nanomedicine
EUROPEAN TECHNOLOGY PLATFORM

NANOMEDICINE 2020

Contribution of Nanomedicine to Horizon 2020

- White Paper to the Horizon 2020 Framework Programme for Research and Innovation -

Recommendations from the Nanomedicine Community

NANO MED 2020

Disclaimer and Contact

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

The ETP Nanomedicine

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1. Executive Summary

Nanotechnology has already provided many different medical solutions both for therapeutics and diagnostics. Nano-delivery of drugs, for example, has and will provide new products to address unmet medical needs in cancer and other diseases. In addition, many nano-features, such as new imaging agents or smart materials will be prerequisites for implementation of personalised medicine.

The introduction of nanotechnologies into medical applications requires nanomedicine stakeholders to understand and apply the process of open innovation, which is essential for translation to the clinic. The best option to successfully implement the open innovation model in Europe consists in establishing a supply chain providing nanomedicine products compatible with industrial processes and strategies.

The creation of this new supply chain requires a major change in thinking of all stakeholders and the empowering of an organisation to actively manage the translation effectiveness of its members (academics and SMEs) to help revitalise industry in Europe.

Key tasks of this organisation will be the set-up of:

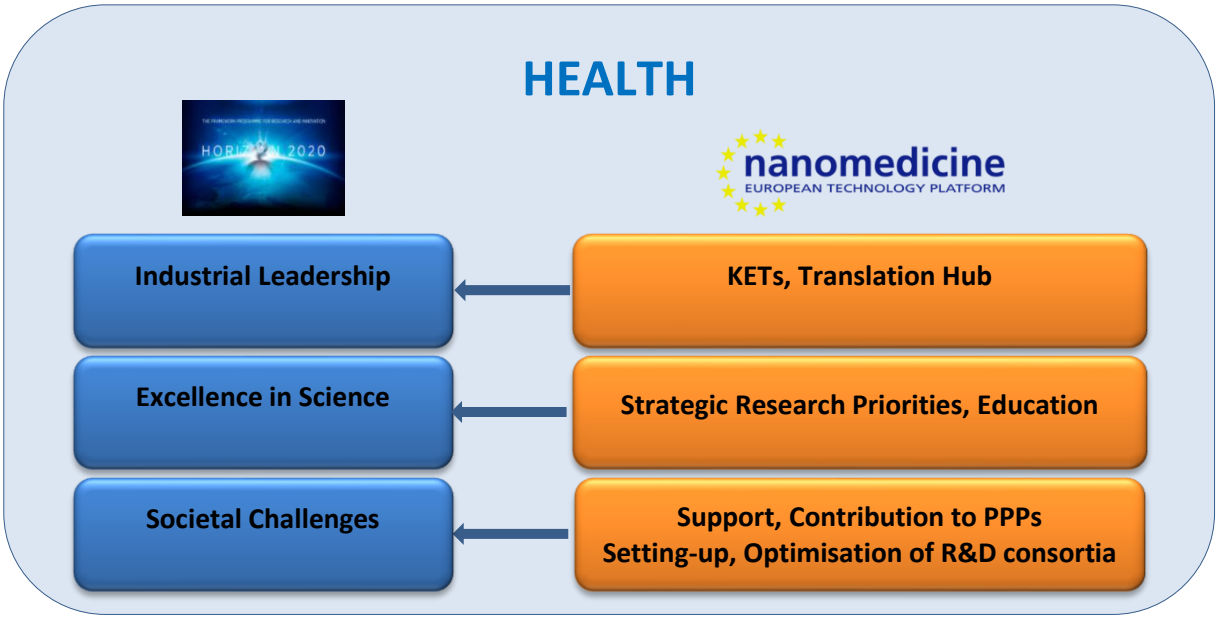
- A Translation Advisory Board with experienced industrial experts, who will apply horizontal innovation filters on R&D proposals from academics and SMEs to select, guide and push forward the best translatable concepts towards funding and clinical proof of concept.
- New infrastructures supporting the translation of nanomedical materials:
    - a European Nano-Characterisation Laboratory;
    - a European Pilot line for GMP manufacturing of batches for clinical trials;
    - a European network of preclinical centres of excellence;
    - a European coordination of nanomedicine effort with clinical organisations.

The ETPN has a track record as a neutral communication platform and think tank for academia, SMEs and industry and knows how they can interact together to translate scientific inventions into healthcare products. Based on this unique European experience, the ETPN offers to collaborate with healthcare industry organisations and the European Commission to discuss and implement the concept on:

How nanotechnology can be managed and translated from a Key Enabling Technology (KET) into new and innovative medical products to help patients.

2. Introduction: Nanomedicine in Horizon 2020

Nanomedicine, also defined as the use of nanotechnologies in medicine, underpins a strong research and emerging industrial healthcare sector in Europe. Based on excellent academic research and innovative SMEs, nanomedicine will actively contribute to the three pillars of the Framework Programme Horizon 2020, which are respectively *Industrial Leadership, Excellence in Science* and *Societal Challenges*.



Contribution of ETP Nanomedicine to the Horizon 2020 pillars

This White Paper outlines how excellent European science and research in Nanotechnology can be managed and translated from a Key Enabling Technology (KET) into new and innovative medical products to be developed for the benefit of the European economy and patients.

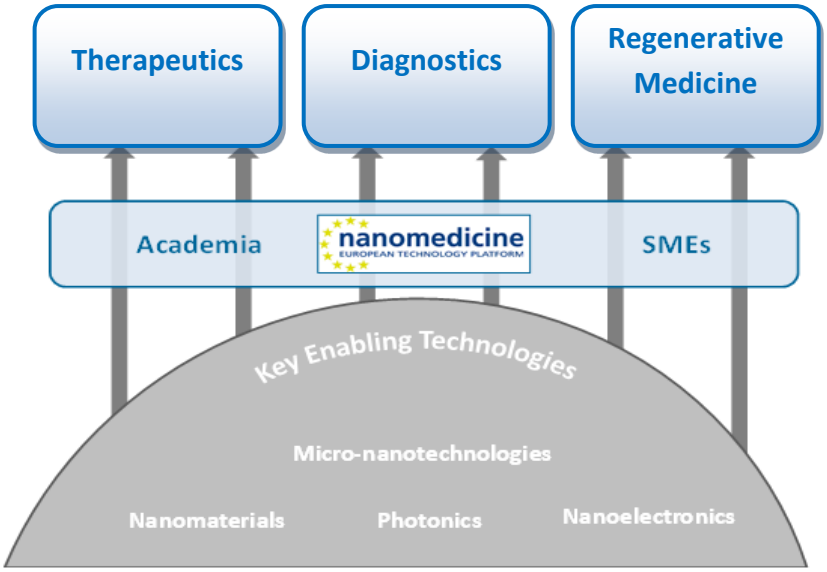
Based on its experience as well as on in-depth analysis of the existing value chain, the European Technology Platform on Nanomedicine (ETPN) identified several challenges to be addressed:

- Significantly improve the dialog and management of the interactions between different academic disciplines, different industries (pharmaceutical, medical devices and diagnostics), clinical organisations and regulatory agencies such as EMA to help structure the development of nanomedicine and to provide channels for early stage clinical proof of concept,
- Create and sustain a continuous R&D supply chain from inventions coming from knowledgeable SMEs or academic research thus acting as innovation drivers to large industry for commercialisation,
- Set-up integrated infrastructures to that will actively assist SMEs and academia to commercialise their innovations thus helping to keep the economic benefits in Europe,
- Provide advisory, educational, financial channels for early stage clinical proof of concept,
- Better select preclinical projects according to their translational potential and the market's needs and guide them towards early clinical trials (up to phase II a) - from Bench to Bed,
- Fill in the pipeline with innovative medical products enabled by nanotechnologies,

- Set up dedicated funding instruments for discovery projects and innovative SMEs to keep excellence in research and development.

The European Technology Platform on Nanomedicine (ETPN) has identified these challenges and is able and willing to tackle them under Horizon 2020, the next EU Framework Program for Research and Innovation. It has a track record of networking research organisations, SMEs, and industries leading to comprehensive Strategic Research Agendas[1], widely used by public funding agencies. In addition, its members have developed and published concepts[2] for structural changes necessary to improve translation of innovations and to keep production and jobs in Europe.

Based on this experience, the ETPN will cooperate with health care industry organisations to bring together EU, national and private resources to create an SME based supply chain for innovative ground breaking therapeutics and diagnostics. It will focus on nanotechnology based medicine and regenerative medicine, moving European SMEs to a position where their knowledge of development competes with the best in the US and Far East. This strengthening of the nanomedicine supply chain will support nanomedicine innovation and **keep high tech jobs in Europe** for the benefit both of the European economy and patients.



Contribution of ETP Nanomedicine to the Health application areas

[1] ETPN 2006 Strategic Research Agenda, *Nanomedicine: Nanotechnology for Health*
Joint European Commission / ETPN Expert Report 2009, *Roadmaps in Nanomedicine Towards 2020*
[2] ETPN Opinion paper (June 2010)
ETPN's contribution to the Europe 2020 Flagship Initiative (2010)
ETPN White Paper to the Horizon 2020 (2011)
Documents available on www.etp-nanomedicine.eu/public/press-documents/publications/etpn-publications

3. Innovation in Health needs Effective Translation

The current White Paper aims at giving concrete concepts and recommendations for the implementation of research and innovation priorities defined in the ETPN Strategic Research and Innovation Agenda (SRIA[3]) in the particular context of the European Framework Programme for Research and Innovation Horizon 2020. The detailed ETPN's vision and overall concepts for an effective translation of nanotechnologies for medical applications are depicted in the SRIA.

3.1 Nanotechnology, a Key Enabling Technology

Nanotechnology is one of the six Key Enabling Technologies (KETs) that has a significant impact on many different medical developments in the three main areas: Therapeutics, Diagnostics/Imaging and Regenerative Medicine. Accordingly, the mapping of nanotechnology research in these areas to diseases is at the heart of the definition of Strategic Research Priorities in nanomedicine. All therapeutic areas will potentially benefit from nanomedicine. The matrix shown below highlights some applications where nanotechnology has already a tangible and substantial impact in the treatment, diagnosis or imaging of some major diseases. Based on such topics specific priorities can be identified jointly by industry and the EC, to be filled by dedicated calls for proposals.

Challenges	Therapeutics	Diagnostics / Imaging	Regenerative Medicine
Cardio Vascular Diseases	▪ Implantable devices (nano surface modification) ▪ Targeted drug delivery into plaques	▪ Nanoparticles for theranostic approaches	▪ Intelligent bioactive materials ▪ Stem cell mobilisation and homing at site of injury
Neuro Degenerative Diseases	▪ Semi invasive nanodevices for drug delivery (for Parkinson) ▪ Nanoformulations for crossing the BBB	▪ Image guided implantation of advanced neurostimulators	▪ Site specific delivery of neuro active molecules ▪ Intelligent biomaterials controlling CNS regeneration
Diabetes	▪ Insulin measurement and delivery by nano enabled devices	▪ Encapsulation and monitoring of labelled islet transplants ▪ Whole body imaging of fat distribution with nanoparticles ▪ Implanted non-invasive continuous glucose monitoring	▪ Functionalization of 2D and 3D materials for time and spatial release of biochemical factors for artificial pancreas
Cancer	▪ New nano formulations for targeting agents to tumours ▪ RF-heatable Nanoparticles for thermal therapy ▪ Implantable devices for localised delivery of drugs ▪ New therapeutic tools with physical mode of action ▪ Monitoring of therapeutic efficacy	▪ Nanoparticle tracers and contrast agents for diagnosis (Magnetic Particle Imaging) ▪ Composite nano particles for monitoring of therapy ▪ Minimal invasive endoscope / catheter for diagnostics and therapy ▪ Nanostructured surfaces for biosensors	▪ Functionalised nanoparticles for targeted in vivo activation of hematopoietic stem cell production
Inflammation	▪ Soft nanomaterials for bone regeneration, Rheumathoid Arthritis and Crohn's disease ▪ Bacterial free nanomaterials to avoid infection by implanted materials	▪ Imaging of nanoparticle labelled white cells	▪ 3D Nanomaterials for stem cell immobilisation at site of injury ▪ Novel implant materials and surfaces to prevent implant infections

[3] ETP Nanomedicine Strategic Research and Innovation Agenda 2014 – 2020 – to be released on the ETPN website

The examples in the table above demonstrate the importance of "smart" nanostructured and functionalised surfaces, scaffolds and nanoparticles for new and advanced diagnostic and therapeutic treatments such as intelligent nanocarriers, multifunctional contrast agents and high-throughput systems. The nano scale brings to materials and molecular assemblies different physical and chemical properties, thus introducing new features for therapeutic or diagnostic applications.

Tissue Engineering, for example, will highly benefit from future nanomedical technologies such as self-assembled and self-repairing soft nanomaterials and the "loading" of these materials with chemicals such as growth factors, drugs or biologicals[4], as they have the potential for instance to overcome the lack of migration of cells into preformed scaffold networks with novel concepts of synthetic matrix polymers (hydrogels) enabling in situ crosslinking in the presence of viable cells. A stronger focus will also be set on the development of surgically connectable vascularised matrices, representing a basic requirement for the implantation of large dimension tissue-engineered constructs.

Another example are multi-functional nanoparticles combining imaging and drug carrier features which will revolutionise the early diagnosis of diseases and their therapy. Cancer, for example, as a major cause of death needs new therapeutic approaches, which target the disease and avoid drug resistance. Targeted nano-delivery of drugs and nano therapeutics represent today a high proportion of drug companies' portfolios in the US and therefore the most advanced area of nanomedicine. They will provide new approaches to address such unmet medical needs in cancer and other diseases. In addition, many nano-features will be crucial prerequisites for implementation of personalised medicine and therapy or even treatment of chronic diseases.

3.2 Introducing Innovation to the Nanomedicine Research Agenda

The Strategic Research Agendas (SRAs) defined by the Nanomedicine community and in particular the ETP Nanomedicine over the last decade were mainly based on technology push and clinical demand. The R&D projects implemented under these research priorities in FP6 and FP7[5] have successfully delivered a lot of new nanomedicines but few products on the market. In consequence the next level of the strategic development of the ETPN is to emphasise the introduction of "Innovation" into the Agenda by improving the translation of nanotechnology R&D into medical applications. This is a Grand Challenge that has been at the core of the ETP since its formation in 2004.

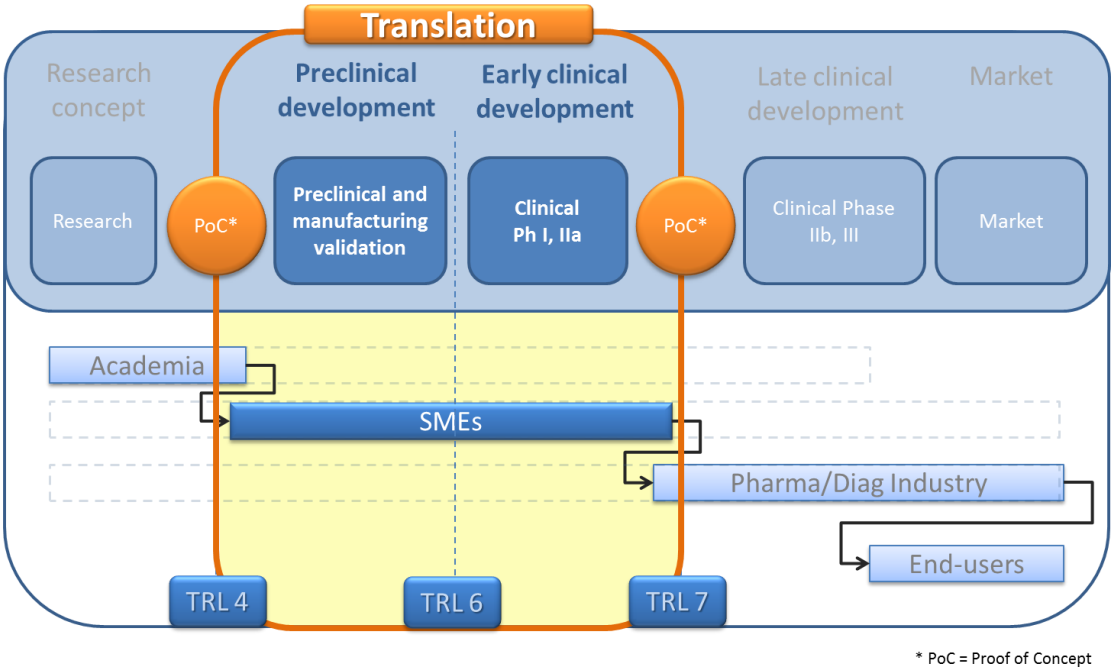
Innovation applied to Nanomedicine for example means enabling personalised medicine through stratification of patients by nano-based diagnostic tests (companion tests for instance) or imaging agents, which is a new and different approach to current medical practice. Another example is the combination of a diagnostic tests and a therapy within one type of nanoparticle thus making some clinical protocols simpler. However, for such innovations to reach the patient, close and well informed interactions between all actors in the nanomedicine research and development chain (academic, industrial, public and private partners) are mandatory, including special structures to

[4] Biologicals encompass peptides, proteins, nucleic acids

[5] 49 nanomedicine related projects have been funded under the 7th Framework Programme for Research and Technological Development with an estimated EC contribution of 400 Mio. € via NMP

actively manage communication and collaboration between all stakeholders, including regulatory bodies to effectively translate and commercialise ideas.

In parallel and in order to maximise European resources, synergy and cooperation with existing initiatives such as EuroNanoMed, national nanomedicine platforms and societies, the European Technology Platforms - NanoFutures, Photonics'21 and EPoSS – as well as with industrial federations in the pharmaceutical and/or imaging sectors should also be further investigated. A specific dialogue should be conducted with the European Infrastructure on Translational Medicine (EATRIS), which is deemed to support later clinical developments. Concerted actions should be defined with EATRIS in order to provide a seamless translational support to innovative nanotechnologies beyond the area of actions covered in the present document.



Nanomedicine value chain, stakeholders and interfaces with focus on translation

3.3 Innovation needs Effective Translation

The ETP Nanomedicine has since its inception defined its role as providing an industrial perspective on the application of nanotechnology to human healthcare. Whilst societal need has been the primary driver for healthcare projects, it is not sufficient without any mechanism to select and fund translatable projects from the inevitably undevelopable majority. The ETPN has already reacted to this translation failure with various papers[6] highlighting the crucial issues. Healthcare research without any knowledge of the development pathways is hugely wasteful. Translation know-how

[6] ETPN Opinion paper (June 2010)
ETPN White Paper to the Horizon 2020 (2011)
ETPN's contribution to the Europe 2020 Flagship Initiative (2010)
Documents available on www.etp-nanomedicine.eu/public/press-documents/publications/etpn-publications

reduces the options and focuses on the real barriers, helping stakeholders and if anything increases the innovation challenge.

Much has changed in the last decade in healthcare companies, with the result that pharmaceutical companies for example are moving to a global Open Innovation model, with a reduction in their own research capacities, especially in Europe. They have found their revenues under pressure and their pipeline of new products unable to provide the income to support the headcount without a loss of jobs. Most large pharmaceutical companies have now radically changed and embraced in-licencing and Open Innovation (OI) to try to reduce risks, to lower costs and to raise innovation standards. One consequence of this move is the cut in R&D staff in Europe's research centres, and an investment in business development with the aim of technology scouting and in-licencing from academia or SMEs. This global strategy aims to recognise novel putative products or concepts, from SMEs and academics, wherever they originate in the world. Large companies are now focusing their business on late clinical validation, regulatory approval and worldwide distribution. The advantage for large pharmaceutical companies as well as for diagnostic and imaging companies is that it does not require early investment of resources, just the use of the knowledge of what makes a good potential marketable product. However, this OI concept will only succeed in Europe, if projects from the emerging healthcare supply chain of SMEs (and even academics) are developable.

An ideal scenario would consist in the set-up of a competitive supply chain of innovative SMEs testing the initial clinical proof of concept of new nanomedicines (up to phase I or IIa) and if successful, transferring their proof-of-concept projects to large companies which probably remain the only financially and technically capable organisations to bring them onto the global market. Such a system is in operation in the US and has underpinned the development of biologicals, which has been the fastest growing sector for new drugs over the last two decades. The difficulty of such a change in ideas and processes in Europe is the fact that a change in academia is compounded by the lack of exposure to Open Innovation ideas and the strength of academia's perception of "freedom of research".

The European academic system trains students well for a career in academia; however it does not train for careers in innovative healthcare. It currently lacks the translational knowledge and this European weakness in development knowledge inevitably feeds into the entrepreneurial industrial sector. Historically large companies have retrained their new staff for translation; such trained staff does not often exist currently in SMEs.

To overcome this situation in nanomedicine, it will be necessary to:

- Inform academia and SMEs about the rules and principles of translational research,
- Introduce course elements on translation/innovation in undergraduate courses in Europe,
- Increase visibility of selected SMEs with translatable products to large companies,
- Involve large companies or industrial experts in the evaluation, selection and tutoring of translational projects under development in SMEs and academia, with perhaps an option to invest resource as an inducement. Only genuinely translational projects should be funded if described as such.

Industrial inputs will be crucial for the success of the *Industrial Leadership* pillar of the Horizon 2020 Framework Programme. In order not to waste European public funding and to maximise its leverage

effect, it is important that together with the Strategic Research Priorities, that horizontal innovation filters are strongly applied to ensure only the best concepts get funded and progress to the market.

Among the 500+ SMEs[7] with an activity in nanomedicine identified in Europe, the European project NANOMED2020 has assessed that some of the major hurdles encountered during the development and translation process were:

1. Missing **relevant knowledge in the field of oncology and in market access** at the early stage of the project; then, it took a long time to acquire the necessary knowledge,
2. Difficulty to find **appropriate funding to finance the proof of concept** in order to further raise investment from venture capitalists; this has slowed down the development of the product,
3. Difficulty to acquire the **appropriate knowledge on clinical trials** and to **identify a competent Clinical Research Organisation** to develop the specific preclinical studies required before going to the First in Man trials; this has highlighted the need to develop new relevant methods and assays,
4. **No availability of a Contract Manufacturing Organisation** to manufacture the first batches of the nanomedicine product. It took a long time to implement a manufacturing process according to the medical requirements for Good Manufacturing Practice.

This analysis highlights the need **to significantly accelerate the translation of nanomedicine** products by overcoming some of the well-known bottlenecks listed above. This can be achieved by facilitating SMEs access to infrastructures and to expertise in translation. Inspired by industrial success stories, the concept proposed by ETPN supports and optimises the healthcare value chain in a risk sharing approach for SMEs and industry. This should increase the speed and efficiency of translation from pre-clinical research to clinical applications, and the concept might be transferred to other industries, which are heavily dependent on new technologies.

[7] Mapping done by NANOMED2020 CSA 2011-305152

4. Making It Happen Under *Horizon 2020*

4.1 Overall concept for a Translation Hub

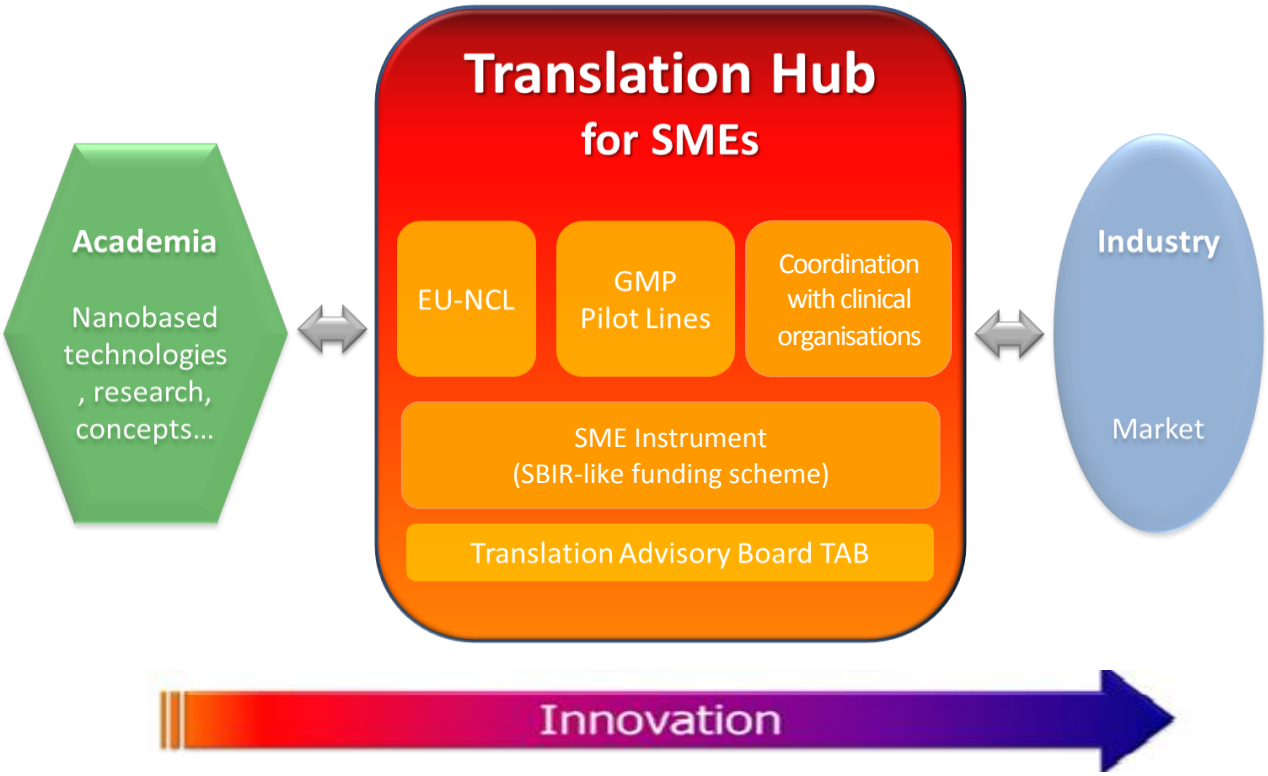
The ETPN and the NANOMED2020[8] project conducted in the recent years different mapping activities in order to gain a comprehensive overview of the nanomedicine community in Europe and to support the identification of gaps and needs for a more effective translation.

In addition to an inefficient selection process of translatable projects, there is a lack of technical infrastructures, such as pharmacology and toxicology facilities, which have experience with and can support nanotechnology-based innovation in healthcare for both SMEs and academics. Building these infrastructures will keep nanomedicine research in Europe and will contribute to re-industrialisation by making the EU more competitive in nanomedicine development. As a consequence the ETPN proposes as a main structural action to introduce a **Translation Hub,** as an umbrella for a set of complementary actions/initiatives such as:

- a dedicated **Nanomedicine Translation Advisory Board** (TAB), with experienced industrial experts, who will apply horizontal innovation filters on R&D proposals from academics and SMEs to select, guide and push forward the best translatable concepts,
- a **European Nano-Characterisation Laboratory** (EU-NCL) for physical, chemical and biological characterisation of nanomaterials intended for medical use,
- **GMP manufacturing pilot lines for clinical batches**, which will both assist academic groups and especially SMEs to develop their nanomedical materials for validation in clinical trials, before transfer to CMOs,
- a strong link with existing **European clinical networks or organisations** to help transfer and provide efficient early clinical trials in nanomedicine,
- an active support towards the setting-up of a dedicated **NanoMed SME instrument** (SBIR[9]-like scheme) aiming at funding discovery projects and innovative SMEs in order to keep excellence in nanomedicine research and development.

[8] NANOMED2020 Support Action (SA) under FP7-HEALTH. Project reference 305152

[9] "Small Business Innovation Research" (SBIR) is a US source of funding awarding monetary grants to small businesses in phase I or II. As it has proven to be successful, a similar scheme is planned to be adapted by the EC as a new SME Instrument under Horizon 2020.



The Translation Hub, an umbrella concept for a set of complementary actions and initiatives

The four key elements composing the Translation Hub (EU-NCL, GMP Pilot Lines, SME Instrument and TAB) are further outlined below and are deemed to be the most relevant concepts for ensuring the competitiveness of the European Research and Innovation Area.

4.2 Nanomedicine in *Industrial Leadership*: contribution to medical nanotechnology as Key Enabling Technology and leveraging innovation in SMEs

The ETPN defined in its Strategic Research and Innovation Agenda scientific research priorities till 2020 to advance and consolidate nanotechnologies as enabling technologies for medical applications. In addition to the proposal of research topics, selected on the basis of the SRIA for topical calls within the KETs sub-programme, the ETPN will strongly contribute to the *Industrial Leadership* pillar with the implementation of the Translation Hub and of its components described in the following sections.

4.2.1 Leveraging Nanomedicine Innovation via the Translation Advisory Board

Mission

One initial step in the set-up of a functional Translation Hub is the establishment of a **Nanomedicine Translation Advisory Board** composed of industrial and clinical experts selected according to their specific knowledge, skills and experience in Intellectual Property, market need/market

access/reimbursement, manufacturing and Chemistry, Manufacturing and Control (CMC), preclinical and clinical development, regulatory, business development, and communication.

Based on this expertise, the Translation Advisory Board will apply innovation filters such as:

1. Safety evaluation
2. Technical evaluation
3. Competitive evaluation
4. Regulatory evaluation
5. Reimbursement evaluation
6. Commercial evaluation
7. Clinical trial design
8. Extent of Paradigm change
9. Societal issues

By doing so, the Translation Advisory Board will select and promote projects with a high translation potential, thus increasing their chance to reach late clinical trials and/or the market.

Objectives:

The primary goal of the Translation Advisory Board is to provide advice and guidance to projects and organisations to ensure that the object will lead to developable nanomedicine product. The scope of work is going from **lab proof of concept (TRL 4) to clinical validation (TRL 7).**

The Translation Advisory Board could, when appropriate, play a role in project selection to get funding.

Another role is to efficiently link **SMEs as main drivers of innovation** in nanomedicine with large companies that could take over projects after reaching a sufficient level of proof of concept and especially after phase IIa. Large companies are the only organisations capable of taking products through regulatory approval and reimbursement issues onto the market. This is particularly relevant for medical applications given the long-term investments needed to provide the data required by the regulatory authorities. Contacts with large industrial federations such as EFPIA, the European Federation of Pharmaceutical Industries and Associations, have been initiated in order to align the projects of nanomedicine SMEs with the pharmaceutical industrial products requirements.

Proposed structure:

The **Translation Advisory Board** is a group of experts made available through ETP Nanomedicine that **have** documented experience in translational research in selected key-areas and can hence **guide and monitor the translation process of previously selected projects.**

The Translation Advisory Board will be composed of:

- permanent members who have a broad view with strong industrial background and have developed projects along the value chain (at least from idea to clinical proof of concept),
- a network of experts with diversified expertise that could be consulted or could help the projects on a case by case approach

Beneficiaries will be selected by the TAB together with the ETPN Executive Board on a **bottom up approach via open calls directed towards SMEs**. However the TAB can also serve to provide advice to FP7 or H2020 R&D projects funded under Health or the NMP programs if requested. The calls and submission processes will be implemented by the ETPN.

Proposed funding mechanism for implementation of the Nanomedicine Translation Advisory Board under Horizon 2020:

- (Large) Coordination and Support Action (CSA)
- A cost model for solicitors and submitted projects is currently under investigation. Advice by the TAB may be in the future eligible for reimbursement via the SME Instrument funds allocated to innovative SMEs soliciting such expertise.
- **Estimated budget/EC contribution until 2020: 14.5 Mio. €**

Proposed implementation plan of the Nanomedicine Translation Advisory Board under Horizon 2020:

Phase I: Building up references / proof of concept: 1 or 2 study cases chosen by ETPN Executive Board within the members -2 permanent members- and ad-hoc invited experts.

Phase II: Expending the services to all ETPN members, enlarging the target and validating the concept with a CSA.

Phase III: Enlarging the permanent members and network of experts to cover the full range of advice.

4.2.2 Leveraging Nanomedicine Innovation via a new Nano-Characterisation infrastructure

Mission

The creation of a European Nano-Characterisation Laboratory (EU-NCL) performing pre-clinical level physical, chemical and biological characterisation of nanoparticles intended for medical applications is required. It will contribute to the competiveness of Nanomedicine products and tools by increasing the industry readiness of research offerings and thus stimulate private-sector investment in this area. Moreover, the EMA'S SME office annual report 2012 highlighted that 39% of objections of a new product review were linked to quality problems related to manufacturing process validation, the setting of specifications and the stability of data. The Nanotechnology Characterisation Laboratory[10] located in Frederick, MD, USA (US-NCL) has offered for several years its characterisation services for free to international projects which have undergone a positive evaluation. Based on such positive experience and in-depth contacts with US-NCL directors, the ETPN has identified that a similar service (EU-NCL) would be relevant and of great value to foster innovation and facilitate regulation in Europe.

The American NCL is backing up the concept of a new European characterisation infrastructure and has already offered full cooperation. The ETP Nanomedicine is in advanced discussions to propose a

[10] US-NCL, directed by Scott McNeil - http://ncl.cancer.gov

concrete concept for such an infrastructure to both ESFRI[11] and as an I^3 – Integrated Infrastructure Initiative, via the FP7 Infrastructure initiative. If evaluated positively, the ETPN, the **EU-NCL and the US-NCL will establish a transatlantic cooperation on the development of nanomedicine with cross training, round robin tests, exchange of experience and joint action towards US and European nanomedicine regulation agencies**.

Objectives

The European Nano-Characterisation Laboratory will provide a comprehensive set of characterisation parameters (physical, chemical, in vitro and in vivo biological properties) allowing researchers to apply their particles to solving problems that affect patients' health. A direct link with the European Medicines Agency (EMA) or other relevant agencies (e.g. notified body) are required to facilitate the approval of Nanomedicine products based on the characterisation report delivered by the European Nano-Characterisation Laboratory eventually completed with CRO's analytical reports for some specific assays under GLP conditions. Another link with EURAMET[12] is necessary for standardisation of analytical methods of nanomedical nanomaterials.

Proposed structure

Europe already hosts outstanding centres characterising some of the parameters required for a legal approval. Therefore **no new centre should be created** and the effort should be set on networking and coordinating the existing centres in order to provide a full characterisation set, with some technical or equipment updates in specific places. Because the selection of analytical tests is correlated with the tests required for the approval of clinical trials, this decentralised centre will not only provide service analysis but also will have a strategic and political role in helping newcomers, like SMEs, find their way towards clinical trials. A distributed network of existing characterisation centres is thus required. This infrastructure should be managed centrally by an independent unit, whose role would be to coordinate the logistics between the centres, to oversee the entire analytical process of each medical nanomaterial in the distributed analytical centres, to guarantee the quality and efficacy of the characterisation process, to manage European funding and to act as a single entry point.
Such a pan European infrastructure would have to ensure at the same time that it can interact locally on a daily base with SMEs which may not be accustomed to international assistance in implementing their R&D processes.

The structure could start with 3 or 4 core nodes and integrate further specialised characterisation centres later on, adding additional characterisation procedures and methods, according to the selection criteria set by the management unit. The addition of new centres will be reviewed by the central unit and steering group. Furthermore, a global collaboration may be foreseen with **the nanomaterials eco-toxicity initiative**. European funding is required to build up and run the management unit, as well as to cover the costs linked to the characterisation of nanoparticles by the individual centres.

Expected Outcome:

- Distributed European Nano-Characterisation Laboratory with central management facility.

[11] European Strategy Forum on Research Infrastructures - http://ec.europa.eu/research/infrastructures/index_en.cfm?pg=esfri
[12] www.euramet.org/index.php?id=homepage

- One-stop shop for the European Nanomedicine, clinical and pharmaceutical community facilitating the standardisation of nanomaterial containing products and the exchange of results for clinical studies.
- Full standardised analytical report compatible with IND dossier (Investigational New Drugs) by medicine regulation agencies.
- Support to the harmonisation of standards between the US and the EU, thus helping transatlantic trade of nanomedicine products and accelerating the introduction of nanomedicines.

Proposed funding mechanism for implementation of the European Nano-Characterisation Laboratory under Horizon 2020:

- Distributed Infrastructure with transnational access, I^3
- Coordination and Support Actions with focus on "International Cooperation"
- Investments by local/regional/national authorities in the distributed analytical centres
- **Estimated overall budget until 2020: 117 Mio. €**, covering the preparatory, implementation and operation phases –management & coordination efforts estimated separately (see annex 1)
    - **Requested EC contribution under H2020: 77 Mio. €**
    - **Requested contribution under EC structural funds / national or regional funding sources: 40 Mio. €**

Proposed implementation plan of the European Nano-Characterisation Laboratory under Horizon 2020:

Phase I (2014-2015): The **design study and the beta test should start with 3 or 4 existing centres**. This core group can be further enlarged by new centres in a selection process still to be defined and coordinated by the central management facility.

Phase II (2016 – 2017): The centres would further **develop and expand their services**. In addition, the decision will be prepared and taken at the end of this phase, if the EU NCL should be concentrated at one location or if it should continue to operate as a network.

Phase III (2017-2020): The EU NCL should be in full operation.

4.2.3 *Leveraging Nanomedicine Innovation via the GMP manufacturing pilot lines for clinical batches*

Mission

The ETP Nanomedicine concept is to have selected manufacturing centres / companies which can scale up laboratory synthesis of materials (mgs) up to larger scale production processes to produce enough material (kgs) for clinical and regulatory tests. The objective of such an endeavour is to help SMEs to produce sufficient amounts of GMP controlled batches of their nanomedicines according to industrial and regulatory standards for early clinical trials thereby improving progress to clinical

practice. The early inclusion of SMEs in this process is essential, as knowledgeable SMEs are the only way to create a productive supply chain in Europe.

Proposed structure

The GMP Pilot Lines infrastructure should offer scale up facilities and GMP manufacturing of batches of nanomedicines to SMEs which don't have access to such facilities. These pilot lines will attempt to address the current developmental and production gap between lab scale production and Contract Manufacturing Organisations (CMOs), will contribute to the efficient synthesis and manufacturing of nanomaterials, components and systems, aim at ensuring the efficient transfer of knowledge into industrial innovation, and finally will support the emergence of innovative nanomedical solutions to address the Societal challenges on Health.

This structure needs public funding and political support via ERDE or "Competitive Industries" programmes in Horizon2020 and should have experience and professional structures in technology transfer and clinical studies, ready for industry to connect to. This is a perfect example of a KET manufacturing pilot lines for innovative materials in medicine, speeding-up the emergence of this nanomedicine industry in Europe.

For EU and given the politics it may also be envisioned to allocate a certain disease mission to each of the NCL/Pilot schemes in order to create an aspirational effort towards new healthcare innovations.

Once regulatory-approved and manufactured, nanomaterials should enter early clinical trials in dedicated clinical investigations centres with experience in nanomedicine. A few of them will be selected according to EMA and US-FDA standards to conduct the clinical evaluation. Indeed the ETPN identified the need for a European network of nanomedicine-related clinical organisations and the opportunity to leverage the scope of such network via a centralised and highly qualified Management Team, in order to:

- ensure that all preclinical studies conducted by the infrastructures are in compliance with quality standards (such as ICH/GCP guidelines) and with all applicable national regulations,
- improve the quality of infrastructures and preclinical centres activities,
- provide advice to projects and to orient such projects to the most relevant clinical centres or organisations,
- elaborate innovation in regulatory aspects related to early clinical development in advanced therapeutics,
- conduct audits, train staff and deliver advice on related matters.

It is envisaged to integrate such Project Management and Quality Assurance Team under the GMP Pilot lines implementation plan and in close interaction with the TAB.

The GMP nanomanufacturing pilot lines will be designed in a way that no unfair business distortion is induced with commercial organisations if any.

Expected Outcome:

- Distributed Nanomedicine translation infrastructure with central management facility.

- Industrial and clinical Catalysts as advisors (from the Translation Advisory Board)
- GMP manufacturing of nanomedicine batches for regulatory toxicity testing and early clinical trials (phase I, II a).

Proposed funding mechanism for implementation of a Translation & SME Inclusion Infrastructure under Horizon 2020:

- Integrated Project (IP), Pilot line scheme, multi-KET approach (see implementation phases below)
- Financial support from local/regional/national authorities for the complementary funding to EC's support
- **Estimated overall budget until 2020: 106 Mio. €** covering the preparatory, implementation and operation phases - management & coordination efforts estimated separately (see annex 1)
    - **Requested EC contribution until 2020: 66 Mio€**
    - **Requested contribution under EC structural funds / national or regional funding sources: 40 Mio. €**

Proposed implementation plan of the GMP scale up Pilot Lines for clinical batches under Horizon 2020:

The plan is to have several distributed pilot lines delineated by types of materials. The GMP scale up pilot lines could be jointly designed with the US-NCL, which has a similar project.

Phase I (2014-2015): The first Pilot Line will focus on soft materials. In this first phase, a **survey and beta tests are also needed to check if voluntary Contract Manufacturing Organisations** exist and are suitable to be upgraded to produce kg batches of nanomaterials. In this case, these companies, mostly **SMEs, would get a certification, which is needed to comply with EMA and FDA standards.** SMEs will have access to these centres.

Phase II (2016-2017): The second one will focus on polymers.

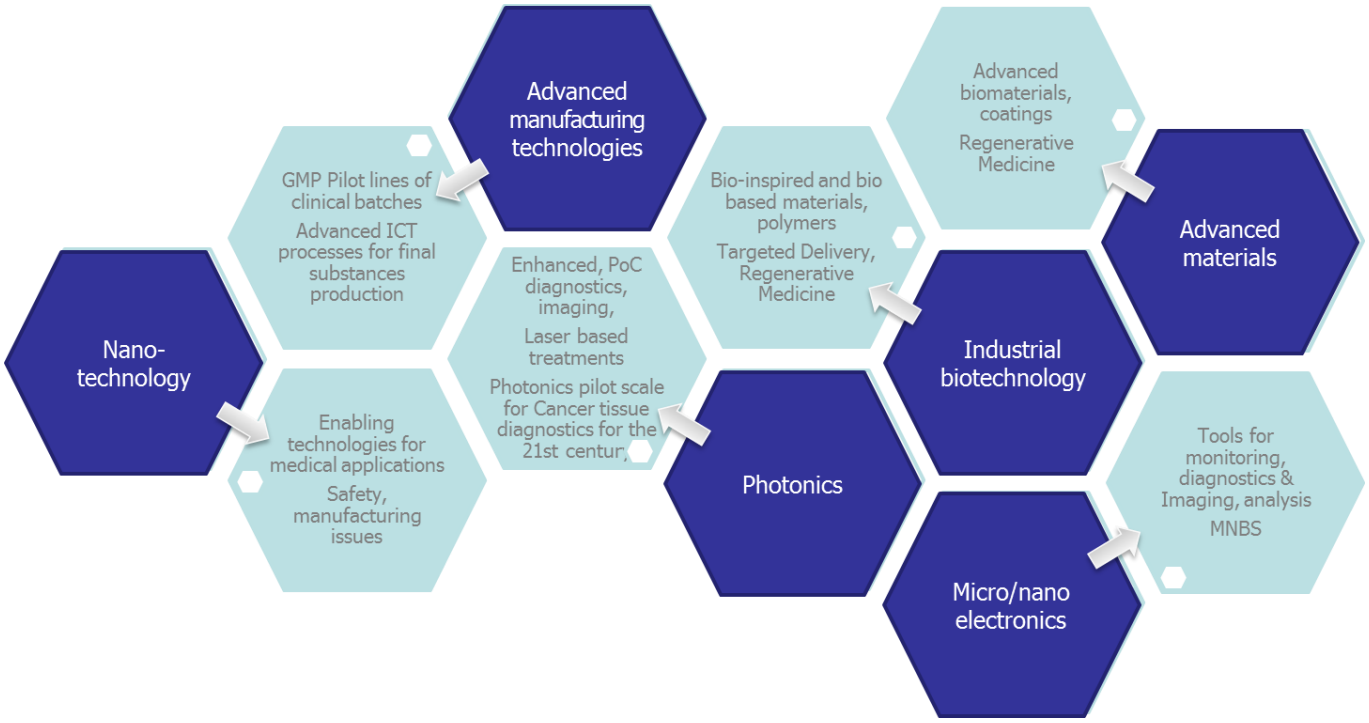
Phase III (2018-2020): The third one will focus on surfaces.

4.2.4 *Leveraging Nanomedicine Innovation via cross-KETS synergies: the case of MNBS*

As a major application of *Nanotechnology*, the field of *Nanomedicine* fits naturally amongst the Key Enabling Technologies (KETs) defined by the European Commission, along with micro- and nanoelectronics including semiconductors, advanced materials, biotechnology, photonics, and advanced manufacturing technologies.

Inherent interactions exist between these sectors and could be mutually beneficial in terms of research innovation. For example, the use of quantum dots and shape-shifting nanomaterials for medical applications could greatly benefit from the latest progress in photonics, and nanomedicine sensors from biotechnology and biological pores.

The ETPN will continuously monitor for opportunities in Horizon 2020, push forward synergies and initiate cross-KETs collaborations in order to enhance and enlarge the tools and possibilities for nanomedicine technologies as pictured in the graph below:



A Multi-KET approach of Nanomedicine: common R&D topics with the KETs

A specific collaboration is already initiated in this regard between Nanomedicine and Micro-Nano-Medical Systems as part of the MNBS cluster[13] for real healthcare opportunities in diagnostic innovations and new roads to deal with major societal challenges.

Beyond facilitating therapeutics, nanotechnology expands abilities to revolutionize diagnostics by providing new formulations and routes for diagnostics. Recent developments into the uses of nanofabricated devices and systems suggest that today's complex processes of bioanalysis, like genome sequencing or detection of gene expression can be made dramatically more efficient through use of nano-fabricated surfaces and devices.

As a result of the development of new analytical tools capable of probing at the nanometre scale, it is becoming increasingly possible to characterise the chemical and mechanical properties of cells and to measure properties of single molecules (biomarkers). These capabilities have to be combined with microsystems and fabrication technologies to develop new devices in the field of in-vitro diagnostic, implanted devices and medical embedded devices for individualised care. In this context, the ETPN objective along with MNBS partners is to concentrate efforts of the nanotechnology community for developing new innovating devices. Breakthrough technologies are expected in terms of automation of complex sample preparation, of development of biocompatible implanted devices or in bio

[13] **Micro-Nano-Bio Systems (MNBS)** are integrated Smart Systems, engineered and enabled at the micro or nano scale that depend upon, contain or interact with biochemical processes, bio materials or living organisms.

sensors with the ability to multiplex massively the detection of a large number of biomarkers species at the same time.

Proposed funding mechanism for implementation of cross-KETs collaboration under Horizon 2020:

- Collaborative Research Projects (Integrated projects and/or STREP)
- Cross-funding between DG Connect and DG RTD

4.3 Nanomedicine in *Excellence Science*: Education and validation of excellent technologies

The ETPN has managed interdisciplinary discussions with leading research institutions across Europe several times, leading to the definition of Nanomedicine Strategic Research Priorities for diagnostic, therapeutic and regenerative medical applications. The resulting Strategic Research and Innovation Agenda encompasses the state of the art of nanotechnologies for medical applications and shapes the future cutting edge research topics leading to Europe's Excellence in nanomedical research.

The ETPN contributes actively to the bottom-up approach applied within the Excellence Science pillar by suggesting through its SRIA new topics for world class research and an orientation for researchers willing to apply for a grant. The ETPN SRIA is updated on a regular basis with a wide contribution of internal and external experts throughout Europe. Furthermore the SRIA and the ETPN experts can be considered as an interesting decision-making support while evaluating proposals.

An effective translation of research into marketable products will be achieved by optimising the interfaces between the different phases as well as between the different stakeholders of the value chain. One main option to address this issue is to cross-fertilise knowledge by introducing for instance international graduate programs and interdisciplinary course elements on translation/innovation in undergraduate courses in Europe as well as training courses for academic actors or SME staff on how to de-risk R&D and to add value for stakeholders out of the interfaces in the value chain.

In order to fill in the pipeline of new products and early stage research, a continuous flow of new discovery projects should be funded as they have been under FP7 but with a different evaluation perspective taken into account their future translational potential. However the funding of these discovery projects should be carried out under a new and dedicated SME Instrument (SBIR-like funding scheme) where research consortia should demonstrate after 1-2 years the novelty and the high translational capacity of their concept[14].

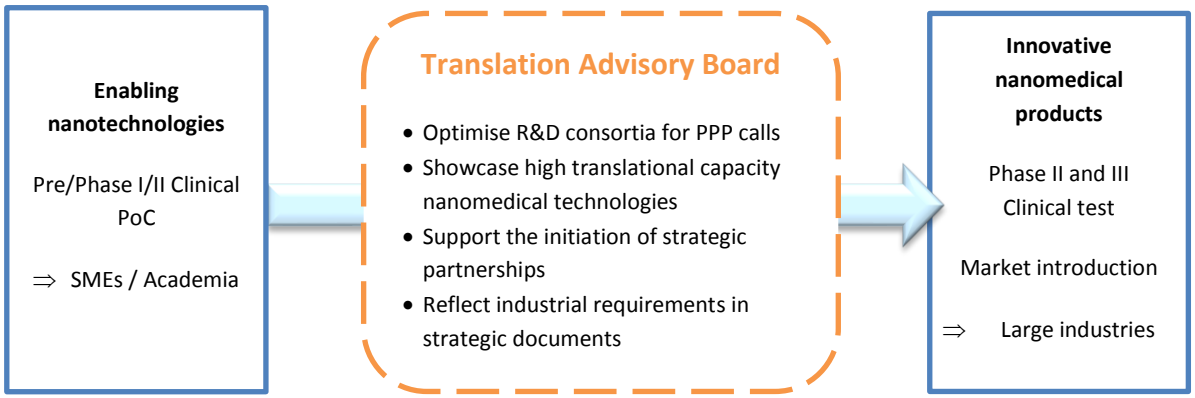
Proposed funding mechanism for implementation of Nanomedicine in *Excellence Science:*

- Funding of discovery projects under a dedicated SME Instrument (SBIR-like funding scheme). **Estimated budget/EC contribution for a 2-steps process until 2020: 212 Mio. €**
- Validation/certification of Individual research proposals (Tender for ERC)
- Marie Curie Actions

[14] http://grants.nih.gov/grants/funding/sbir.htm

4.4 Nanomedicine in *Societal Challenges*: support and contribution to PPPs on Health

For nanomedical products the *Societal Challenges* pillar of Horizon 2020 provides a route to the market, consisting of building up Public Private Partnerships for specific applicative areas. As described previously, such link to the private sector, especially to large companies (pharmaceutical, diagnostic/imaging), is a crucial step in the nanomedicine value chain for R&D actors such as academia and SMEs. It defines whether a novel enabling nanotechnology developed for medical application can meet the patients' and markets' needs, becoming thus an innovative medical technology.



Contribution of nanomedicine to Societal Challenges

Currently the nanomedicine community is mostly composed of academic institutions and SMEs conducting research, pre-clinical development and clinical trials in phase I. Their goal generally is to transfer their products to large companies for final clinical validation, regulatory approval and commercialisation, because generally they don't have the resources and time to commercialise their innovations in a regulated sector.

For instance the biopharmaceutical company Amgen as well as the top pharmaceutical industries AstraZeneca and Pfizer recently entered deals with BIND Biosciences (US), potentially worth more than 180 Mio. $ each to develop and market a kinase inhibitor for treating solid tumours based on nanomedicine technology[15] [16] [17]. Last December, CytImmune and AstraZeneca have also entered into an agreement to study the feasibility of a new cancer nanomedicine that will bind an oncology compound from AstraZeneca to CytImmune's CYT-6091 nanomedicine platform[18].

The ETPN hence strives for the leveraging of nanomedical technologies and for their implementation in medical products through the optimisation of the interface with large pharmaceutical and diagnostic companies. An intensive and continuous feedback from end-users / stakeholders close to

[15] Joe Barber, January 8th, 2013,Business Wire, Boston Business Journal

[16] April 22nd, 2013, AstraZeneca website: www.astrazeneca.com/Media/Press-releases/Article/20130422--astrazeneca-and-bind-therapeutics-collaboration-cancer-nanomedicine

[17] Drew Armstrong & Meg Tirrell, April 3rd, 2013, Bloomberg: www.bloomberg.com/news/2013-04-03/pfizer-to-pay-bind-up-to-210-million-in-nanotechnology-deal.html

[18] December 27th, 2012, AstraZeneca website: www.astrazeneca.com/Research/news/Article/27122012--cytimmune-and-astrazeneca-to-research-potential

the market is also essential to drive research and development and to define Strategic Research Priorities in an efficient way. Therefore, although the nanomedicine community cannot apply for its own PPP model it can actively contribute to future PPPs on Health by:

- Suggesting research topics for the SRA of established PPPs, in particular related to Health,
- Showcasing nanomedical technologies with high translational capacity to large companies,
- Participating in R&D consortia for PPP calls for projects.

To achieve this, the Nanomedicine Translation Advisory Board described in the previous section shall be in close contact with the PPPs steering committees and support them actively with the selection of promising research topics and technologies in order to optimise R&D consortia for PPP calls for projects. The Translation Advisory Board will thus be able to provide the nanomedicine community with advice on translational opportunities and support the R&D actors with the initiation of strategic partnerships with large industrial organisations. In addition the Advisory Board will reflect end-users and markets requirements when updating strategic documents as SRIA or roadmaps. Such negotiations on possible interactions already took place between ETPN and EFPIA as leader of PPP on Health.

5. Summary of ETPN Contributions for optimising the translation chain via *Horizon 2020*

The complexity of stakeholders and the global competition in Nanomedicine require a major effort at the European level in order to optimise public funding and maximise the return for the European economy. They have to address the described need for supporting activities to form competitive partnerships in Nanomedicine in Europe, as well as to exploit the proposed Nanomedicine-related translational structures in Europe in a focused way. Professional support by national and European authorities and funding bodies of the activities proposed in this White Paper is of utmost importance to create a competitive environment with respect to quality, time, risk assessment, early translational funding support, etc. within Europe to be competitive with other regions of the world.

5.1 ETPN as strategic partner to coordinate and support Nanomedicine in H2020

Based on a combination of a top-down scheme with a bottom-up follow-up and the existing body of strategic concepts and information provided by a comprehensive partnership covering the whole Nanomedicine value chain at hand, the ETP Nanomedicine is ready to further elaborate and extend the proposed actions under Horizon 2020 to sustainably establish "accelerated" pathways on how to bring European research and manufactured products into the market. This will make nanomedicine an important contributor to the future European healthcare system, providing improved treatments for patients, tackling societal challenges such as the ageing population, and impacting the European economy through an improved and cost-effective health care system.

In this regard the core activities of the ETP Nanomedicine in Horizon 2020 are to:

- Elaborate strategic documents, including the identification of skills requirements and of regulatory barriers,
- Encourage industry participation, help widen participation, build capacities,
- Provide networking opportunities to stakeholders, facilitate the formation of partnerships,
- Identify opportunities for international cooperation,

Proposed funding mechanism for supporting the ETP Nanomedicine under Horizon 2020*:*

- Supporting activities to structure the European nanomedicine sector, i.e. Strategic Research Priorities, SRIA updates, foresight, and ETPN operations.
  Estimated budget/EC contribution until 2020: 20.4 Mio €
  - Coordination and Support Actions (**CSA)**
- Supporting activities towards the European nanomedicine community, including Education & training, dissemination, scientific events.
  Estimated budget/EC contribution until 2020: 48 Mio. €
  - Coordination and Support Actions (**CSA)**
  - **Marie-Curie Actions**
- Supporting activities beyond the European nanomedicine community, including international co-operations and coordination activities with industrial organisations, Public information and awareness.
  Estimated budget/EC contribution until 2020: 26.5 Mio. €
  - Coordination and Support Actions (**CSA)**

5.2 Ethical and Societal issues

The ETPN is well aware of the importance to address the ethical issues being raised by nanomedicine. For example, as nanomedicines open new potential ways of body performance resulting in enhancement rather than reconstruction of lost or missing body functionalities, there is a need to establish ethical vigilance and awareness, especially regarding the open debate on *Human limits.*

As the field is answering to major current and future societal challenges, addressing societal and ethical issues in a broad responsible research and innovation concept shall not be an option but must be explicitly taken into account in future proposals.

The ETPN will find ways under Horizon 2020 to initiate sustainable and dedicated actions in this regard, including:

- Improved public perception of nanomedicine and making the public aware of the benefits of nanomedicine,
- Greater public involvement in nanomedicine directives and more public consultation and dialogue (such as in EPSRC "nanotechnology to medicine and healthcare grand challenge programme“),
- Clear regulatory guidelines for nanomedicines,

- Increased information about ethical issues in nanomedicine education programmes of schools and Universities,
- Inclusion of societal experts and representatives in the selection of projects (in the TAB in particular),
- Encouraged dialogue between and inside related laboratories and between all stakeholders for a responsible innovation. An ethical nanomedicine chart could be pushed forward.

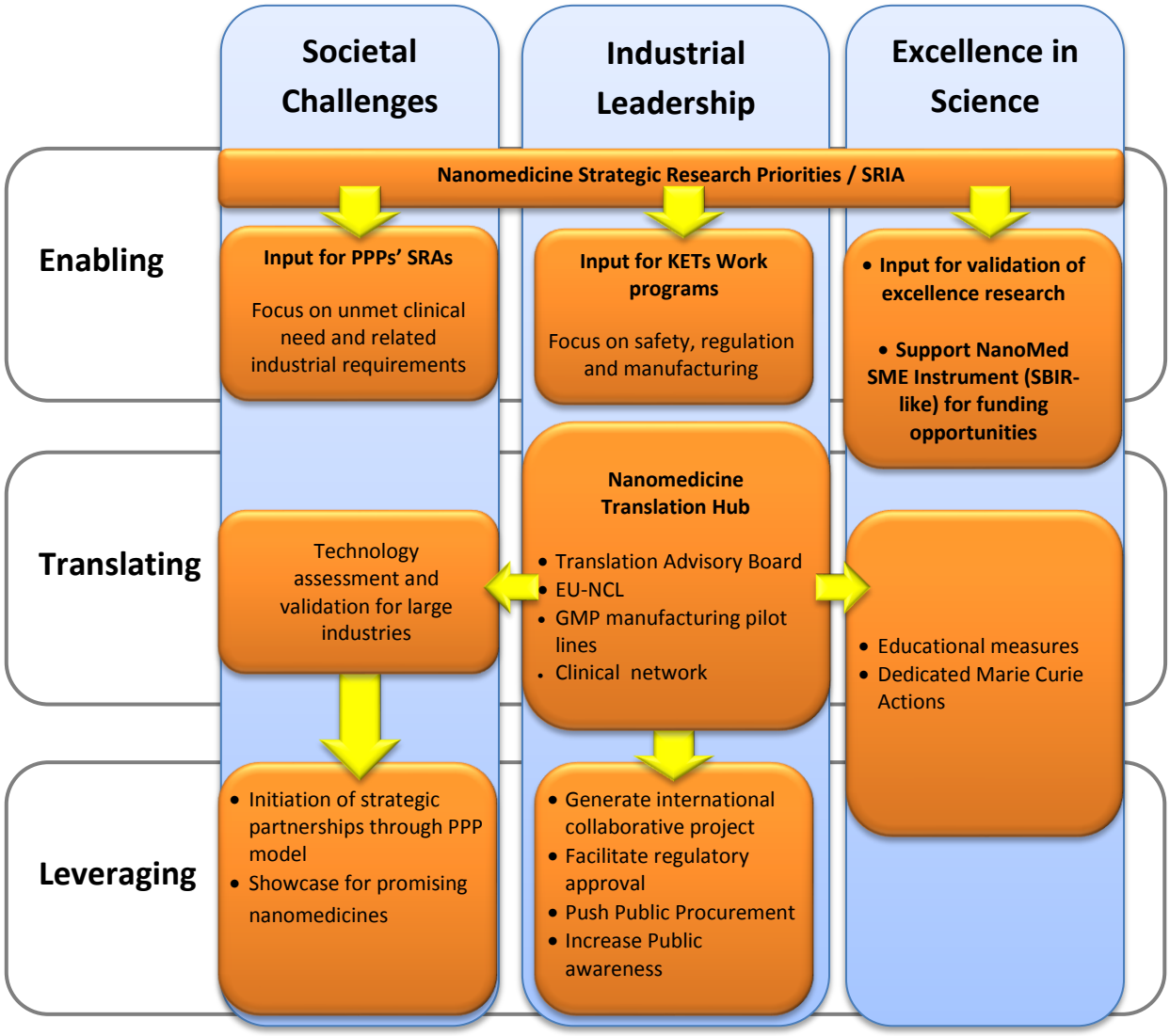
Proposed funding mechanism and budget*:*

- Screening of EU and national projects in the middle and at the end of FP8 for potential and future ethical and social issues involving experts from medicine, nanotechnology, social science, ethics, healthcare and social security systems.
- **Estimated budget/EC contribution until 2020: 10 Mio €**
  - Coordination and Support Actions (**CSA)**

You have the possibility to endorse this White Paper by using the dedicated form on:

www.etp-nanomedicine.eu/public/special-issues/nanomedicine-white-paper-2013-endorsement

5.3 Overview: Contribution of Nanomedicine to Horizon 2020



Cross integration of ETPN concept for an effective translation with Horizon 2020 priorities

List of Abbreviations:

BBB:	Blood Brain Barrier
CMOs:	Contract Manufacturing Organisations
CROs:	Contract Research Organisations
CSA:	Coordination and Support Action
EATRIS:	European Advanced Translational Infrastructure in Medicine
EC:	European Commission
EMA:	European Medicines Agency
EPoSS:	European Platform on Smart Systems integration
ERDE:	European Regional Development Fund
ESFRI:	European Strategy Forum on Research Infrastructures
ETPN:	European Technology Platform on Nanomedicine
FDA:	US Food and Drug Administration
FP 6-7:	Framework Program 6-7
GCP:	Good Clinical Practice
GMP:	Good Manufacturing Practice
I^3:	Integrated Infrastructure Initiative
ICH:	International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use
KET:	Key Enabling Technology
(US-EU) NCL:	(US-EU) National Characterisation Laboratory
OI:	Open Innovation
PoC:	Proof of Concept
PPP:	Public-Private Partnership
SBIR:	Small Business Innovation Research
SME:	Small and Medium Enterprise
SR (I) A:	Strategic Research (and Innovation) Agenda
TAB:	Translation Advisory Board

6. Annexes

6.1 Proposition of EC Contribution for the implementation of Nanomedicine in Horizon 2020

(Mio. €)	2014	2015	2016	2017	2
Infrastructures & Pilot lines					
EU-NCL (investments)	10	12	10	2	
EU-NCL (support to projects)	6	6	5	5	
GMP nanomanufacturing pilot line (support to projects)	8	8	10	10	
EU-NCL/GMP Pilot Line management	2	2.5	3	3	
Coordination with US-NCL	0.7	0.7	0.5	0.5	
Coordination with EMA, US-FDA	0.5	0.5	0.5	0.5	
Translation of projects to the clinic					
Calls for early clinical Proof of Concept	20	24	30	30	
Translation committee (operation)	1	1.5	2	2.5	
Validation of clinical centres; QA and GC	1	2	3	3	
Discovery program (SME Instrument-SBIR like programs)					
Step 1 (feasibility stage)	8	11	13	15	
Step 2 (prototyping)	8	12	16	20	
ETPN					
Strategic research agenda, foresight	0.2	0.2	0.2	0.2	
Education & training	3	3.5	5	5	
Public information, ethical and societal issues	2	2.5	3	3	
Dissemination, scientific events	1	1.5	2	3	
Operation of ETPN	2	2	3	3	
International cooperation					
Coordination with industrial unions	1	1	1	1	
TOTAL	**74.4**	**90.9**	**107.2**	**106.7**	

6.2 Key EC Directorates for the implementation of Nanomedicine in Horizon 2020

Due to the high trans-disciplinary nature of nanomedicine, an efficient coordination of the EU funding programmes is required for success:

- **DG RTD:**
  - **Directorate Health**:
    - Defines medical challenges and priority diseases
    - Funds successful nanomedicine developments mostly from the clinical testing phase, starting from a rather mature KETs basis
  - **Directorate Industrial Technologies** (NMP unit):
    - Funds cross-cutting-KETs research projects providing enabling technological tools and solutions applicable to medicine, mostly in the pre-clinical and early clinical research phase (TRL from 4 to 7)
    - Provides funding for GMP scale-up Pilot Lines (TRL from 6 to 7)

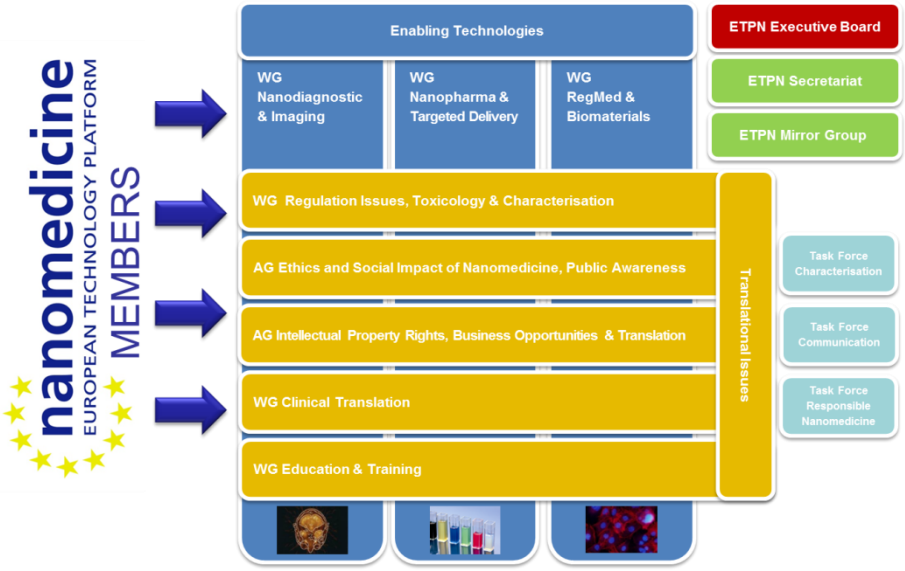
- **Directorate ERA** (Research Infrastructure unit) provides funding for integrating activities of EU NCL together with **Directorate International Cooperation** (US-EU NCL collaboration), in complement to the funding from Member States
- **Directorate SME, for the setting-up of new SME funding instrument under Horizon 2020**
- **Cross-Directorates:** NMP/Health to provide funding for TAB setting-up and activities

- **DG CONNECT** provides funding for cross-KETS actions and partnerships (e.g. Nanomedicine and Micro-Nano- Medical Systems, multi-KETs GMP Pilot Lines)

- **DG SANCO** (Health and Consumers) provides funding for coordination efforts with EMA/FDA and for raising public awareness in the sector.

6.3 About the European Technology Platform on Nanomedicine

The ETP Nanomedicine has been established in 2006 as a joint venture of the European Commission and CEOs of large industrial companies such as Philips, Siemens and UCB, SMEs and academic research institutions to investigate and advance joint activities in the area of nanotechnology in medicine. The ETPN supports its members in coordinating their joint research efforts and improving communication amongst the members as well as towards the EC and the EU Member States. The ETPN counts today over than 120 active members from industry, academia, healthcare providers and public authorities, organised in thematic Working Groups covering scientific areas (Nanodiagnostics, Nanopharmaceutics and Regenerative Medicine) and horizontal issues (Regulation, Ethical and Societal issues, IPR). Furthermore the ETPN disposes of a Mirror Group and of an Executive Board, a smaller executive and operational representation of the platform, set up in the interest of dynamic and efficient management and internal communication. The Mirror Group is currently been enlarged and will represent more than 20 Member States and Associated Countries.



ETPN Structure and Governance (under revision)

Since 2005 the ETPN published a number of strategic documents outlining the needs and roadmaps for nanomedicine research in Europe. Furthermore the ETPN contributed to set up numerous

European funded projects providing a first impression of the conditions for a suitable social and economic environment and the structural requirements for an efficient translation of R&D results into innovative Nanomedicines.

ETPN Strategic documents available on: www.etp-nanomedicine.eu/public/press-documents/publications/etpn-publications

6.4 About NANOMED2020

NANOMED2020 is a Coordination and Support Action under the FP7-Health which started in September 2012 for a total duration of 18 months.

The NANOMED2020 Coordination and Support Action under the FP7-Health aims at delivering **concrete recommendations** to the European Commission to push forward the field of nanomedicine under Horizon 2020. Amongst other activities, NANOMED2020 is currently focusing on:

- **Federating the nanomedicine community** and establishing a European landscape via mapping all relevant actors, projects and infrastructures.
- **Identifying the key bottlenecks of the value chain** to focus on to leverage the translational possibilities of the development process and to bring in the end more products onto the market.

This project involves seven partners across Europe including the ETPN Secretariat but also the CLINAM foundation (Switzerland), the National Institute of Health Carlos III (Spain), Bioanalytik-muenster e.V (Germany), Nanobiotix SA (France), the Fondazione Don Carlo Gnocchi ONLUS (Italy), and SINTEF (Norway).

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