#### **Main Contact**

Patrick Boisseau CEA 17, rue des Martyrs 38054 Grenoble Cedex 9 France eMail: eu-ncl@ersprojects.eu

#### **Application Contact**

Simon BACONNIER CEA/Clinatec 17, rue des Martyrs 38054 Grenoble cedex France eMail: tna@euncl.eu



# Call for the characterisation of nanomedicines

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## The Context

The use of nanotechnology in healthcare promises new diagnostic opportunities and innovative therapeutic concepts that may help to tackle major medical challenges such as cancer, neurodegenerative diseases and resistance to antimicrobials.

## The Challenge

However, as the manufacturing process of nanomedicines is potentially complex, inconsistencies between batches must be carefully monitored before clinical applications can be considered. Furthermore, safety concerns related to the use of nanomaterials must be addressed as early as possible during product development.

The recently established European Nanomedicine Characterisation laboratory (EU-NCL)<sup>1</sup> will address these issues by providing the critical infrastructure and characterisation services required that are needed to analyse physical and chemical attributes, in vitro biological properties, and in vivo characteristics of emerging nanomedicines ready for translation and clinical trials.

## **The Service**

The EU-NCL services will be accessible to all organisations based in Europe and developing candidate nanomedicines, both prior to their submission to regulatory agencies for clinical trials approval and at a later stage for marketing authorisation. Product developers will benefit from a detailed and confidential characterisation data set that supports their decision making for further product development. EUNCL is <u>NOT</u> a CRO<sup>2</sup> performing GLP characterisation but a Research Infrastructure offering access to state of the art analytical assays for candidate nanomedicines. In the longer term, the scientific and regulatory communities will also profit from the EU-NCL database – containing results derived from highly standardised tests – that will allow a better understanding of how the physical and chemical properties of a material relate to their biological effects. Such a comprehensive database is essential to develop methods and tools that can help in early prediction of toxicological effects and bio-incompatibility.

#### The Focus

The EU-NCL characterisation platform is intended to assess all categories of nanomedicines developed in the EU. The submission of applications is an on-going process with two cutoff dates per year until 2018.



Full call details and further information on the application procedure can be found at *http://www.euncl.eu/working-with-us/call-for-proposals/*.

2. Contract Research Organisation

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