

Improving Translation of Public Healthcare Nano-Research in Europe

- White Paper to the Horizon 2020 Framework Programme for Research and Innovation –
Recommendations from the Nanomedicine Community

Disclaimer and Contact

This document has been compiled by collaborative work of many people involved in the ETP Nanomedicine and is the outcome of a long discussion process that took place in the ETPN. It does not necessarily reflect any individual position and opinion of the authors but shall reflect the general state of discussion within the Nanomedicine community.

No specific author list will be published but a list of people and organisations endorsing the ETPN White Paper shall be published later.

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The ETP Nanomedicine

Contact:

Sebastian Lange, ETP Nanomedicine Secretariat c/o VDI/VDE-IT, Steinplatz 1, 10623 Berlin, Germany,
Tel. +49 30 310078 299, sebastian.lange@vdivde-it.de

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1. Rational

The ETP Nanomedicine has discussed the needs for novel strategic activities in the area of nanotechnologies for medicine and health for more than 2 years now, taking into account the current developments in the Medtech and the Pharmaceutical sector. The ETPN published an advisory roadmap document in 2009 which outlined the industrially driven implementation plans for Nanomedicinal products in the area of diagnostics, pharmaceuticals and regenerative medicine. For further guidance for this white paper the ETPN recently launched an online consultation to the Nanomedicine community to gather input on the needed innovations in the upcoming framework programme.

Based on this large body of information and an industrial partnership covering the whole Nanomedicine value chain, the ETPN, together with its partners, is prepared to contribute to shaping the implementation of Nanomedicine in the “Horizon 2020 - Framework Programme for Research and Innovation” the European Commission recently launched^{1,2}.

This contribution is important, as Nanotechnology applied to medical applications – usually called **Nanomedicine** – is one of the key enabling technologies to achieve and enable earlier and more precise, individual diagnosis (the sooner, the better the treatment), better targeted therapies (less side effects) and better therapy monitoring (faster recovery). Thus, Nanomedicine is understood to be THE enabling instrument for personalised, targeted and regenerative medicine and will enable the next level in delivering new drugs, treatments and implantable devices to clinicians and patients.

Nanomedicine provides important new tools to deal with the grand challenge of an aging population. Beyond that, Nanomedicine is thought to be instrumental for improved and cost effective healthcare, one crucial factor for making medicines and treatments available to all. Disruptive technologies such as Nanotechnologies in medicine create or pull on new supply chains, and thus it is most important to implement measures that help this supply chain being created in Europe. Only then will the field of Nanomedicine be an important contributor to European economic growth and employment.

Nevertheless, it has become apparent that a number of key issues are inhibiting the transfer of Nanomedical research into big industry and thus products onto the market in Europe. This paper elaborates on these factors and provides some important recommendations on how to overcome the barriers to Nanomedicine translation³ and thus to create a competitive environment with respect to quality, time, risk assessment, early translation funding support, etc. compared to other regions of the world.

Recently, an unprecedented effort of consolidating the area of Nanomedicine research has been undertaken within the major organisations in the Nanomedicine field in Europe joining forces; namely the ETP Nanomedicine, the CLINAM Association, the European Medicines Agency (EMA) and

¹ “Delivering the Common Strategic Framework for Research and Innovation” - Document prepared for the college seminar 4-5 May 2011

² “New name for the future EU funding programme for research and innovation”, Press Release of the European Commission, June 21, 2011

³ The term “Translation” here means bringing research results from “Bench to Bed” as well as from Academia to Industry

the European Science Foundation (ESF). This brings together all relevant stakeholders from industry, academia, clinic and public authorities to define a common view on Nanomedicine and defining the actions needed.

In particular, the ETPN and its partners are striving to

- leverage existing forces in Nanomedicine and build globally competitive centers of excellence in Nanomedicine in Europe to insure the proper representation of the Nanomedicine topic in upcoming strategic research activities
- guide research funding and project building to take translation needs into account
- open the dialogue with all stakeholders involved in Nanomedicine and related medical fields

1.1 Introduction

Nanomedicine is the use of applied research to develop nano-sized drugs, delivery systems and delivery devices as well as nanostructured biomaterials, nano-engineered cells and diagnostic tools to benefit patients and other stakeholders including tax payers. Some of the recommendations outlined in this paper apply more to the nano-pharmaceutical field as targeted delivery is currently becoming a prominent and promising field, but nano-diagnostics as well as regenerative medicine and other related fields are equally addressed by the recommendations.

Although there are various official definitions of Nanomedicine it is in reality an area with no sharp boundaries. The development of nano-pharmaceuticals (also known as “targeted drug delivery”) for example can be seen as a continuation of a long-term trend over recent decades for drug sizes to increase (chemical molecules are smaller than nano-particles). It may be helpful to simply consider nano-pharmaceuticals as drugs bigger than biologicals⁴, occupying the under-exploited area of large molecular weight (i.e. nano) drug space. It should be noted that this definition includes regenerative medicine, where nanomaterials contribute to cell therapies⁵ (cell transfection and tissue engineering) or to the development of functionalized biomaterials, an area of therapy which is coming of age, but is encountering many of the problems seen with nano-pharmaceuticals.

1.2 Current State of Nanomedicine

In Europe, Nanomedicine research has been funded *inter alia* for over five years under the auspices of the Industrial Technologies Programme (NMP) within the EU Framework Programme 6 and 7 (FP6/7). In FP 6 projects with a volume of about 200 M€ and in the first four calls of FP7 (2007-2010) projects with a volume of about 265 M€ have been funded. Likewise, the programmes Health, ICT, ERC and PEOPLE also funded projects related to Nanomedicine, though to a lesser extent.

The funded projects cover and covered preclinical research on nano-diagnostics and imaging, targeted nano-pharmaceuticals, biomaterials for implants and regenerative medicine, and nano-technologies for intelligent implants and prostheses. However, translation aspects were not always

⁴ Biologicals: medicinal preparations made from living organisms and their products, including serums, vaccines, antigens, antitoxins, etc; Dorland's Medical Dictionary for Health Consumers

⁵ Most recent trends on regenerative medicine look at nanotechnology as opportunity to mimic the nano-scale features of native tissue. Biomaterial nanostructures (both in cellular and acellular solutions) influence cell-biomaterial interaction and, at the end, the functional regeneration of damaged tissue.

adequately taken into account despite the fact that disease areas such as cancer, neurological diseases (Alzheimer disease), Crohn's disease, HIV, diabetes, osteoarthritis and rheumatoid arthritis, diseases of the eyes and ears have been addressed.

Nevertheless, this preclinical research performed in Europe confirms the high potential of the use of nanotechnology in medicine and underpins that considerable experience and research capacity that has been built up in the European research community. Over the past years a 'toolbox' has been created that is now available for carrying out further Nanomedicine research and development.

Starting from this strong position in research, in the next development phase more emphasis will be needed on translating innovation, in other words on mobilising considerable industrial investments and public funding for R&D to actually bring promising Nanomedicine products and therapies to the clinic.

This development phase will however be much more expensive as it will involve meeting medical regulatory requirements (e.g. from the European Medicines Agency), developing Good Manufacturing Practice (GMP) for Nanomedicine products and completing preclinical and then clinical testing phases. At the same time, exploratory research obviously has to continue in parallel taking translation aspects strongly into account to find new avenues for improved disease diagnostics and therapies.

As an example of translation driven research funding one can observe a trend in the US where “targeted pharmaceuticals” are currently beginning to be a core topic for advanced research and development and where major public and private investments are being made in this area now that many projects are maturing to Phase 3 trials. These activities should alert the European community and stimulate new urgently needed increased efforts in the area of Nanomedicine.

Despite all efforts, the question is, if European efforts currently are producing adequate return and delivering appropriate new treatments and diagnostics and if not, why not? The immediate question to follow is, how funding measures can be improved in terms of selection of quality research projects and provision of a budget. Obviously, level of funding is not the sole limiting factor in the development of Nanomedicine, nevertheless it is an important factor that needs to be addressed.

Nanomedicine in Europe is developing at a time when open innovation is forcing evolution of the industrial-academic interface to achieve efficient translation of research results into products. Particularly in the area of Nanomedicine Europe has a good starting position with three leading companies, Siemens, Philips and Roche, having their headquarters in Europe, and a fourth, GE, with the headquarters of their Healthcare division in the UK. However, the educational system in Europe has unfortunately created a rather bipolar system where academia is often unaware of business needs and industrialists do not appreciate the difficulties of being a solo performer in academia. Over the last decade stakeholders have failed to recognise the importance of this interface.

Since open innovation is increasingly relevant to academia and SMEs the ETP Nanomedicine has a brief to advise on industrialisation of Nanomedicine. It has highlighted and published areas of concern, but the fundamental funding paradigms are unchanged and out of its control or are only changed slowly. It has watched the majority of European projects often being non-translatable from the outset because of the factors described below. When tackling the problem of translation in Nanomedicine - two questions arise: Why is translation a problem in Europe? What is missing?

1.3 Need for bringing Nanomedicine(s) to the market

Translation, especially in Nanomedicine is still a challenge and underestimated in the process of defining and running scientific applied research projects. A number of issues hindering Nanomedicine in Europe from achieving its full potential are highlighted below.

1. A number of academic centers of excellence in Nanomedicine exist, but with no adequate understanding of the resources and expertise for the development of nanomedical products aligned with regulatory requirements, they are rarely organized in the form of Translational Research Centres (Bench to Bed), they are not organized for the validation of early stage results and have no access to market information >>> **Need to UNDERSTAND development processes**
2. Pharma, Med-Tech companies and Healthcare providers have access to the market but new therapeutics and devices must be de-risked with respect to financial investment and translation i.e. they must be developable with reduced or lower risk. To achieve this industry today is looking globally (not only in Europe) for solutions with sufficient evidence for success to be adopted as development candidates >>> **Need to DE-RISK innovation**
3. A small number of qualified SMEs involved in Nanomedicine exists but they have only extremely limited development capacities >>> **Need to LEVERAGE capabilities**
4. Early stage research projects are frequently not market and medical need oriented (not translatable) and thus a lot of money is spent with limited output >>> **Need to REFOCUS projects, ADJUST funding allocation criteria and programmes. Technical knowledge does not equate to translational knowledge.**

In consequence **EFFICIENT TRANSLATIONAL RESEARCH PROCESSES** from discovery to development and commercialization are required. A more in-depth analysis of the challenges and needs of the European Pharma and Medtech industry is given in chapter 3.

2. Recommendations

The ETPN and its partners propose below recommendations to address the above needs. They target the issues of translation of research results in Nanomedicine to the market and provide some directions on how Europe can improve its competitive advantage in Nanomedicine for the benefit of patients, stakeholders and investors. The recommendations that are highlighted in this paper cluster around the following topics,

1. Implementing a dedicated translation oriented Nanomedicine funding programme
2. Establishing a novel translational Nanomedicine infrastructure
3. Selection of translatable research areas and definition of clear translatable research calls for Nanomedicine programme
4. Uptake of the translation principles into the review system for the Nanomedicine programme

2.1 Recommendation 1: Implementing a dedicated Translation Oriented Nanomedicine Funding Programme

In addition to the existing funding programmes, a dedicated large translation oriented Nanomedicine programme which is well coordinated with other health and medicine funding programmes in the EU will ensure the proper provision of funding resources and at the same time enable the control of the translation process. Together with sources from the EIB⁶ this programme will help to de-risk of Nanomedicine research and development for European industry and keep employment and knowledge in Europe.

Within the new Framework Programme “Horizon 2020” of the European Commission an adequate budget MUST be reserved for translational Nanomedical topics. Joint calls with other programmes, such as regenerative medicine, personalised medicine and around nanotechnologies and Microsystems are highly desirable to establish a synergistic effort.

Nanomedicine funding programme that is inherently translation oriented

The proposed measures could be implemented under the umbrella of the Horizon 2020 Framework Programme within the sub-programme “*Creating industrial leadership and competitive frameworks*”, in the form of a Public Private Partnership (PPP) and thereby fulfilling the need for “*increased strategic investment ... in enabling technologies...*”. Such a PPP will be industrially and clinically driven and inherently translation oriented. The precise outline of such a partnership obviously must be defined in a multi-stakeholder approach separately. Certainly the ETPN and its partners will be ideal platforms to provide qualified input. Beyond the research funding approaches of such an initiative, actions must be integrally planned to further structure the Nanomedical environment and support the Nanomedicine community building process; only by building a strong networked community one can truly achieve the breakthroughs needed. Such actions may be implemented through dedicated coordination measures.

Such a proposed PPP that inherently takes translation into account and goes beyond proof of concept funding will massively de-risk research for industry. Industry will most certainly be attracted

⁶ European Investment Bank

strongly to such programme as it supports rapid launch of products with reduced risk which may provide an clear advantage over having to search for solutions outside Europe.

Linkage between Nanomedicine funding measure and infrastructure

A further possibility to increase sustainability will be to link the funding measures to the recommended Nanomedicine infrastructure (see next recommendation) which could provide tutoring and guidance (catalyst model) for establishing and running translatable Nanomedicine projects.

It is important to mention, that this dedicated translational funding programme inherently takes recommendations 3 and 4 into account and is thus a means of implementing these recommendations on a restricted subsection of the Framework Programme without having to impose translation rules to all areas of the Framework Programme.

2.2 Recommendation 2: Establishing a Novel Translational Nano-medicine Infrastructure

The ETPN recommends establishing a novel translational Nanomedicine infrastructure based on federating existing distributed Nanomedicine research and clinical centres of excellence. The structure will have to interface existing centres and entities to ensure efficient translational R&D programs, from the ideation and discovery phase up to the first in man or proof-of-concept studies, according to the highest standards required by industry and regulatory bodies. The objective is to increase the attractiveness of future innovations for large industry by reducing the associated risks of the early stage of development and proving efficacy and safety of such products in clinical practice.

Distributed Nanomedicine translation infrastructure with central management facility

The Nanomedicine centre shall also implement/establish a small central management facility that serves as operational basis and guarantees sustainability and quality of efforts. The extent to which this central entity is focusing only on coordination or is also involved in the actual R&D needs to be defined.

Nanomedicine stakeholders that constitute and participate to the Nanomedical value chain such as Pharma and Medtech industries, Contract Research Organisations (CROs), manufacturing facilities, research platforms and academic research group shall be associated to the novel infrastructure to provide their knowledge under the scope of their current activities. The strong connection to their advice and knowledge sharing will ensure transferability of the projects. The advantage of such distributed approach is its fast implementation, its use of existing resources with what they are best at and the reasonable funding sources required.

The operational lead of development by a central entity will increase sustainability and also guarantee the ability to capitalize on the developments by individual entities. Such a distributed model will as said utilise and build upon existing European centres of excellence as indicated above in manufacturing (including GMP requirements), quality assurance and quality control, regulatory affairs toxicology, analytical services, IP, healthcare economics and marketing and provide management and clinical support to ensure translation. Details of organisation and structure need to be further elaborated, but certainly have to take into account characteristics of the industries and the applications (disease areas) involved.

Industrial Catalysts as advisors

Furthermore, it is proposed to initiate an approach where industrially experienced “Catalysts”⁷ act as advisors to the research project (one per project - maximum two projects per advisor) and ensure the project manager or principal investigator has access to state of the art advice on translation in Pharma and Medtech. As an example, problems the ETPN industrial members have observed in scaling-up processes and products can be taken as evidence that such expertise solely resides with manufacturing companies and is not easily accessible to SMEs and academia. Lack of knowledge here can lead to a non-standard industrial process being chosen with inevitably disastrous consequences. Furthermore, projects involving academia and spin-offs often lack definition of design parameters for a specific clinical indication, evaluation of added value with respect to competitors and of IP scenarios for the proposed therapeutic solution. Lack of knowledge on existing regulation and standards for prototype characterization often adds to the problems. These issues can be avoided by installing the proposed “Catalyst”-Model. The persons acting as catalysts can possibly be funded as a basic service provided by the Nanomedicine programme and infrastructure.

The operational steps proposed to define the real needs and missing links to set up such an infrastructure are to A) map existing facilities and their expertise and to B) define and analyse the interest and expectations of all stakeholders in the value chain.

Based on this evaluation, it will be possible to design the operational structure that will fill the gap in rapidly guiding research towards translation to market, patients and clinics.

Fully integrated Nanomedicine translation facility as long term goal

In the long run a fully integrated facility for translation of Nanomedicine-based solutions could be established under the roof of the distributed infrastructure umbrella by extending the central management facility with dedicated and specialised R&D facilities and skilled personnel. This approach then would resemble a centralised research incubator, institute or company. In essence it could incorporate the distributed model as described above but would provide further resources in one dedicated central location. Similarly to the JRC concept where dedicated institutes have been funded in support of the stakeholders in Health-, Protection- and Industrial- development the European Nanomedicine incubator / institute could be envisaged to be run as a company oriented business such as Genentech was in its early days. It should be able to handle at least a few projects at a time and guide them through the development process up to the market. Nevertheless it could stop at various interface points i.e. Phase 1, 2 or 3 in the case of pharmaceutical development, or even go the whole way and include healthcare economics and clinical evaluation, in the case of medical devices. Compared to the distributed model this centralised effort will of course be easier to manage as all parts of the R&D value chain are located in one physical location but might require more initial funding to create a sustainable critical mass.

⁷ In the US inter alia there is the Deshpande Centre scheme (<http://web.mit.edu/deshpandecenter/>) where funding up to \$0.25m is dependent on the involvement of a successful industrial “catalyst” or guide who will actively assist in building a credible team, assist with finance and networking the project in a non-executive role.

2.3 Recommendation 3: Selection of translatable research areas and definition of clear translatable research calls for Nanomedicine programme

When defining the research areas and priorities to be supported and funded within the framework programme and a potential future Nanomedicine programme the main emphasis shall be laid on translation aspects and require projects to follow translation principles. To do so an even higher priority needs to be set on including industrial and clinical translation experts in the development of the funding programmes.

This is in many ways the hardest issue to resolve as it requires industry to reveal their wish lists! It also requires academia to have exposure to such problems as well as requiring university departments to have research strategies, often an antagonistic concept to academic freedom! And finally it requires clinicians and patient organisations to play their role in identifying important unmet needs that can be met by Nanomedicine solutions. In many EU countries this dialogue does not happen at all, in others such as the UK, Germany, etc., universities do not automatically capitalise on their opportunities. For example universities will look to industry to be funded but do not actively ask companies (nor clinicians and patients) what they need. Universities and SMEs need to adapt their culture and strategy to follow translational funding.

Some active and funded areas have been dead with respect to translation for decades and are likely to stay so! These therefore should be only funded by basic research sources, until the fundamental problems have been recognised and resolved, and they may become suitable for funding by the Framework Programme.

Good selection of applied research areas to focus on is mandatory.

There is an existing process to design calls but bearing in mind the point above, more could be done to involve industry. The ETPN is consulted on European nano-healthcare industrial priorities, although the subsequent political process where the priorities are set is not always transparent. In addition it is necessary to implement measures to allow the involvement of the clinical community in this process to adequately address the different disease areas and to best define the integration of Nanomedicine in clinical practice. Inclusion of clinical experts and patients would create the side-effect of engaging with the national funding and reimbursement debate.

Furthermore it could be worthwhile to consider following the SBIR type grant model established in the US⁸ which allows for fast and efficient translational research. This topic shall be further elaborated in a follow up paper.

In this recommendation R3, the ETPN briefly outlined its suggestions on how to shape a translation focussed Nanomedicine funding programme. The subsequent recommendation R4 touches upon the necessary improvements of the review system to be made to allow for selection of successful, high impact Nanomedicine research projects really capable of delivering treatments and/ or products.

⁸ <http://grants.nih.gov/grants/funding/sbir.htm>

2.4 Recommendation 4: Uptake of translation principles into the review system for the Nanomedicine programme

Current funding of Nanomedicine is in essence research funding aiming for disruptive results and not so much translation focused funding, even though some improvements have been observed in the past year. As a direct result output is still overwhelmingly non-translatable. It is managed by many research led infrastructures, with peer reviewing focusing on research quality only. It is unlikely that this system will change radically, although some *ad hoc* efforts have been put in place by the EC to eliminate technologies with no chance of translation, such as materials with fundamental toxicities.

The solution to overcome this shortcoming is to have such applied research funding directed by people with translational knowledge and know-how. Translation know-how is not easily accessible to the academic sector or to the majority of SMEs. It is a totally different skill set and it is critical that this is recognised.

Funders must be able by virtue of their review processes to identify areas which are not translatable and are more suitable for basic research. This will require a significant change to peer review in many cases, where industrial or clinical experience is absent or minimal. The impact of societal value should be considered alongside commercial value, when there is neither - then it is likely to be academic basic research that should be funded under the ERC scheme, not within the Framework Programme.

It is unlikely that publically funded researchers will change their research culture, unless funding radically changes and there is a new motivation to do so. ETP members have published guides to translation^{9, 10, 11} but whilst these are helpful, grants continue to be approved without in depth knowledge of these considerations and indeed taking account of these factors may reduce success during (the present approach to) peer review¹²!

To help Nanomedicine deliver some real added value products to patients, research projects need to anchor translation thinking deep into the layout and operations of the project. However, to select for those projects that truly take translation aspects into account an adequate review process embracing the appropriate reviewers is mandatory. If you select for research you will get research, if you select for products you will get products. For translation you do need translation experts and not technical experts.

- ⇒ Peer review has to select for translation and the reviewers MUST have hands on know-how in developing clinical solutions based on Nanomedicine. Being a technical expert in nanotechnology is not adequate.

Even though some representatives from industry have been involved in the review system in the past years it is now time to involve more experienced industrial and clinical people and make sure that they contribute adequate translation knowledge. Europe should be inspired by the various

⁹ Eaton M., Nature Materials. April, 2007, Vol. 6, pp. 251-253

¹⁰ Eaton M., Nanomedicine. DOI NNBM manuscript is 10.1016/j.nano.2011.05.015

¹¹ www.etp-nanomedicine.eu

¹² It may be argued that the FP7 projects have a section on socio-economic impact, which is one of parameter taken in consideration in the evaluation of a proposal. However, this section is often filled out with generic information because the clinical indications are often not defined.

funding mechanisms put in place in other parts of the world such as the US, Japan, China and India. In comparison, each of these regions is funding research at almost the same percentage but for the development phase these regions are massively product oriented, whereas in Europe projects are funded with no or almost no focus on the market. Thus, it is highly recommended that Europe puts in place a mechanism that better capitalises on existing research efforts and leads to a tangible return on investment through improved translation towards patients and market.

3. Funding & Translation in Nanomedicine – Current status & analysis

This chapter provides a more in-depth analysis of the translation challenge in the area of Nanomedicine as well as some further remarks on implementation options of a Nanomedicine funding programme and infrastructure.

3.1 Open innovation leads to a new paradigm in research

During the last decade much has changed in the pharmaceutical and Medtech sector in Europe. The sectors have been major contributors to the European economy and have stimulated basic research, but particularly the Pharma sector is now entering challenging times that have been discussed widely in the media. At the same time patients are demanding for better treatments, and thus clinicians are searching for new and more efficient solutions. To deliver them, Industry is seeking solutions increasingly taking advantage of the Open Innovation model, already widely adapted by the Medtech sector, and now increasingly embraced by Pharma as well, putting pressure on European academia and SMEs to compete globally.

With Open Innovation being more and more implemented and the on-going re-structuring of in particular the pharma industry, the increased expectation for risk investment being placed on academia/government means that the skill gap is, in-fact, likely to increase for many companies. In fact, companies moving R&D labs out of Europe or even away from areas of research may de-skill their ability to engage academia, making it even more important that academia invests more in mutual dialogue/understanding/knowledge to close the emerging gap.

However, there is, in some academic minds, insufficient financial and/or academic reward for commercial engagement. Dilution and expert negotiation often renders universities and inventors impotent and with little substantial return (especially when they evaluate the ultimate returns if their idea is a success; obviously, they do not see the substantial cost of the failures). Their IP strategy often reinforces a ‘publish or perish’ paradigm, literally forcing a choice between academic success and commercial engagement.

Given the expectation in academia of increased risk being transferred from industry to academia by Open Innovation, and of work that is more applied and less publishable (at least in the shorter term), more successful translation of research must be encouraged with more academic incentives, if Open Innovation is to work in Europe.

3.2 Global best practice in funding schemes

Research funders have started to recognise the translation problems and have come up with some experimental approaches. The EC has acknowledged the need for true innovation as opposed to research in the post FP7 era. The UK’s Technology Strategy Board is establishing Innovation

Centres¹³. The MRC again in the UK with its Developmental Pathway Funding Scheme (DPFS)¹⁴ has decentralised peer review encouraging academic institutions to make investment decisions based on translatability rather than academic criteria. Where this has been used in conjunction with industrial know-how there has been a significant improvement in translation with a higher likelihood of patient benefit and a lowering of the risk for industry. The Dutch Council for Health Research e.g. puts emphasis on clinical utility and end-user engagement, which includes patients as well as care providers, in the selection of Healthcare research projects.

This is perhaps not surprising, but illustrates how wide the communication gap between universities and industry has grown over recent decades, such that Open Innovation leaves Europe at a disadvantage with respect to other economic areas. It is important that value is created by aligning research to commercial needs.

4. Summary

Where projects are of interest to industry it has not proven difficult to engage them, as illustrated for example with the output from the DPFS scheme. Contrary to a widely accepted academic view, industry is interested in radical innovation, especially now, but it is not interested in projects with fatal translational flaws.

Improved communication with large industry is required

The changes proposed in this white paper will be certainly regarded as radical by academics whose fields have grown now for decades, but which in reality hold no or very little hope of translation. Industry in these circumstances would move on, but often academic groups avoid clinical proof of concept, but their funding still continues.

To overcome the described hurdles the ETPN proposes the outlined measures towards the public authorities to be implemented under the Common Strategy Framework for Research and Innovation. The ETPN believes that if recommendations outlined in section 2 are addressed properly then industry will be more engaged and Europe will play a significant part in the emerging business area of Nanomedicine and Targeted Pharmaceuticals. The actions proposed could also be a tool to transform research and development in Europe towards a more entrepreneurial culture with a track record of translational success. The ETPN together with its partners is striving to bring this emerging field to success and help keep business and jobs in Europe.

Elaboration of proposed measures

The partners of the ETPN are eager to continue elaborating the previously summarised suggestions. Obviously for implementation detailed activities and measures have to be defined. Also the rules and conditions under which the proposed structures can be implemented have to be detailed and worked on. This shall be done in a follow up implementation paper which shall also take the public debate on this ETPN “White Paper” into account.

¹³ <http://www.innovateuk.org/deliveringinnovation/technology-and-innovation-centres.ashx>

¹⁴ <http://www.mrc.ac.uk/Fundingopportunities/Grants/DPFS/index.htm>

