



## NANOMED2020 – Project summary

### NANOMED2020 Summary

Successful translation of research results into medical products has been identified to be one of the major challenges in the innovative area of nanomedicine. Major hurdles were identified between the Proof of Concept (PoC) - TRL4 - and the clinical PoC (TRL7), along technical, regulatory, clinical and business issues. Striving to overcome these bottlenecks, NANOMED2020 partners published in June 2013 the White Paper entitled “*Contribution of Nanomedicine to Horizon 2020*”<sup>1</sup>, laying hereby the groundwork for the establishment of a Translation Hub to support the creation of a coherent and strong SME based supply chain for innovative nanomedicines as a profitable industrial sector in Europe. To be implemented under Horizon2020, this Translation Hub has been designed as an umbrella for a set of complementary actions and infrastructures encompassing:

- a dedicated Nanomedicine Translation Advisory Board with experienced industrial experts to select, guide and push forward the best translatable concepts,
- a European Nano-Characterisation Laboratory for the full characterisation of nanomaterials intended for medical use before their regulatory submission,
- GMP manufacturing pilot lines to manufacture batches of nanomedical materials for validation in clinical trials,
- a funding instrument dedicated to SMEs and taking into account the specificities of the nanomedical value chain.

Accelerating the nanomedicine development process must go hand in hand with the federation of its community in order to ensure a sustainable and structured nanomedicine landscape. Within NANOMED2020, a series of initiatives were launched in this regard, notably with the release of the European Nanomedicine Map, displaying on a single chart 1,500 actors involved in the field, providing detailed and easily accessible information as well as opportunities for new partnerships. This tool, welcome by the community contributes to reduce the fragmentation of the community.

In addition, NANOMED2020 contributed to two of the main European events in the field of nanomedicine, the European Summit for clinical nanomedicine (CLINAM 2013 - 500 participants) and the ETP Nanomedicine Annual Event 2013 (150 participants), with unprecedented international contacts, notably with the US, collaborations initiated and partnerships and dissemination activities.

Raising awareness of the field in and beyond the community has become one main objective of the project, with attendances and presentations on numerous community events and with promotional and educative material such as a 2-minute animated movie. The first Nanomedicine Award during BIO-Europe 2013, the largest biotech event in Europe provided also NANOMED2020 partners a unique opportunity of showcasing innovative nanomedicines towards the pharmaceutical industry, a crucial stakeholder in the final development steps of products.

Furthermore, the “Nano World Cancer Day” concept has been further developed in NANOMED2020 in 2013 and 2014. This annual pan-European event promoting the applications of nanomedicine against cancer in the framework of the World Cancer Day (Feb 4<sup>th</sup>) has proved to be a crucial instrument to reach a large public by targeting the press and by multiplying the locations in EU countries (3 countries in 2013, 13 in 2014) addressing thus international, national and local media.

---

<sup>1</sup> White Paper: Recommendations from the Nanomedicine Community, 06/2013: [www.etp-nanomedicine.eu](http://www.etp-nanomedicine.eu)

Finally, NANOMED2020 and EuroNanoMed ERA-NET paved the way towards harmonized strategic policies, notably by launching the process to update the Nanomedicine SRIA expected in 2014.

This project involved 7 partners including the ETPN Secretariat, CLINAM, the Institute of Health Carlos III, Bioanalytik-Muenster e.V, Nanobiotix SA, the Don Gnocchi Foundation, and SINTEF.

## **Context**

Nanotechnology applied to medical applications – usually called Nanomedicine – is one of the most promising out of the six Key Enabling Technologies (KETs), even in terms of expected compound annual rate, individuated in the Final Report from the High-Level Group on KETs (EU Commission, June 2011) and is one of the most important emerging areas of health research expected to achieve earlier and more precise, individual diagnosis, better targeted therapies and better therapy monitoring. Thus, Nanomedicine is understood to be THE enabling instrument for personalised, targeted and regenerative medicine by delivering the next level of new drugs, treatments and implantable devices to clinicians and patients. Beyond that, Nanomedicine provides important new tools to deal with the grand challenge of an ageing population and is thought to be instrumental for improved and cost effective health-care, one crucial factor for making medicines and treatments available and affordable to all. To be able to excel in Nanomedicine and by that to meet the high expectations of society in terms of health-care quality and effectiveness of treatments, Europe needs to federate key players from different academic fields such as biology, physics, chemistry and engineering on one side and physicians and clinicians on the other side with different industries such as pharma or medical device companies. In addition, regulatory agencies at the European and international level have to be involved to bring new innovations to the patient quickly in this highly regulated area. This complexity of stakeholders and the global competition in Nanomedicine require a strong effort at the European level, which needs to be supported by the national and European authorities and funding bodies.

The Nanomedicine community in Europe suffers from fragmentation into many groups of subcritical size, both geographically scattered and / or academic, industry and/or clinical/public health based. These groups do not have enough gravity to exploit the possibilities of nanotechnology in health in its full extent. Their deeper participation of the biomedical and health sectors are critical for creating a comprehensive and inter- and multidisciplinary effort in Nanomedicine and its consequences to foster translation and innovation. Therefore, there is a strong need for supporting activities to form strong partnerships in Nanomedicine in Europe, as well as to exploit the Nanomedicine-related infrastructure in Europe in a focused way.

In the last years, unprecedented efforts of consolidating the area of Nanomedicine research have been undertaken with the major organisations in the Nanomedicine field in Europe joining forces; namely the European Technology Platform on Nanomedicine (ETPN), the European Foundation for Clinical Nanomedicine (CLINAM), the European Medicines Agency (EMA), the European Science Foundation (ESF) and now EuroBioForum. Together with the EuroNanoMed ERA-NET as funding initiative this brought together all relevant stakeholders from industry, academia, clinic and public authorities to define a common view on Nanomedicine. As a first result of the discussions amongst these stakeholders some initial recommendations on how to organise the Nanomedicine community and how to overcome the barriers to Nanomedicine translation were formulated.

Professional support of such activities proposed in this supporting action is of out-most importance to create a competitive environment with respect to quality, time, risk assessment, early translation funding support, etc. within Europe to be competitive with other regions of the world.

Based on the existing body of strategic concepts and information and having a comprehensive partnership covering the whole Nanomedicine value chain at hand, the project partners further elaborated and extended the necessary recommendations.

Obviously, for implementation of the requirements detailed activities and measures had to be defined. Also the rules and conditions under which new collaboration and dissemination structures in new innovative partnerships can be implemented had to be detailed and worked on. Accordingly, the objectives of this project were:

1. Develop the Nanomedicine community by federating all key stakeholders with ETPN and CLINAM as nucleation points.
2. Together with all stakeholders identify and assess existing research and innovation resources, including Nanomedicine-related infrastructure as well as gaps and needs for successful implementation of nanotechnologies in medicine in close relationship to the clinical and Public Health stakeholders.
3. Harmonise and specify existing strategic research agendas and technical roadmaps.
4. Develop new models for improved translation in Nanomedicine based on identified gaps and needs
5. Establish working groups on today's societal challenges and major issues
6. Initiate international collaborations in the Nanomedicine area, especially coordinate international / worldwide regulation of Nanomedicine products.
7. Improve dissemination of research results and facilitate translation by cataloguing research results of on-going and past research projects for later use in clinics and industry.

Based on the above objectives the expected output of this supporting action aimed to be a strong, established partnership of relevant stakeholders in identified key areas of Nanomedicine with novel concepts for translation of nanomedical innovations into clinical practice and efficient and transparent communication channels. This made Nanomedicine an important contributor to the future European healthcare system with a beneficial impact on improved treatment for patients in general and societal challenges such as ageing population, in particular, as well as an economic impact through an improved and cost-effective health care.

Overall, NANOMED2020 Coordination and Support Action under the FP7-Health aimed at delivering concrete recommendations to the European Commission to install Nanomedicine as a main European research topic in the next framework program and to push forward the field towards a profitable industrial sector in Europe.