Nanoformulation of biologicals

This call addresses nanoformulation of biologicals (like proteins, peptides, nucleic acids and enzymes). With an appropriate formulation the biologicals can be effectively transported through the relevant biological barriers to the targeted organs, tissues and cells.

Formulation of nanomedicines has in general been empirical and often produced in an amorphous or undefined structure, which produces regulatory and manufacturing control issues. The aim of the research is to achieve excellent quality control of the assembly by using self-assembling systems. The resulting processes should provide a high degree of control over the physico-chemical parameters like shape, size and chemical composition while incorporating non-Lipinski molecules such as nucleics acids, proteins or peptides. Characterisation aspects of the nanoformulations therefore have to be properly addressed. The benefit will be easier manufacturing and process control, as well as optimised nanoformulation of biologicals with tailored transport through biological barriers.

Projects will develop a nanoformulation of biomolecules to provide a solid pre-clinical proof of concept, address scale-up to the quantities needed for late pre-clinical and clinical study and prepare for future clinical testing. Partners will also have to describe how the various barriers for advancing their new therapy to clinical application will be overcome; they will especially take into account the medical regulatory requirements and the scale-up production for clinical study. As relevant, the proposed activities should address sex and gender specific aspects[[See definition of the 'gender dimension approach' in the introduction of this Work Programme part.]].

The clinical focus should be notably on age related diseases, neglected diseases and rare diseases or inflammatory diseases, but excluding cancer and infectious diseases.

Activities are expected to commence at Technology Readiness Levels 3 /4 and reach 5/6.

This topic is particularly suitable for SMEs.

The Commission considers that proposals requesting a contribution from the EU between EUR 5 and 6 million would allow this specific challenge to be addressed appropriately. Nonetheless, this does not preclude submission and selection of proposals requesting other amounts.

Many biomolecules (e.g. proteins, peptides, nucleic acid, enzymes), in opposition to classical small molecules, have demonstrated interesting therapeutic activities in vitro. However, they are too often not druggable because once in pre-clinical in vivo development, they show disappointing loss of efficacy and/or unacceptable toxicity. For example, a high in vitro efficacy of a therapeutic biomolecule can disappointedly become low in vivo, because the biomolecule is processed by the immune system or by enzymes of the host before reaching its targeted tissue. Nanotechnology represents a promising opportunity to overcome these drawbacks. Indeed, the formulation of nanocarriers containing biomolecules ('biologicals') for drug/vaccine delivery can greatly improve their in vivo efficacy and/or decrease their toxicity and provide the capability to cross biological barriers (e.g. intestinal, blood-brain barrier, nasal, ocular, pulmonary, skin).

- Developments of new solutions for the particularly needed delivery of biologicals;
- Radical improvement of therapy through the development of new nanoformulation solutions for the delivery of biologicals;
- Foster the translation of nanoformulation of biomolecules towards clinical development / application;
- Improvement of the competitiveness of the European healthcare industry through accelerated introduction of new nanotechnology enabled therapies;
- Improved understanding by academics and research organisations of the requirements of the pharmaceutical and medical devices industry and of medical regulators.

Proposals should include a business case and exploitation strategy, as outlined in the Introduction to the LEIT part of this Work Programme.

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