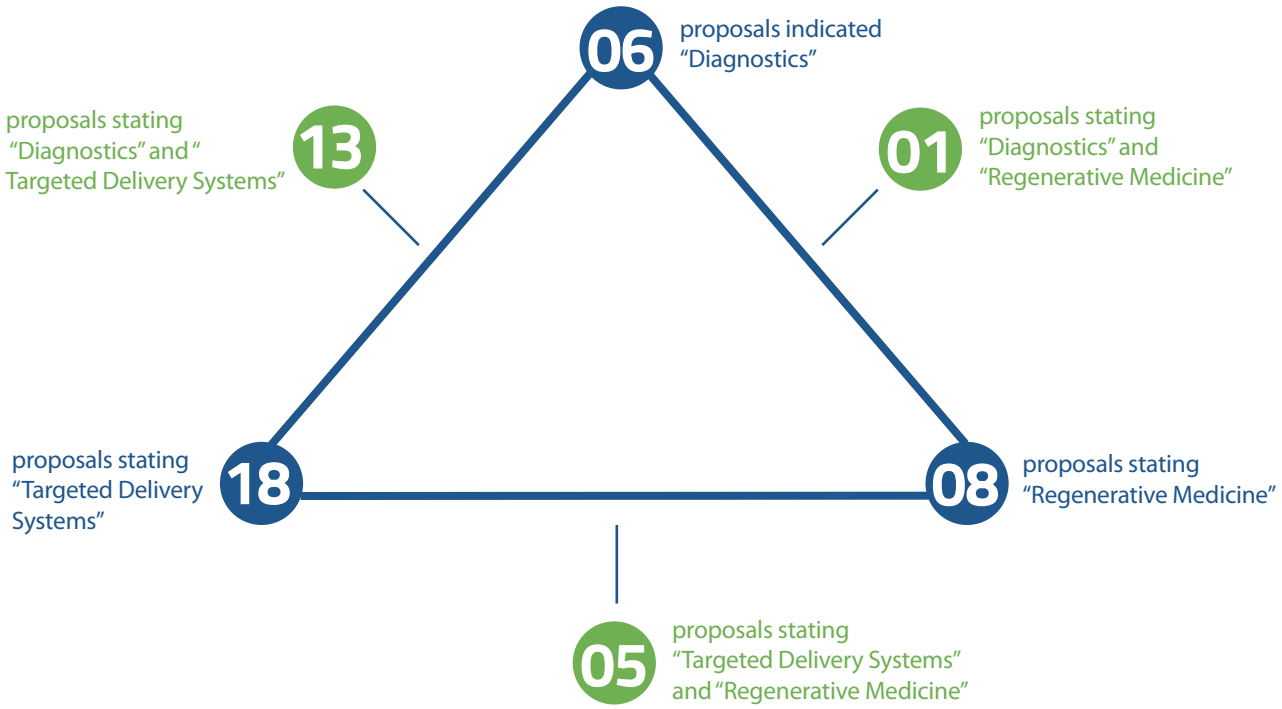
NEWSLETTER 2

EuroNanoMed II

Content

EuroNanoMed 5th Call for Proposals now closed

A total of 266 partners from 21 countries / regions submitted proposals. Evaluation of the proposals will be conducted in the coming months, and research is anticipated to commence at the beginning of 2015. Many of the 51 proposals stated to address more than one topic:



2. Workshop on regulatory affairs

The goal of the workshop was to provide information regarding regulatory, IP and ethical issues to the EuroNanoMed (ENM) - funded projects. It was demonstrated that most cases of translational failure (despite successful proof-of-concept) can be attributed to a failure to sufficiently take regulatory issues into account. Regulatory issues must be taken into account at an early stage of a research project to raise the chance of translatability and awareness of these and other translational issues, such as IP protection, is crucial.

Workshop on regulatory issues in Nanomedince Dusseldorf, Germany

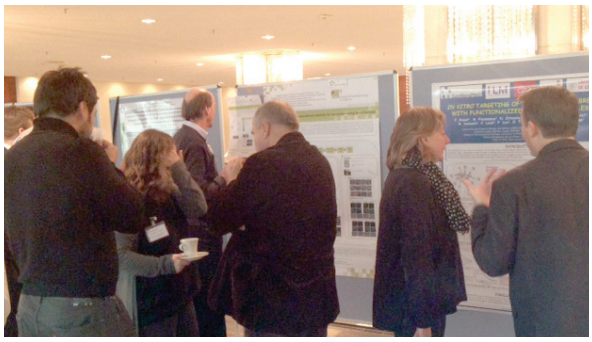
Development of new imaging agents:

The development of a new imaging agent is long, costly, and extremely challenging. It is crucial to select the agent and indications carefully.

- Target unmet medical needs.
- Focus on a single promising indication for initial development. Avoid "whole body" indication.
- Theranostics have tremendous potential but are challenging to develop and commercialise, since both diagnostic and therapeutic efficacy must be demonstrated.
- Nanotechnology is a promising platform for the development of new imaging agents, but should be used sparingly. Do not try to do with nano what is already done well without it.
- Be aware of developmental and regulatory issues as early as possible in the research/conception phase. Not all brilliant concepts are given to commercialisation.

3. Review seminar

At this seminar 42 participants, made 16 oral presentations and 20 posters reviewing the progress of projects funded in 2009, 2010 and 2011 calls. The projects were represented by the participating scientists, a majority of which (56%) by their respective coordinators. Three Peer Review Panel (PRP) members attended the meeting: Dr. Frank Barry (call 2009),
Dr. Nesrin Hasirci (call 2010) and Dr. Philippe Bourrinet
(call 2011). The three PRP members agreed that the ENM calls attracted the strongest elements in nanotechnology across Europe and that the net delivery of findings was very strong. Emerging technologies for delivery, imaging and regenerative medicine are engendered from ENM-funded research.



Status review seminar of the funded projects
Dusseldorf, Germany

IP Issues in Research Collaborations:

Key points should be settled at an early stage of any collaboration. The later the phase and more successful the project, the more difficult it is to get the parties to compromise.

- Who will own (as opposed to be inventor of) future joint inventions?
- Will all partners be entitled to use the technology protected by previously filed IP rights?
- Who is entitled to file the application, choose and instruct attorneys, decide in which jurisdictions to file, etc. ?
- Who will pay for prosecution of the IP rights, legal disputes, etc. ?
- If commercialization is successful, how will the proceeds be split between the partners?

3.1 Interview with Prof. Dr. Nesrin Hasirci

Middle East Technical University, Faculty of Arts and Sciences, Chemistry Department
Ankara, Turkey, member of the EuroNanoMed PRP

You were one of the PRP members attending the latest status seminar held in Dusseldorf, the final seminar for the JTC-2009 call. What is your general impression of the projects?

The main purpose of the EuroNanoMed is to translate Nanomedical research from the lab to the bedside and in so doing find solutions to the health problems affecting patients. This is not an easy process. Even when the results of a study are very impressive, there is still a long way to go. Drugs and medical devices have to be approved by the authorities and there are many rules and regulations that must be satisfied. What I have observed in Dusseldorf was that the academic side of the projects was very strong. Novel research was carried out and many publications and conference presentations were made. On the other hand, however, prototype design, the conversion of findings to products and to patient care was still somewhat slow or lacking.

> "Novel research was carried out and many publications and conference presentations were made"

What do you like best about being a EuroNanoMed PRP member and what do you dislike?

Being a PRP member is a prestigious position with great responsibility. I examined dozens of proposals and listened to hundreds of presentations over the past five years. What I like most is getting an overview about the state of nanomedicine in Europe and learning about the expertise of the teams from different countries.
It is hard to pinpoint the parts I dislike.

What message do you have for the JTC-2009 project coordinators?

I congratulate them all for their novel studies. I have seen very innovative research results. On the other hand, I also noticed that some studies encountered unexpected problems and some deviated from their initial, proposed forms. My message would be that the coordinators should be able to foresee potential problems as much as possible during the preparation of their proposals and should be prepared to solve them quickly by switching to the proverbial "Plan B". In addition, they should conduct the research using the methods, techniques and studies they originally proposed. Last, but certainly not the least, the most important point is that they should take the steps necessary to translate their research findings with an eye to reaching patients.

"Solving crucial health problems is possible with 'NanoMed' research by translation of their results to patient care"

Do you have suggestions for the EuroNanoMed-funded scientists?

In order to accelerate the translation of their studies, researchers should seek guidance regarding regulation, standards of good manufacturing, laboratory and clinical practice, (GMP, GLP, GCP), and intellectual property rights (IPR). Actually, it is better when they possess this knowledge, and are aware of the difficulties, prior to submitting their proposals.

Is an organization like EuroNanoMed important to have?

Yes, definitely it is important. As you know, the average life span is increasing and people wish to live healthy and happy lives. Society needs efficient diagnostics and effective therapies which do not entail damaging side effects. Solving crucial health problems is possible with 'NanoMed' research by translation of their results to patient care. EuroNanoMed highlights this need and brings the related members together for a common goal. Nanotechnology and its use in the diagnosis and treatment of disease is one of the key issues of 21st century medicine. Quality, efficiency and safety are very important for each product. Many countries, such as the USA, Japan, China and Singapore are conducting impressive studies and introducing many novel biomedical products. This means that Europe faces stiff competition. I hope that EuroNanoMed helps European scientists and companies remain in the forefront and maybe even lead the development of nanomedicine.

Regulatory issues regarding device-drug combinations tips!

Common Issues	Tips
Unrealistic project plans	Set realistic expectations, consult with people with experience
Quality of medicinal product dossier submission	Use extensive guidance and common technical format
Medicinal substance supply	Make medicinal substance source an early and critical decision
Technical gaps	Use medicinal product guidance

3.2 Interview with Dr. Ling Peng

Centre Interdisciplinaire de Nanoscience de Marseille, CNRS, France
former coordinator of DENANORNA

The project you coordinated, DENANORNA was funded within the EuroNanoMed JTC-2009. What did the project aim to achieve in terms of patient health and new technology and in what way was it innovative or unique?

Our project aimed to apply nanotechnology to engineer nanovectors for targeted drug delivery in RNAi therapeutic applications, with a view to providing novel solutions for the treatment of cancer and HIV infection. It incorporated two new technologies. The first is RNAi technology for generating specific RNAi therapeutics to treat specific diseases. The second is the development of dendrimer platforms for engineering nanocarriers, which effectively target and deliver the RNAi therapeutics to the right place to treat the right disease.

The first novel aspect of this project is the use of RNAi technology, a Nobel Prize-winning discovery, to generate powerful therapeutics. In the RNAi process, small interfering RNA (siRNA) molecules break down the target mRNA in a sequence-specific manner and impede the related gene expression. The process is applicable to any target gene with a known sequence. The potential for siRNA to efficiently downregulate specific genes brings new hope in the treatment of incurable diseases and diseases given to drug resistance, ushering in a new era of pharmaceutical science which may revolutionize medicine.

The second novel aspect of this project is the application of dendrimer nanotechnology. Dendrimers are a special class of polymers with a well-defined spherical architecture bearing unique radiating branching units. Their dimensions range between of 1-10 nanometers and serve as ideal drug delivery systems. A dendrimer can carry a high drug payload confined to a nano-sized volume. Their multivalency and cooperativity in drug transport and in the optimization of drug concentration and release potentially improves the efficacy of pharmacological treatment by providing a high local concentration of drugs directly to target cells.

> "Although from different backgrounds and countries, all partners work together to make use of their complementary expertise"

What are the main achievements of your project in practice?

The primary achievement of our project is that we have validated our proof-of-concept regarding the dendrimer nanovectors for targeted delivery of RNAi therapeutics in disease models such as prostate, liver and ovarian cancers and HIV infection. One of our dendrimers is scheduled for clinical trials for the treatment of cancer once the GMP product becomes available.

"multinational collaboration allows us to benefit from the diverse resources available to undertake research and achieve the final objective"

Is there any new or future collaboration "conceived" from your project?

Based on the results obtained from this project, we have developed new collaborations with other EU members, which are not included in this EuroNanoMed program as well as with researchers in other countries such as the USA and China. These collaborations have turned out to be very successful and fruitful, and we want to continue them because of the complementary expertise, mutual understanding and trust developed through working towards the common goal of discovering new therapeutic solutions in the treatment of diseases. We are trying to organize new EU and intercontinental collaborative projects.

Can you describe your personal experience as the coordinator of DENANORNA?

It was a really fantastic experience and extraordinary pleasure for me to coordinate this project. Although from different backgrounds and countries, all partners work together to make use of their complementary expertise. They are extremely dynamic and share the same interest, enthusiasm and ambition to achieve the project goal.

Were there any tangible advantages to multinational collaboration ? Is it really important to support transnational research instead of focusing only on the national level? What did you gain from the collaboration besides funding?

First of all, the project evaluation is international, which allows the best project to be selected without bias. Secondly, multinational collaboration allows us to benefit from the diverse resources available to undertake research and achieve the final objective. Besides funding, we benefit of course from the scientific collaboration and results. We earn friendship and trust among us, which allows us to further collaboration at the European and international levels.

What is the message you would like to send to the EuroNanoMed partners including suggestions for the future?

Make Europe a really big family that works together through research under EU projects such as the EuroNanoMed program.

Do you think that EuroNanoMed is a valuable organization in terms of research funding? How can it improve?

Yes it is. It may be improved by removing the different restrictions fixed by the national funding agencies.

Do you wish to add anything?

I hope that EuroNanoMed continues! I

4. Upcoming Events

Coming soon: a workshop on Unique Ethical issues in Nanomedicine, December 3, 2014 Leonardo Club Hotel, Dead Sea, Israel. For details please visit our webpages: http://www.euronanomed.net/

Find us on:

http://www.euronanomed.net/

EuroNanoMed