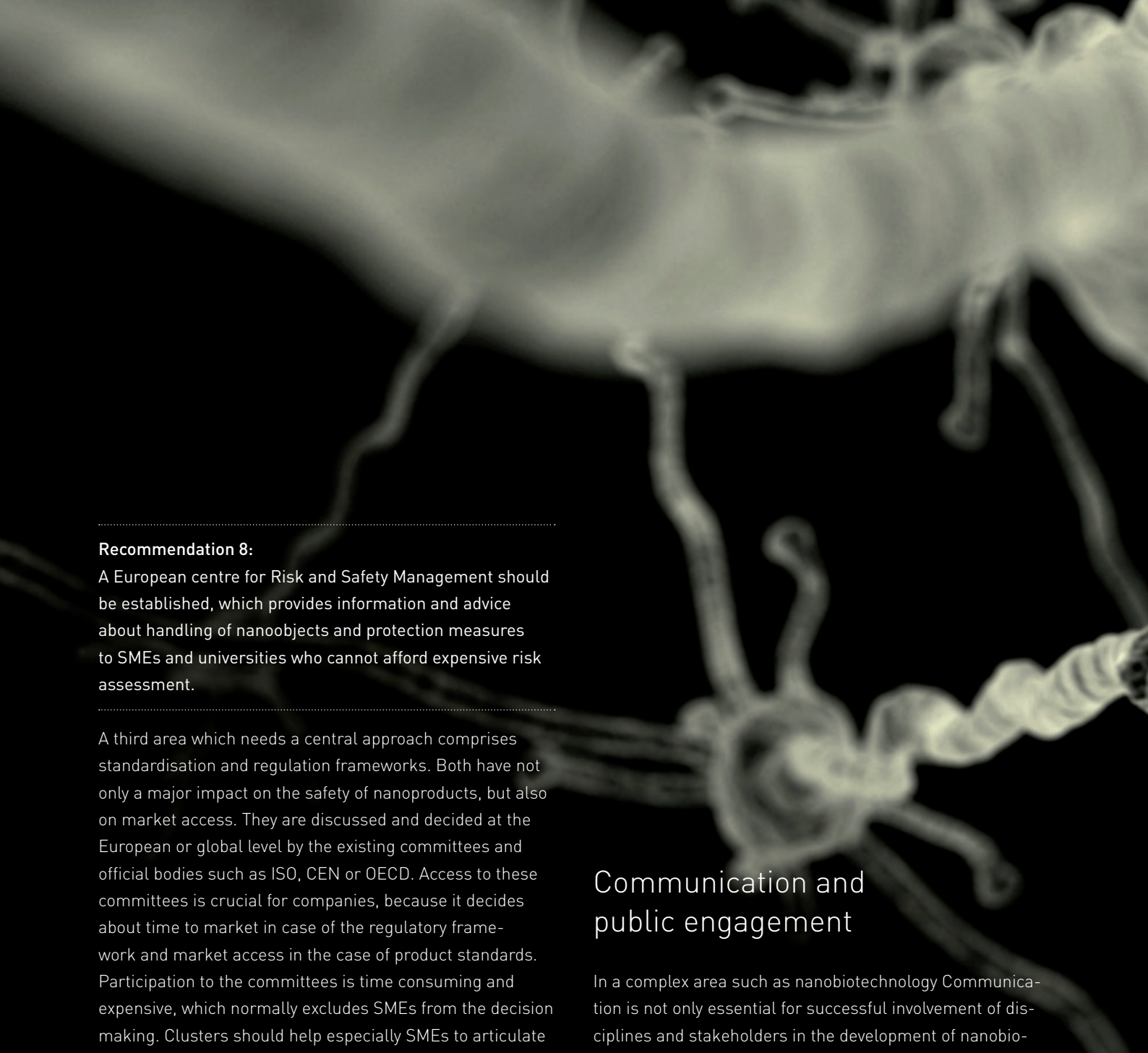
Central services

Nanoobjects are a substantial part in many nanobio products. There are issues about the reproducibility and precision of the synthesis processes of nanoobjects. There are also major challenges to be addressed with respect to nanoobject toxicity. Another issue is the physical and chemical characterization of nanoobjects according to common standards and procedures. Combined, the issues relating to nanoobjects need a multidisciplinary approach with a critical mass of expertise and facilities which can be logically provided in a Nanobio reference centre with a large functional infrastructure. As an example, if standardisation of nanoobject synthesis processes and characterization could be achieved comparable to the levels of semiconductor thin film processing and validation, this could facilitate much more reproducible outcomes for nanoobject applications. This challenge should be set as the key goal of European Nanobio development, as currently nanoobject synthesis and characterisation appears to be a limiting step for several nanobio products.

Furthermore, it is important when addressing the compliance of nanoobjects for therapeutic purposes or in vivo diagnostics with the current European regulations to prepare SOPs (Standard Operating Procedures) containing clear protocols of validation and monitoring of biocompatibility and potential toxicity. These SOPs should be shared within the whole nanobio community between research centres and companies in order to work on common documents.

Recommendation 7:
A European reference centre is needed for characterization and toxicology studies of nanoobjects, which can be accessed by all nanoobject producers and users from academia and companies similar to the Nanotechnology Characterisation Lab at NCI/USA.

Nanoproducts, being a substantial part of the nanotech field are "a thing without a definition" because the kind and amount of "nano" within a product varies widely. To meet the upcoming concerns about the safety of nanotechnology, a precautionary approach of all stakeholders is needed that will encourage the generation of more data and the definition of potential risk covering the whole lifetime of a product. Another safety issue is the creation of a safe workplace. To balance risk and benefits, safety officers in companies have to be trained and informed specifically about the properties of nanoobjects handled at their location. Such a centre would not only provide a central information platform but could also drive the harmonization of national safety procedures and protocols.



Recommendation 8:
A European centre for Risk and Safety Management should be established, which provides information and advice about handling of nanoobjects and protection measures to SMEs and universities who cannot afford expensive risk assessment.

A third area which needs a central approach comprises standardisation and regulation frameworks. Both have not only a major impact on the safety of nanoproducts, but also on market access. They are discussed and decided at the European or global level by the existing committees and official bodies such as ISO, CEN or OECD. Access to these committees is crucial for companies, because it decides about time to market in case of the regulatory framework and market access in the case of product standards. Participation to the committees is time consuming and expensive, which normally excludes SMEs from the decision making. Clusters should help especially SMEs to articulate their needs and interests to regulatory and standardisation bodies.

This support for SMEs will increase their chance to introduce their innovations to the market, because according to the EC Nano Action Plan especially "standards provide a level playing field for markets and international trade and are prerequisites for fair competition, comparative risk assessments and regulatory measures." The same is true for IPR rules and agreements, which should also be an important field of support for SMEs and research institutions provided by clusters.

Recommendation 9:
Clusters should help especially SMEs to articulate their needs and interests to regulatory and standardisation bodies.

Communication and public engagement

In a complex area such as nanobiotechnology Communication is not only essential for successful involvement of disciplines and stakeholders in the development of nanobiotechnology. It is also necessary to engage with the public in a timely manner to explain the technology and its risks and benefits, to understand how citizens see the developments, including potential concerns, and to get acceptance of this new technology. How early this should be done will depend on the development of the technology and also the social context. Engagement may take many different forms. Many tools are available, including focus groups and citizens juries or Internet-based approaches. Science centres also have an important role for example with interactive experiments or science exhibits.

Recommendation 10:
The infrastructure should provide pools of experts and professional communication tools necessary for engagement with the public.

Up to now, nanotechnological discoveries are mostly made in academic laboratories without a clear idea of a possible application. In addition, many nanoobjects can be applied to several applications, but many possible users have no clue about new developments in nanotechnology and how they can utilize them for new innovative products. To increase the translation of nanotechnologies into new products it is necessary to develop more efficient matching of nanotechnology developers and putative users.

Recommendation 11:
Promotion of the capabilities of nanobio-technology to SMEs and clinicians should be facilitated by showcasing examples of successful exploitation of nanobiotechnology.

A European infrastructure consisting of complementary clusters will not represent the whole community, because outside of the infrastructure there will be other leading research centres in Europe and around the world. Furthermore, other networks or initiatives might exist, which focus on the same area of nanobiotechnology and gather important stakeholders. To exploit the full potential of nanobiotechnology it is mandatory to interact with these centres and organisations.

This engagement should facilitate benchmarking of EU research in nanobiotechnology, collaboration on the development of international standards, recommended regulatory requirements, and also promote access to EU expertise and infrastructure facilities for clusters from developing countries.

Recommendation 12:
Engagement of the European infrastructure with nanobio clusters and research centres outside Europe should be encouraged.

Education and training

The interdisciplinary nature of nanobiotechnology requires new approaches for cross disciplinary education. At present there is a great variety not only concerning the types of courses, but also in the considerable range of curricula. This can be attributed to the fact that nanobiotechnology is not a clearly-bordered domain but a diverse and multidisciplinary field which can be considered as a subfield of nanotechnology or an extension of biotechnology, as well as chemical or biological engineering. A strong necessity for a more precise and comprehensive definition of the field was identified which will help to define educational needs for nanobiotechnology (NBT).

The requirements and interests of stakeholders vary widely. The most productive approach will be to incorporate NBT modules into already existing undergraduate and master level education in science and medicine instead of further investing in complete NBT M.Sc. courses. There is furthermore a demand for in-depth training on NBT, which can be met by PhD graduate school programs, but other approaches will also be needed in cases where a PhD does not normally include formal teaching modules.

Recommendation 13:
The highly interdisciplinary nature of nanobio-technology requires the integration of dedicated nanobio modules preferably at the MSc or PhD level.

European societies increasingly expect scientists who are given public money to be accountable for what they do with it. Accordingly, scientists are required to address ethical questions in research proposals, because funding agencies will increasingly ask for such considerations. Especially in nanotechnology application fields such as medicine or food, awareness about ethical implications is crucial to meet critical sentiments about the potential dangers. For all these reasons it is essential to re-integrate ethical thinking into scientific research dealing with application areas such as medicine or food to ensure a responsible development. One practical approach would be to include courses or modules on ethical and social aspects in engineering or life science studies and courses of relevant application areas.

Recommendation 14:
Because nanobiotechnology touches on many important wider issues, teaching an understanding of ethical and social aspects together with training in science communication and public engagement should be included at the MSc and PhD level.

Nanobiotechnology is a recent and fast developing area. In addition, it is an enabling technology for many different industries. To cope with the speed and the implementation of it in existing industrial processes it will be necessary to continuously educate and train the technical and academic workforce. Specific training courses on NBT may be needed for engineers, technicians, scientists, safety officers and other relevant personnel.

Recommendation 15:
Due to the rapid development in nanobio-technology targeted education and training programmes for in-career training need to be developed.

Conclusion

The study has shown that a distributed infrastructure based on a coordinated pan European alliance of research driven clusters is the most efficient instrument for fast and efficient translation of nanotechnological discoveries into biological and medical applications. The reasons for proposing clusters as the building blocks of the infrastructure are that they provide

- the necessary close vicinity of state of the art expertise and facilities as well as research centres, SMEs and large companies,
- regional political and financial support for upgrading of facilities and SME support,
- a dedicated communication platform with different pools of experts and tools for engagement with different research communities, industries, investors, media and the public at large,
- the critical mass for implementation of new interdisciplinary education and training concepts, which also include horizontal disciplines such as ethics and social sciences, and
- a structured approach for benchmarking and interaction with other centres or clusters around the world, especially in developing countries.

It will need a concerted action of regional, national and European authorities to provide the political and financial support for the set-up and upgrade of such infrastructures. This mutual investment will make sure that Europe stays competitive at the global level in nanobiotechnology.

Nanobiotechnology research infrastructures - Potentials and limitations of single-site facilities or distributed resources

The current situation of nanobio research clusters in Europe has been analysed in order to establish definitions, identify best practices and set up evaluation criteria, in order to recommend the most suitable model for an EU nanobio infrastructure and assess its impact on research and development.

This analysis has taken into account aspects such as integration of research activities, the efficient use of resources, regulation of access to facilities, private-public partnerships, alliances, entrepreneurship, and the implementation of interdisciplinary approaches for the development of applications in medicine, environment and/or food in order to understand the reasons for success for the most developed clusters in the EU.

One challenge was to validate the input (e.g. research & development, human resources, research equipments, funded common projects) and output (e.g. papers, patents, companies) of different initiatives because reports are often not specific and key people inside clusters are hard to identify. Nanobiotechnology activities are hidden under the term nanotechnology, because nanobio or nanomedicine are not well defined. Presently, many clusters are a bottom-up structure, yet loosely organised and rarely managed by an agency. The have a sufficient critical mass of scientists originally coming from diverse disciplines with ongoing collaborations with industry and hospitals, which are so far mostly occasional, not structured partnerships. Existing clusters are often located around leading research centres with core nanotechnology facilities, plus spin off ventures. Diverse models have been observed, however, depending on the tradition and research culture of the region (more central for electronics, more disperse for life sciences).

Nanobio clusters need to be more tightly connected and organized at the EU level especially with regard to regulatory affairs, standardisation and access to clinical trials. Such well organised interconnection of high quality clusters or "poles of excellence" would combine multidisciplinary research centres that join modern nanotechnology facilities in a multidisciplinary way. Additionally, the implementation of managing agencies to facilitate the connection of clusters would support the innovation processes so that translation of innovation to market and clinics becomes more efficient.

The first step to reach this "ideal" scenario is to ensure the integration of different disciplines at a local level within a city/district/region with the potential to become a pole of excellence. The second step is the set-up of a cluster management agency which mediates between stakeholders and organises strategic meetings for academic institutions and between academia and industry. A complete directory of all the partners and their collaborators in existing projects as well as their papers and patents and a characterization of research & development funding levels and outcomes would be required to move forward into the third level, the upgrading of individual clusters and the network as a whole to become a competitive European infrastructure of nanobio clusters. This infrastructure would help to build a knowledge exchange based community and ease the access to other markets or to clinical trials. Furthermore, the infrastructure provides a comprehensive information pool needed to raise public acceptance of new technologies, to give advice for regulation and standardisation of Nanobio objects, and for a strategic plan for funding at the national and European level.

Definitions of cluster, innovation cluster, research cluster, and cluster management agency applied in this document:

Cluster: Concentration in geographical space of all the partners (R&D centres, universities/departments, hospitals, industry, entrepreneurs/spin off companies, tech transfer advisers, technological foundries...) whose contribution is required for innovation to happen in a particular, interacting and effective fashion to bring new products/services into the market/hospital. These interactions can be led and/or managed by an agency or office, with dedicated staff.

Moreover, a nanobio innovation cluster is built up around a nanobio research cluster. This is mostly due to its cross-disciplinary profile, characterized by the effective interaction of scientists and engineers from very diverse expertise (materials science, microelectronics, photonics, cell biology, molecular biology, inorganic and organic chemistry, medicine...) among each other and with high-tech SMEs and Spin.offs .

NOTE: Geographical size varies largely from one to another. Roughly, in most cases, it will imply one large city and a suburban radius of 100 kms.

From proof of concept to market – Analysis of nanobiotechnology-based industrial activities in Europe

Our objectives were to establish a representative panel of top level industrial managers with experience in nanobiotechnology based product and process commercialisation, and the analysis of case studies of successful technology transfer or exploitation of nanobiotechnology. From these studies the critical needs of, and opportunities for, industry were to be deduced, especially for high-tech SMEs strong in nanobiotechnology research. An accomplished expert survey proved difficult to evaluate as the included companies differed widely in size, target market type and their level of experience or activity with nanobiotechnology. Therefore, the responses varied and to yield a consensus opinion additional experts were recruited.

It was found that a well-built nanobio infrastructure could significantly ease access for large and small companies to a range of expensive equipment. In general, companies would be willing to pay for infrastructure access, the rates depending for example on whether work was carried out as co-development or as licensable technology. Sharing equipment can make sense especially for SME´s as it helps them to save money and potentially can yield new collaborators. But while collaborating with other companies is considered advantageous, an important precondition for most companies is that the safety of intellectual property has to be guaranteed.

For multinational companies (MNCs) the situation is different than for SMEs. Large companies generally prefer to directly fund research & development and subsequently own resulting intellectual property or share it with an academic research providing organisation (RPO). Their expertise for regulatory issues and protection of intellectual property is usually in-house. On the other hand, SMEs often have to license intellectual property rights from a research organisation because of high costs involved, and could profit from the availability of external expertise provided by a nanobio infrastructure. It has to be mentioned that innovation in nanobio much more takes place in high tech SMEs testing new developments on niche markets than in MNCs which are usually more conventional and doing incremental innovation.

Future recommendations:

The recognized gap in nanobio expertise can be closed by a clear and defined roadmap that would include each nanobiotechnology application area. This roadmap would foster collaboration not only among related companies within sectors of the nanobio industry along the value chain, but by complementing industry requirements could also facilitate collaboration between industry and academia. Through the creation of a critical mass of expertise and facilities within a nanobio cluster, industry and academia can be more efficiently linked to implement the roadmap(s) leading to developments of innovative and converging technologies. Innovations could be brought to the markets much faster by such concentrated centres.

The often quite diverging agendas within different application fields of the nanobio industry can be met by a collective roadmap complemented with the parallel development of standards for existing and emerging nanobio products and processes. Nanoobjects are a substantial part in many nanobio products. There are issues about the reproducibility and precision for the synthesis processes of nanoobjects. There are also major challenges to be addressed with respect to nanoobject toxicity. The potential to improve biocompatibility of some forms of nanoobjects may be an option in some situations. Combined, the issues and opportunities relating to nanoobject need a multidisciplinary approach with a critical mass of expertise and facilities which can be logically provided in a nanobio cluster with a large functional infrastructure. As an example, if standardisation of nanoobject synthesis processes could be achieved comparable to the levels of semiconductor thin film processing, this could facilitate much more reproducible outcomes for nanoobject applications. This challenge could be set as the key goal of European nanobio development, as currently nanoobject synthesis appears to be a limiting step for several nanobio products.

Furthermore, with the current European regulations, it is important when addressing the compliance of nano materials for therapeutic purposes or for in vivo diagnostics to prepare SOPs containing clear protocols of validation and monitoring of biocompatibility and potential toxicity. These SOPs should be shared between research centres and companies in order to work on common documents.

To create such nanobio clusters, a large scale European initiative is required that is focussed on selected regions where the relevant critical mass in research capacity and expertise has already been reached. Collaborations between industry and academia should be large-scale and widespread and resources should be dedicated to promote these regions. Nanobiotechnology can provide a type of cement to enable collaborations among companies specialised in ICT, medical devices, pharma and biotechnology.

Within such nanobio clusters, there are greater opportunities for SMEs and MNCs to engage in mutually beneficial collaborations and to maximise the synergy from interactions of MNCs, SMEs and academic researchers. The SMEs can leverage IP opportunities from the MNC as well as gaining insights into new R&D opportunities, management practices, innovation implementation and greater access to external knowledge and advice. In some cases, collaborations may lead to opportunities to recycle IP for new technologies / applications leading to regeneration of companies.

Through the added value of close links of MNCs with local companies and the facilities and expertise from academic research infrastructures, a basis can be formed for MNCs to leverage new investment from parent companies, and it can also lead to more commercially focussed researchers. This in turn creates an environment with potential for MNCs to become more deeply embedded in EC countries through local interactions with nanobiotech supply chain and multidisciplinary R&D collaborations.

Education towards a knowledge based nanobiotechnology economy

Our objective was to identify (1) the educational and training methods that are required to distribute information and awareness about nanobiotechnology (NBT) in the communities of interest and (2) how to build a knowledge-based economy and infrastructure.

At present, there are already courses with nanobiotechnology content in 17 European countries. There are 4 master programs that fully focus on NBT but a larger number of programs in nanotechnology or nanoscience exist where NBT constitutes a track or specialisation. Finally, there are also master programs that teach subfields of NBT (e.g. Medical Electronics, Cellular Biotechnology, biophysics and –informatics). While the total number is not high there is a great variety not only concerning the types of courses, including master degree programs as well as summer schools and continuing professional development, but also in the considerable range of curricula. This can be attributed to the fact that nanobiotechnology is not a clearly-bordered domain but a diverse and multidisciplinary field which can be considered a subfield of nanotechnology or an extension of biotechnology, as well as chemical or biological engineering. A strong necessity for a more precise and comprehensive definition of the field was identified which will help to further define educational needs for NBT.

Does the current situation meet the requirements of different groups of stakeholders and how can NBT education be improved? Representatives from industry, academia and clinics were asked in a survey if their institutions would see an added value either by the possibility to hire M.Sc. candidates specialised in NBT instead of in classical subjects (chemistry, biology, physics) or to train current employees in NBT specific short courses.

It was quickly evident that the requirements and interests vary widely. Industry stakeholders often hire PhD level employees trained in classical subjects who are expected to adapt to new technological developments and areas e.g. at conferences with no need for additional training. On the other hand, for B.Sc. trained technical staff, the primary requirement is for courses on very specific techniques. Therefore, complete M.Sc. programs in NBT are not judged to be of added value.

Academic stakeholders agree that interdisciplinary and theoretical knowledge about NBT should be part of any up to date curriculum in the classical subjects – but as a modular part within existing programs and as continuing professional education courses, not as stand alone NBT M.Sc. courses. The most positive responses came from clinical stakeholders. Added value is expected from overview courses as well as from specific training courses concentrating on the clinical needs that can be addressed by NBT.

Future recommendations:

Our conclusion is that the most productive approach will be to incorporate NBT modules into already existing undergraduate and master level education in science and medicine instead of further investing in complete NBT M.Sc. courses These modules should be designed in an individual way that suits the context of the course they are embedded in. Different technological perspectives have to be considered as well as the biological and clinical relevance.

There is furthermore demand for in-depth training on NBT which can be met by PhD graduate school programs, but

other approaches will also be needed in many cases where a PhD does not normally include formal teaching modules. For clinical needs, partnerships with institutions strong in research will be most helpful for targeted education programs including short courses and continuous professional education. Specific training courses on NBT may be needed for safety officers and other relevant personnel.

To meet the educational requirements of an emerging and rapidly growing field such as NBT appropriately, a clear definition of what the term NBT actually encompasses, and universal accreditation criteria that can be adapted to courses and modules will be of high priority. Furthermore, since innovations for biological or medical applications often have an impact on ethical, social and legal issues, training of students in these areas should be included in Master or PhD courses.

Ancillary factors of nanobiotechnology

Different ancillary factors will significantly influence the success of a nanobiotechnology economy in Europe. Important prospective ancillary factors were found to be ethical, legal and social aspects (ELSA), risk management and safety of products and methods, technology transfer, and communication. After analysing the current situation problems and difficulties concerning the different aspects were identified and recommendations are made of the actions necessary to implement these areas in an EU nanobiotechnology infrastructure.

In new technologies ethical and social thinking and the further development of technology and science are not connected anymore as they were in the last century during the area of scientist such as Humboldt for example. The situation varies in different countries, but in most cases the current qualification system for scientists does not leave room for such considerations and presently only few nanobiotechnology programs even include any ELSA activities. Most countries do not have designated programs for ELSA of technology in general or nanotechnology in particular.

But why are these activities still important?
European societies increasingly expect scientists who are given public money to be accountable for what they do with it. Accordingly, scientists will be required to address ethical questions in research proposals, because funding agencies will increasingly ask for such considerations. Especially in nanotechnology application fields such as medicine or food awareness about ethical implications is crucial to meet critical sentiments about the potential dangers. While no nanotechnology specific issues have been identified, the developments which nanotechnology enable often present new aspects of existing issues, or increase the scale of their impact. For all these reasons we consider that it is essential to re-integrate ethical thinking into scientific research dealing with application areas such as medicine or food to ensure a responsible development. One practical approach would be to include courses or modules on ethical and social aspects in engineering or life science studies and courses of relevant application areas. In addition we recommend that departments of philosophy, theology and social sciences are encouraged to work collaboratively with science departments, research institutes and industry in mutual projects. In this way advice on ethical and social aspects of research projects needs to be made available for science and industry, especially to SMEs which will often have no in house capacity.

In a complex area such as nanobiotechnology Communication is essential for successful involvement of disciplines and stakeholders in the development of this very interdisciplinary field and to engage with the public in a timely manner to get acceptance of this new technology. Engagement with the public is a two-way process in which scientists and industry not only give information on unfamiliar technologies, but also listen to valuable insights and perspectives from lay publics. How early this should be done will depend on the development of the technology and also the social context. If it is done after the key technological choices have been made, publics are unlikely to consider their views will be taken into account. If it is done too early, there is a risk of anticipating the wrong applications or ethical questions.

Engagement may take many different forms. Many tools are available, including deliberative methods (focus groups and citizens juries), grassroots initiatives (e.g. card games), and internet-based approaches. Science centres have an important role for example with interactive experiments or science exhibits. Sensitive and well planned events are usually well received, and can help promote the development and application of nanobiotechnology in a more transparent way, and help create public trust on one side and developments which are sensitive to public values and attitudes on the part of the developers

Usually communication between scientists is well organized but in a new and extremely interdisciplinary field such as nanobiotechnology it should be improved among scientific disciplines, academia and industry at the regional, national as well as the European level. This can be accomplished by regional clusters that support the exchange of ideas and information not only inside but moreover between clusters. The connection of such clusters into a complementary alliance will be a crucial step for promoting the recognition of nanobiotechnology in Europe at the global scale. Furthermore, such a cluster alliance can serve as a pool of professionals providing information for journalists, politicians and the public, and who can communicate and engage in a way understandable by non-scientists. The transparency and accessibility of data and stories can also help to attract funding and investments.

How can risk management be improved and a better safety of nanoproducts and research be guaranteed? Nanoproducts, being a substantial part of the nanotech field are "a thing without a definition" because the kind and amount of "nano" within a product varies widely. Today, there is an improvable amount of data that describes the hazard and maximum levels of exposure (risk = hazard x exposure). To meet the upcoming concerns about the safety of nanotechnology a precautionary approach of all stakeholders is needed that will encourage the generation of more data and the definition of potential risk. To meet the concerns about the safety of nanotechnology, there needs to a be a dynamic approach which seeks to distinguish materials or applications where special risks are anticipated, and where a precautionary approach of all stakeholders is appropriate, from other areas where no special risk is involved.

To create a safe workplace and to balance risk and benefits existing safety officers in companies have to be trained and informed specifically about the properties of nanoobjects such as nanoparticles handled at their location as it was done during the NanoCare project for a number of relevant substances. A European centre for risk and safety management in nanobiotechnology providing information and advice on existing safety standards and SOPs in Europe would best serve the needs of SME´s and universities who cannot afford expensive risk assessment. Such a centre would not only provide a central information platform but could also drive the harmonization of national safety procedures and protocols.

To keep up with the speed of technology development a proactive regulatory partnership at all levels is necessary connecting ELSA, testing, training and communication aspects. In the long term a clear legal frame is inevitable describing how to handle nano objects.

Technology transfer of nanotechnology is a challenging task as nanotechnology is at the beginning of the value chain and additionally, university patents are mostly for a very early phase of a product – it takes a lot of time to reach the market. Scientists become more and more interested in patents, because patents are crucial for collaborations of universities with industry, for university marketing, for spin-offs as their main value, and prototype development. However, the development of prototypes often takes too much time so that scientists needed to monitor and support the developments drop out of the process. Therefore, it is of strategic importance to identify the scientist who is willing to leave the research environment and is prepared to follow the potential product to market.

One adequate way to facilitate technology transfer is to create professional transfer offices inside universities or research organisations with good quality management skills and networks of scientists, relevant companies or market experts. However, these agencies can only be successful, if the top management of the research institution creates an entrepreneurial spirit and students can attend courses on business management and entrepreneurship. The latter is also crucial for the creation of spin-off companies, which are still the most efficient way to transfer technology to industry. For development and growth of such start-ups business incubators with local financial support are most important.

Future recommendations:

Connecting these findings it becomes clear that the education of scientists in both ethical and social implications of nanobiotechnology and also in science communication and engagement is crucial to deal with the increasing complexity of science and the impact of nanotechnology in areas such as medicine, food, cosmetics or environment. In doing so, it will be important to distinguish among the different types of nanobiotechnology, their applications, and the evaluation of their relevant risk potential. Clusters can provide an organized communication platform for both stakeholders and the general public to promote a holistic and proactive approach for the responsible development of nanobiotechnology in a trusting environment

Project and partner description

Project

EuroNanoBio is a Support Action funded under the 7th Framework Programme of the European Union, which has explored the definition, establishment and further development of a European scale infrastructure on nanobiotechnology and the associated realistic implementation plan. It aimed at defining not only the key features of a potential European infrastructure in nanobiotechnology, but it has also established the way it should be designed.

EuroNanoBio proposes the creation of a network of some leading poles of excellence that will be able to support industrial activities, in particular benefiting high-tech SMEs, education, research and development, risk management and engagement with the public. To substantiate this proposal the project was divided into two phases:

- An analytical phase where the existing data were scrutinised and analysed to extract some success factors to be used for defining the EU infrastructure in nanobiotechnology.
  This analysis was conducted in four directions
  - existing top class infrastructures or clusters inside and outside Europe, assessing their positioning with respect to the international scene
  - modes of technology transfer from research to industry
  - multidisciplinary education and training
  - ancillary aspects of nanobiotechnology
- A building and consensus phase where many diverse stakeholders were invited to jointly define and adopt the key features of the infrastructure, and the way to build it.

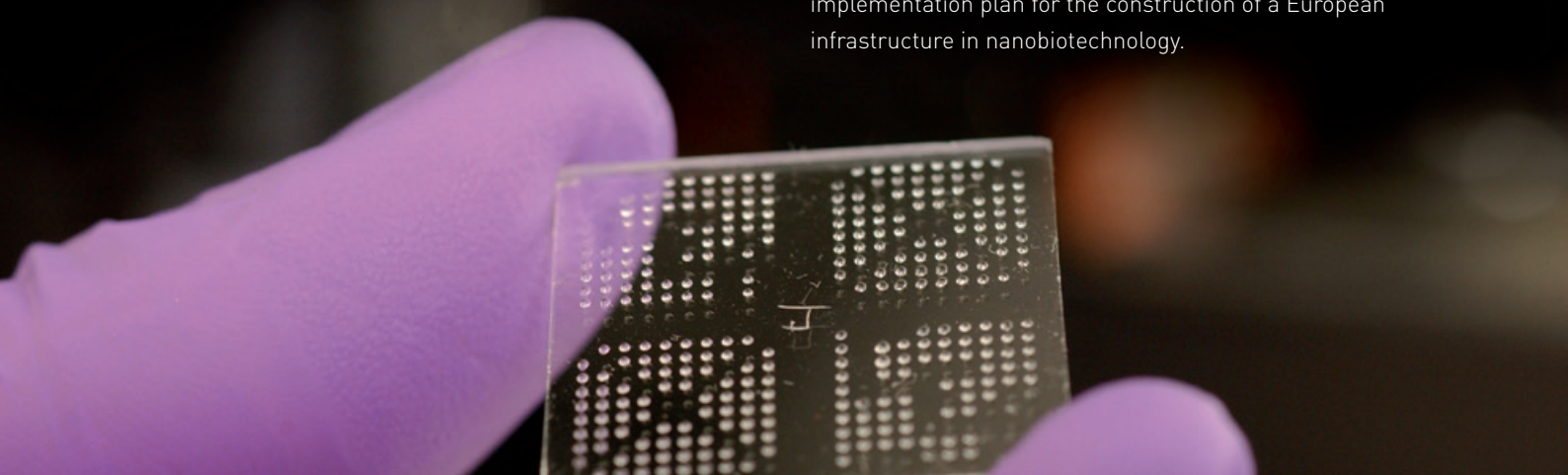
As a result of this process EuroNanoBio proposes 15 recommendations for a distributed European infrastructure in nanobiotechnology along the four dimensions of the European infrastructure – research, education, technology transfer, ELSA – targeted at a wide range of stakeholders among which are policy makers, cluster managers, universities, tech transfer offices, and research organisations.

The major expected impact of EuroNanoBio is to initiate the emergence of a European capacity in nanobiotechnology, which should support the development of new nanobiotechnology-based products and industrial processes and foster their reliability, safety and future commercialisation on the global market.

The implementation plan provided by EuroNanoBio meets the requirements of the European Commission's Action Plan for Nanotechnology 2005-2009, which proposes: "World-class R&D infrastructures and 'poles of excellence' are essential for the EU to remain competitive in N&N. Europe needs an appropriate, diverse but coherent system of infrastructure that comprises both 'single sited' (in one location) and 'distributed' (networked) facilities.". Furthermore, the consortium was in frequent contact and alignment with two leading projects or initiatives namely the FP7 project NanoMed Round Table – www.nanomedroundtable.org – and the European Technology Platform on Nanomedicine – www.etp-nanomedicine.eu to adapt the implementation plan to the special requirements of nanomedicine, one of the most important subareas of nanobiotechnology.

Partners

The EuroNanoBio partners are highly experienced in EU integration in nanobiotechnology in general as well as in specific aspects studied in this Support Action by being involved in projects such as two large FP6 networks of excellence in nanobiotechnology - Nano2Life and Frontiers – the European Technology Platform on Nanomedicine and similar national Platforms in Nanomedicine in Spain, France and Romania, and the FP7 Support Action Nanomed Round Table, which focuses on the ancillary factors of nanomedicine such as ELSA, economics and patient's interest. They use their unrivalled access to a wide panel of stakeholders in governments, industry, and academia to create a realistic implementation plan for the construction of a European infrastructure in nanobiotechnology.



1 CEA
www.leti.fr

2 Bioanalytik-muenster
www.bioanalytik-muenster.de

3 Tyndall National Institute
www.tyndall.ie

4 MESA+ Institute for Nanotechnology
www.mesaplus.utwente.nl

5 Fondazione Don Gnocchi
www.dongnocchi.it

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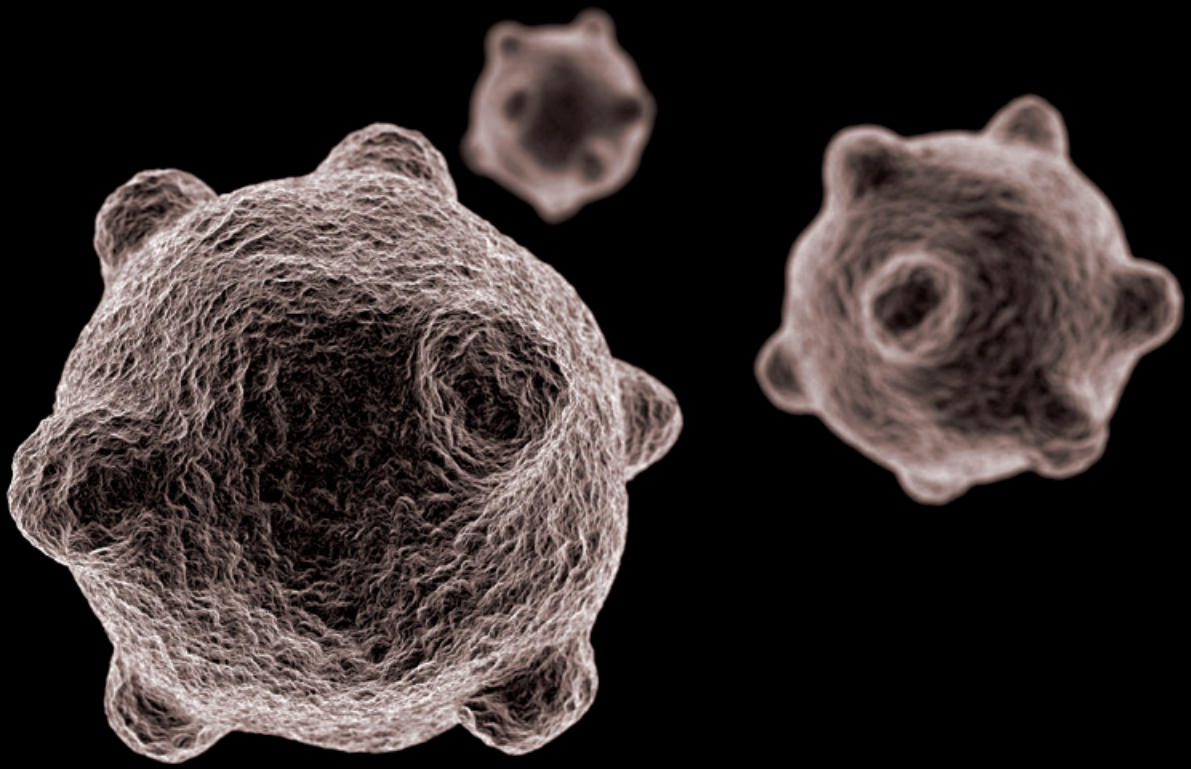
www.imt.ro



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