



# European Infrastructure to improve translation in nanomedicine

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EU innovation network, EMA, London

# Outline

- What is EU-NCL
- How does it work
- Where does it stands

# ID

- Research Infrastructure funded under H2020
  - « *Starting community* »
- Grant agreement
  - #654190
- Funding period
  - May 2015-April 2019
- EC Grant
  - € 4,995,181.00
- 8 partners



## EU-NCL

### European Nanomedicine Characterisation Laboratory

#### Our Mission is:

- To provide a trans-disciplinary testing infrastructure covering a comprehensive set of preclinical characterisation assays (physical, chemical, *in-vitro* and *in-vivo* biological testing) allowing researchers to fully comprehend the biodistribution, metabolism, pharmacokinetics, safety profiles and immunological effects of their Med-NPs.
- To foster the use and deployment of standard operating procedures (SOPs), benchmark materials, and quality management for the preclinical characterisation of Med-NPs (nanoparticles used for medical applications).

To promote inter-sectorial and inter-disciplinary communication among key drivers of innovation, especially between developers and regulatory agencies.

### Events where you meet EU-NCL

#### Biospain 2016 – 5th International Meeting on Biotechnology

28 - 30 September 2016, Bilbao, Spain

#### ETPN2016

12 - 14 October 2016, Heraklion, Greece

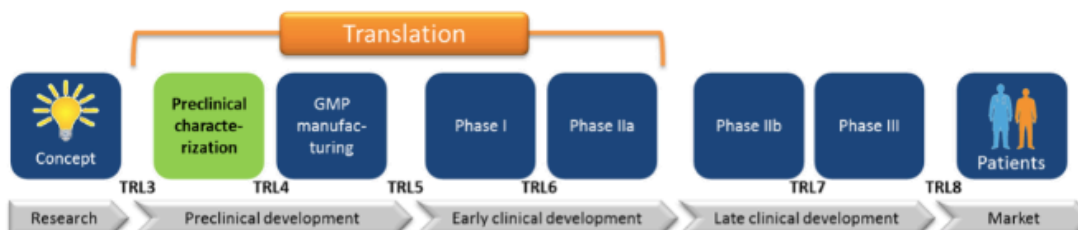
#### The Fifth International Conference NANOSAFE 2016

7 to 10 November, Grenoble, France

#### MedTech Forum

30 November to 02 December 2016, Brussels, Belgium

[More Events ...](#)



European Nanomedicine  
Characterisation Laboratory (EU-NCL)

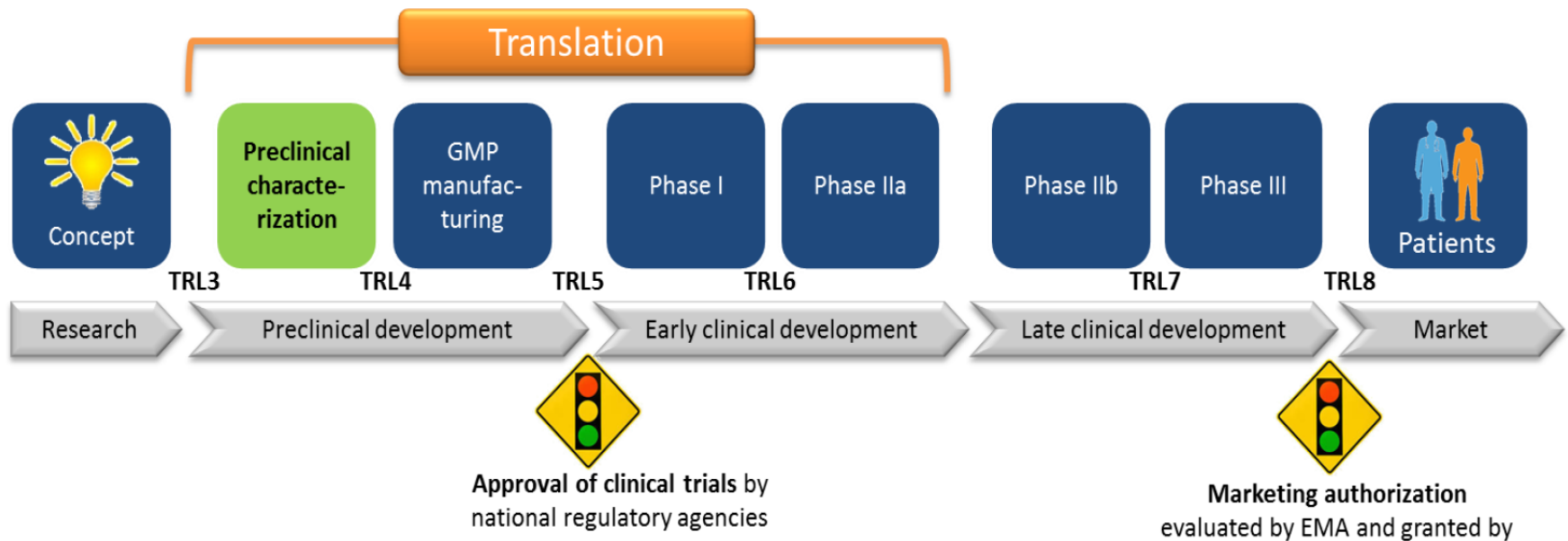
Call for

News

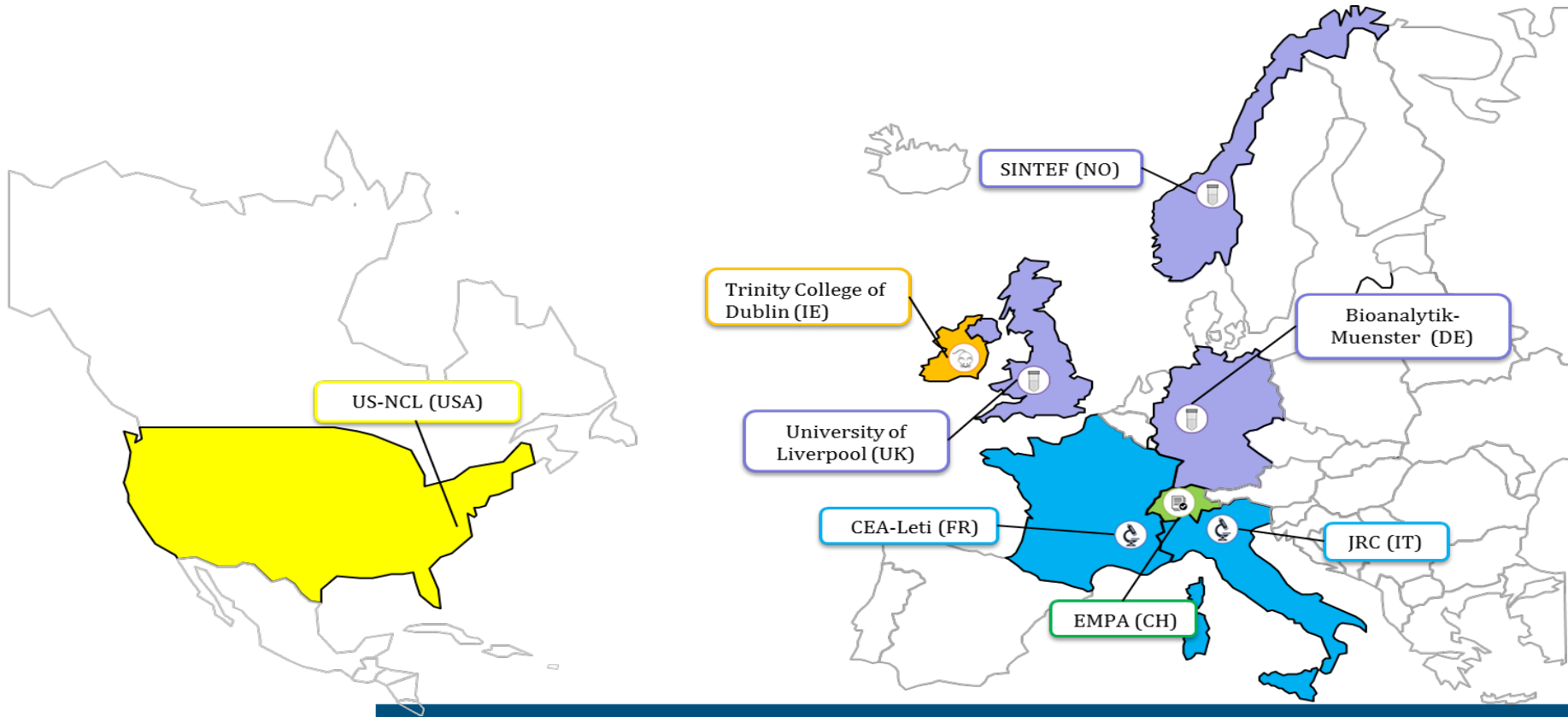
# Our mission

- To perform and standardize the **pre-clinical characterization** of nanomedicines
- To identify and characterize **critical parameter** related to nanomaterial interaction with biological systems
- To **develop improved analytical methods** to answer regulators' needs

# Innovation chain in nanomedicine



# Who are the Core Members?



# Who are the Satellite labs?

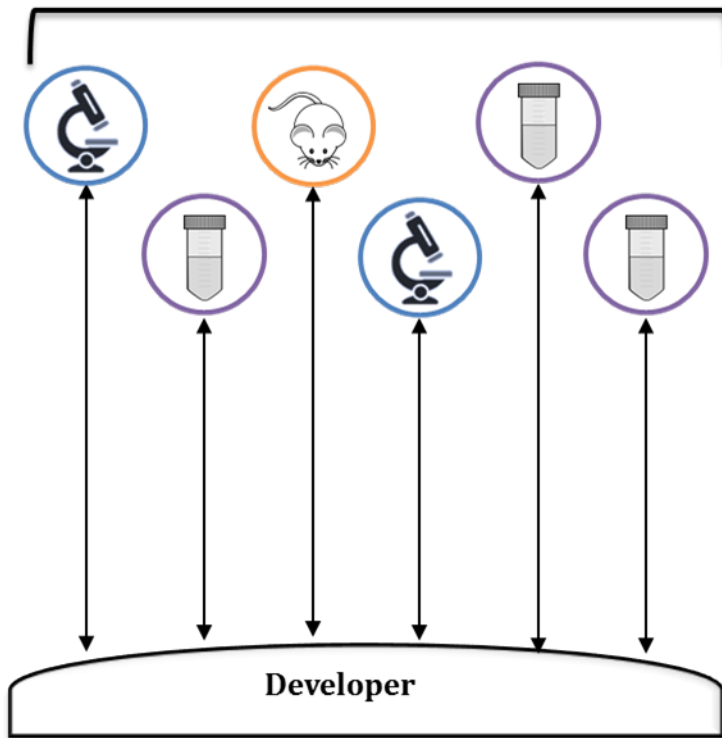
- CyberNano, Nates, FR
- FORTH Heraklion, GR
- INL, Braga, PT



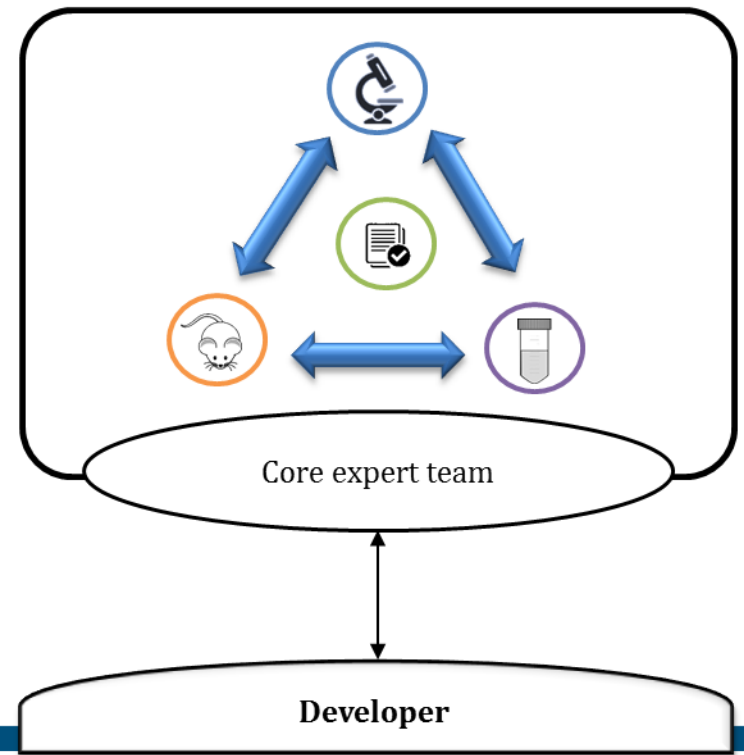


# Why EU-NCL?

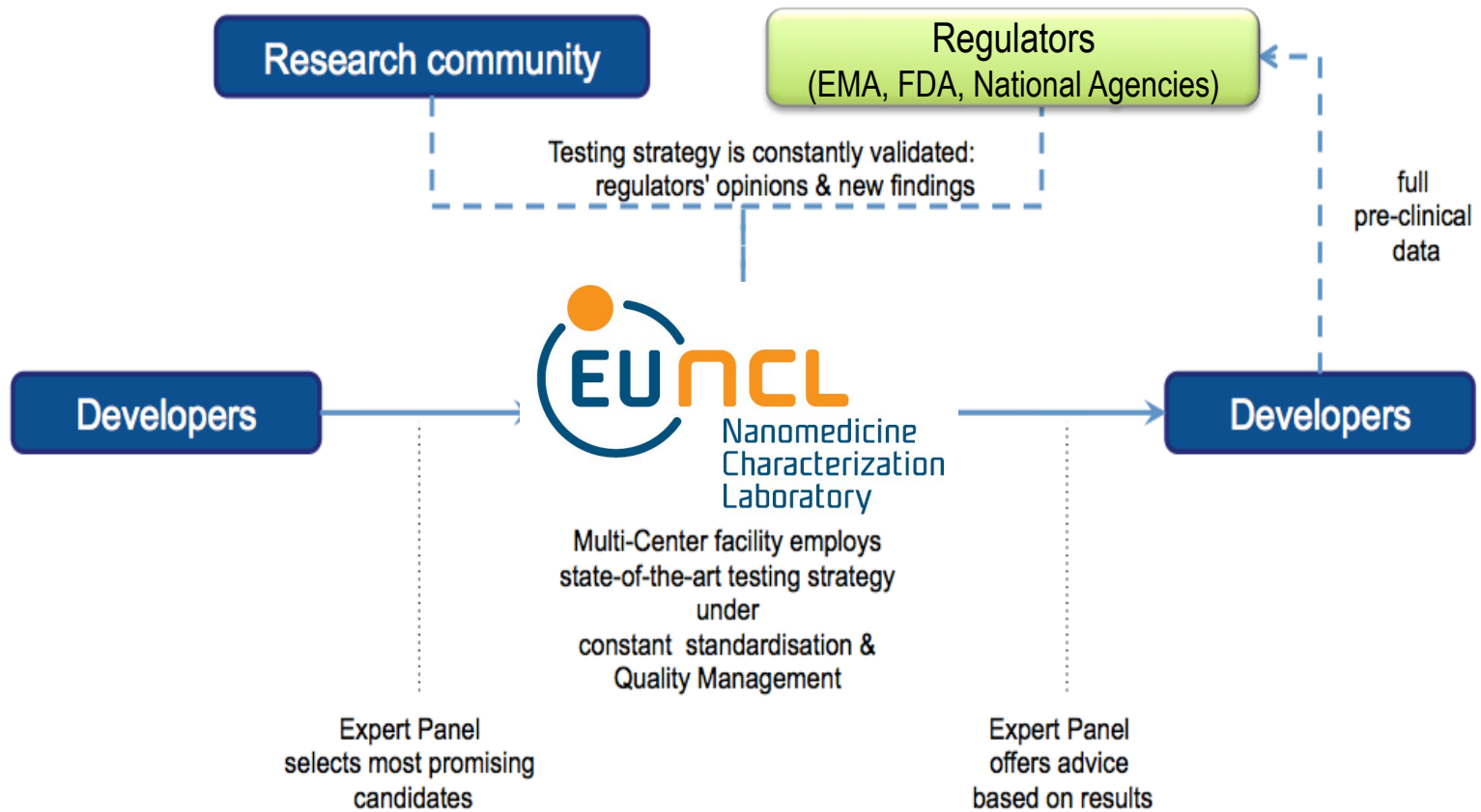
Current situation in Europe:  
Multiple non-integrated providers



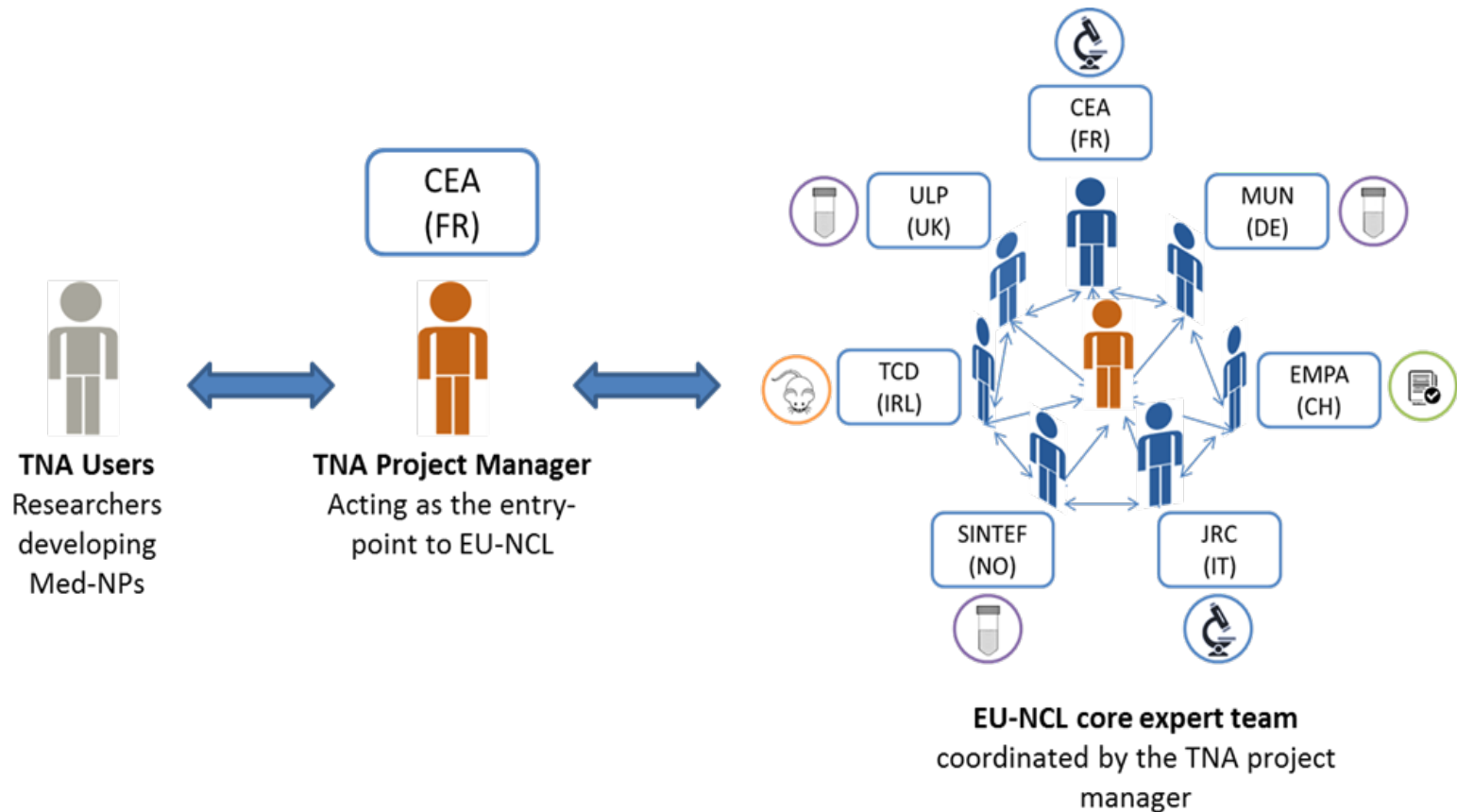
Progress beyond the state-of-the-art with  
EU-NCL: Integrated multi-disciplinary  
infrastructure



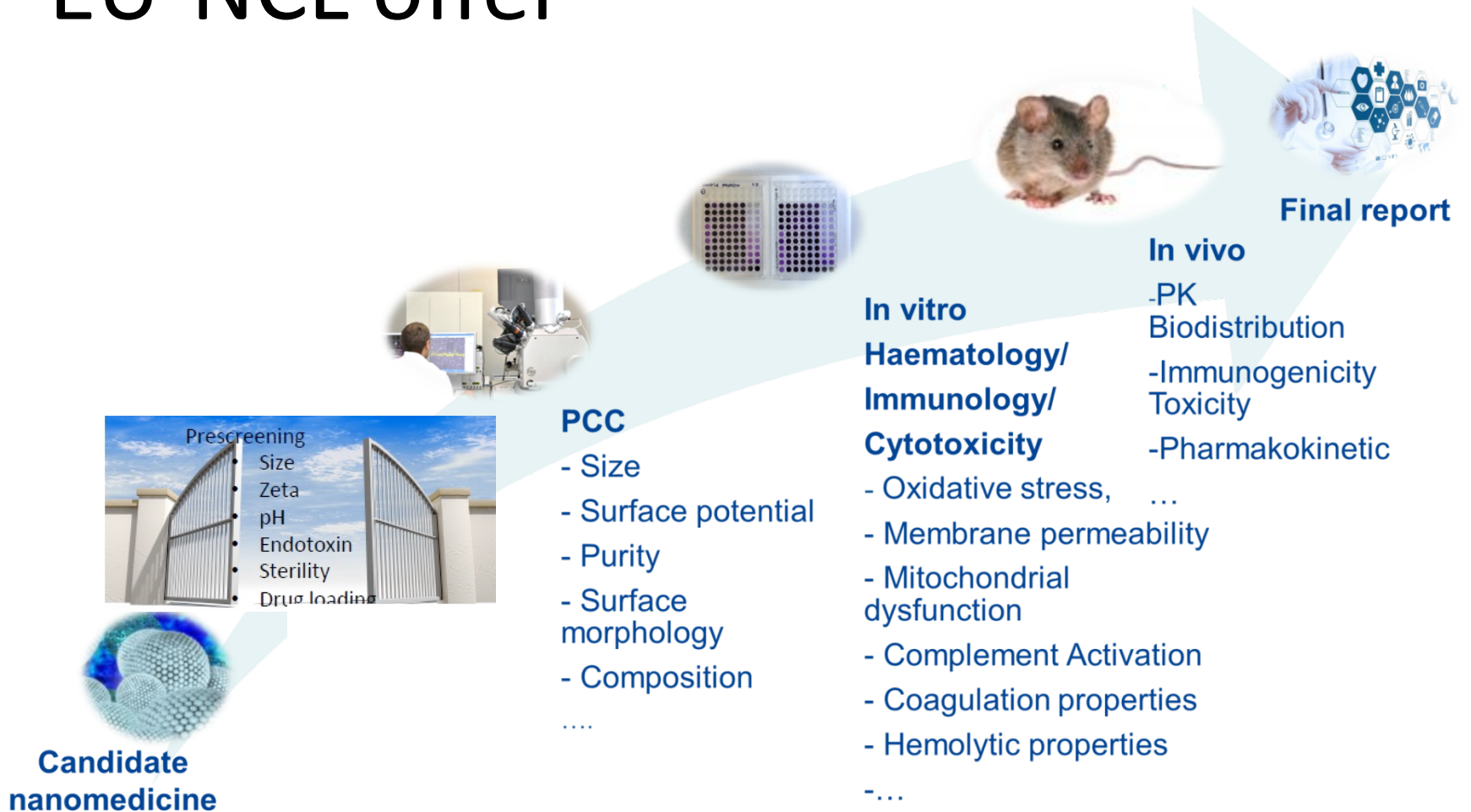
# EU-NCL Concept



# How does EU-NCL work



# EU-NCL offer



# Standardized and validated SOP

Step1

- Definition/transfer of the SOPs and of the quality controls
- Qualification: inter-laboratory comparison

Step2

- “Bugged” samples to test our problem solving capability

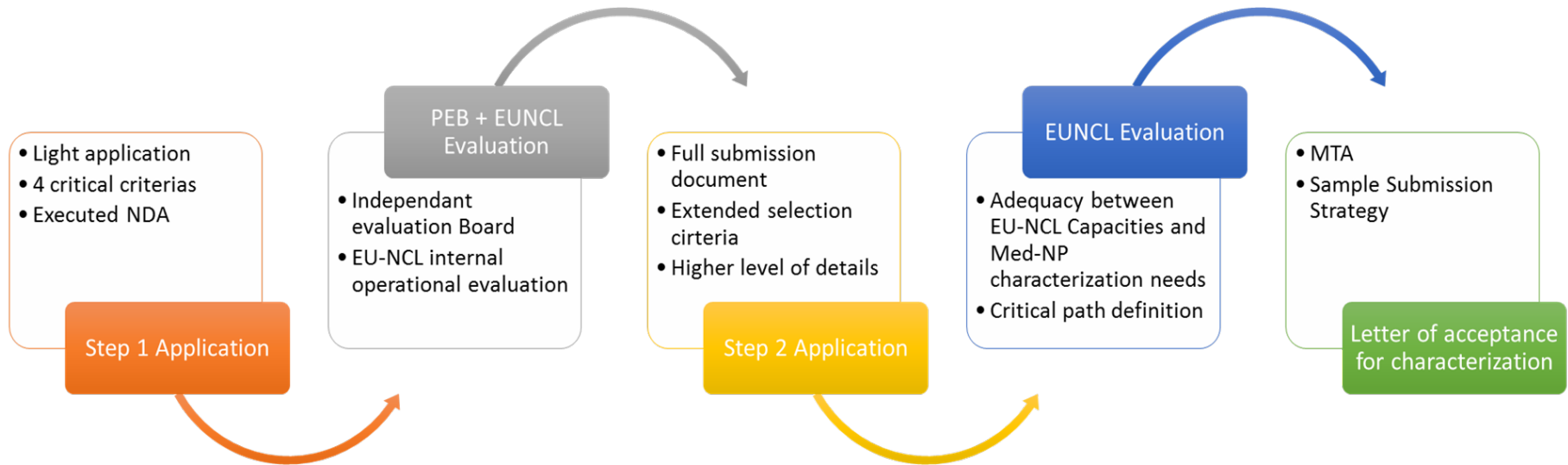
Step 3

- Validation of the laboratories (comparison with results from NCI-NCL)

The Standard Operating Procedures (SOPs) have been qualified and validated in all the laboratories of the EU-NCL consortium..

Quality controls are defined according to the ISO 17025

# Application process



- Demonstrate the efficacy of the Med-NP in biological systems
- Ability to produce two independent batches(reproducibility)
- Provide a detailed production plan and its scaling up plan
- Propose a clear strategy to transfer the technology to the clinical environment

# Who can apply?



Academics



Inventors



Startups



SMEs

## Acceptance criteria:

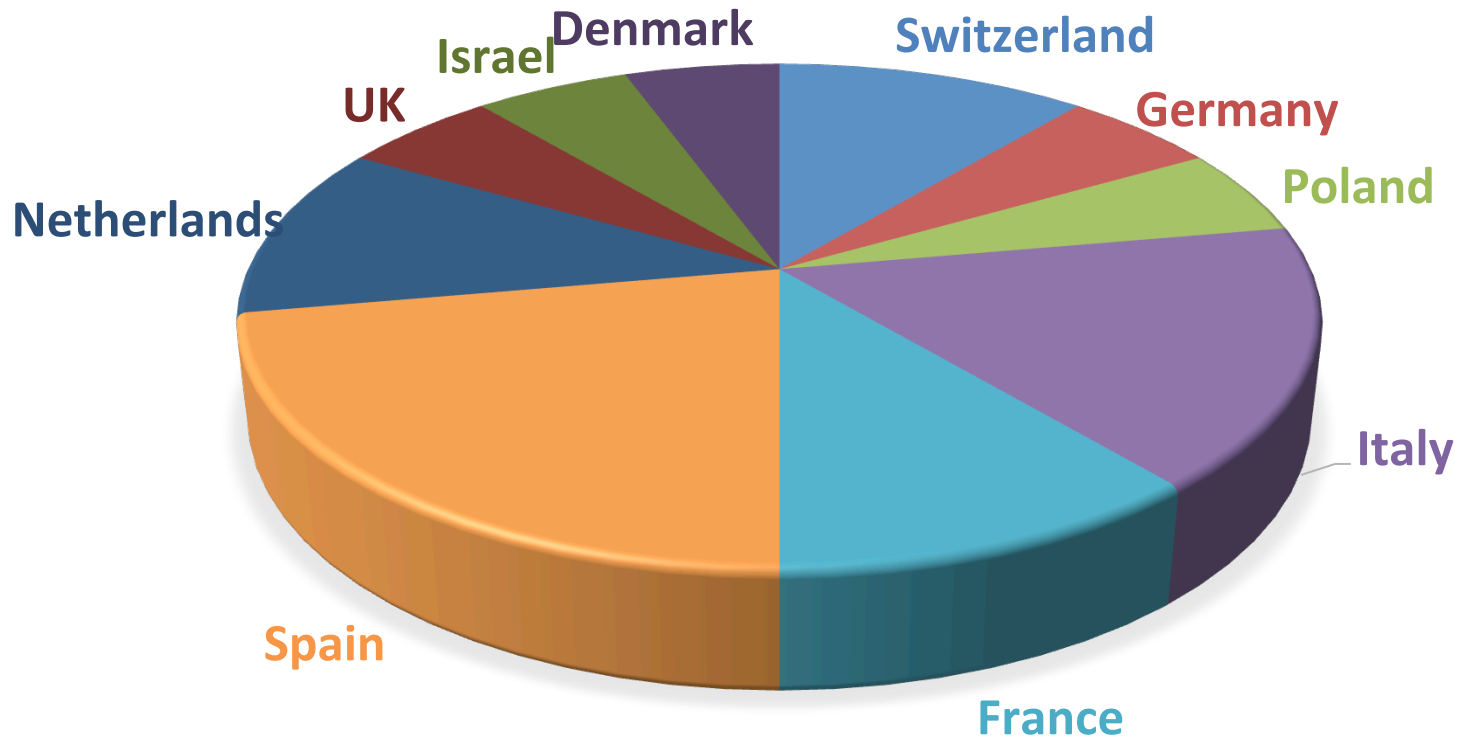
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# TNA numbers

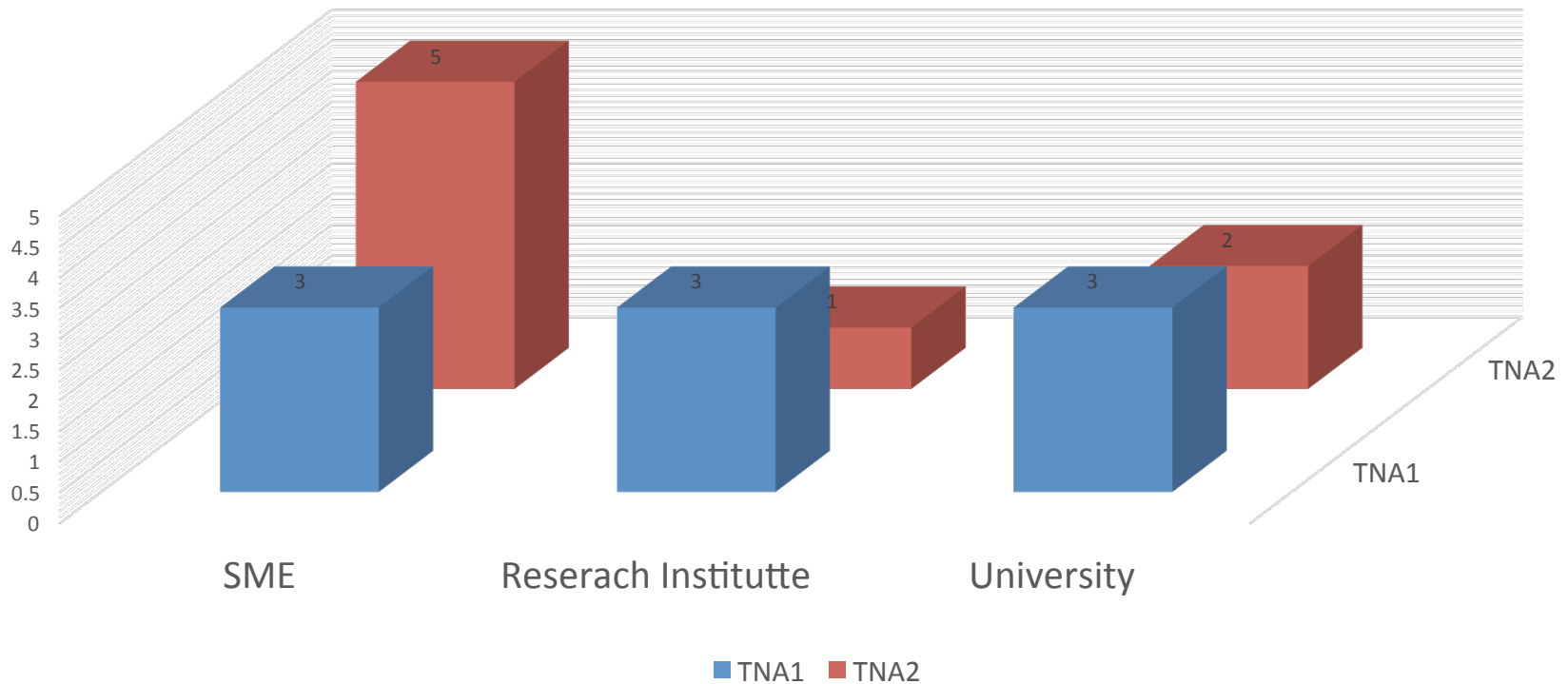
- First TNA campaign launched early 2016
  - 2<sup>nd</sup> session of second TNA campaign just closed (Nov. 17)
- 18 applications so far
  - 14 accepted to step 2
  - 2 entered characterisation
- ≈50% of applications comes from SMEs
- 90% cancer focus in TNA1, 75% in TNA2 (Oct review not included)



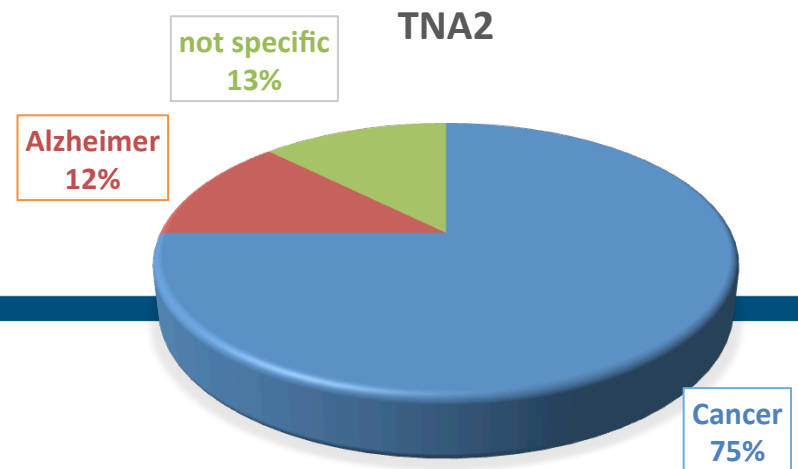
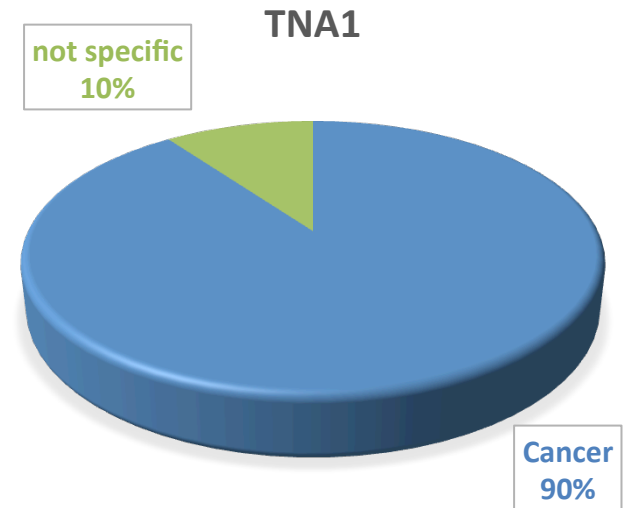
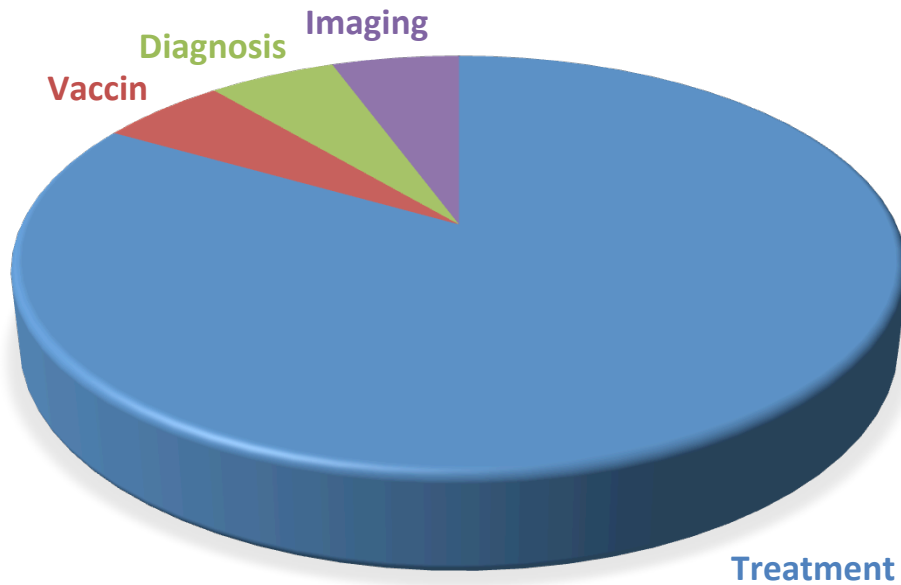
# Applications' origine



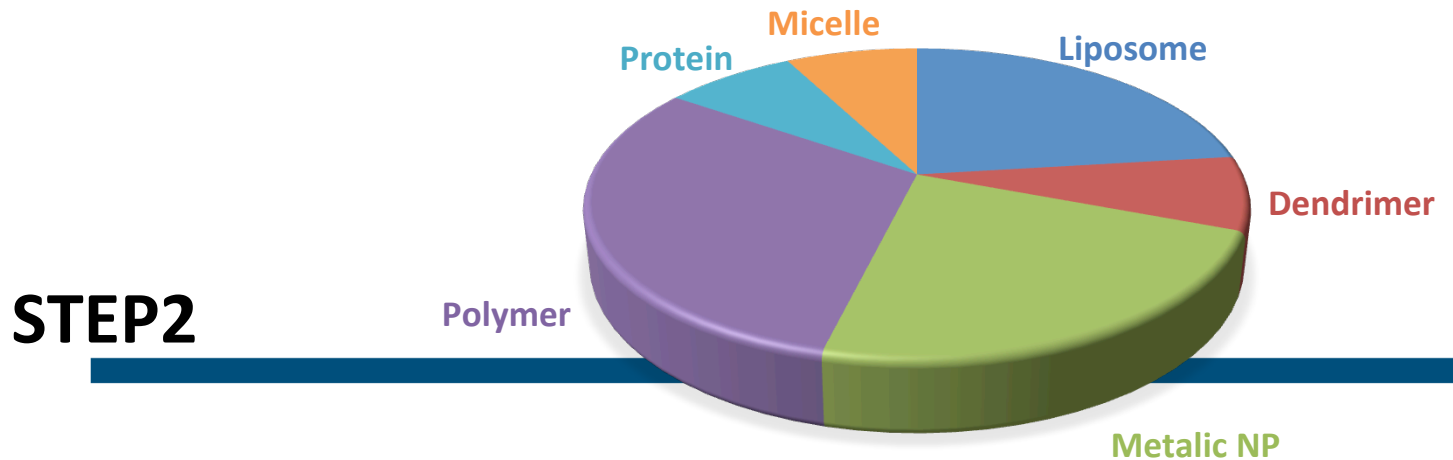
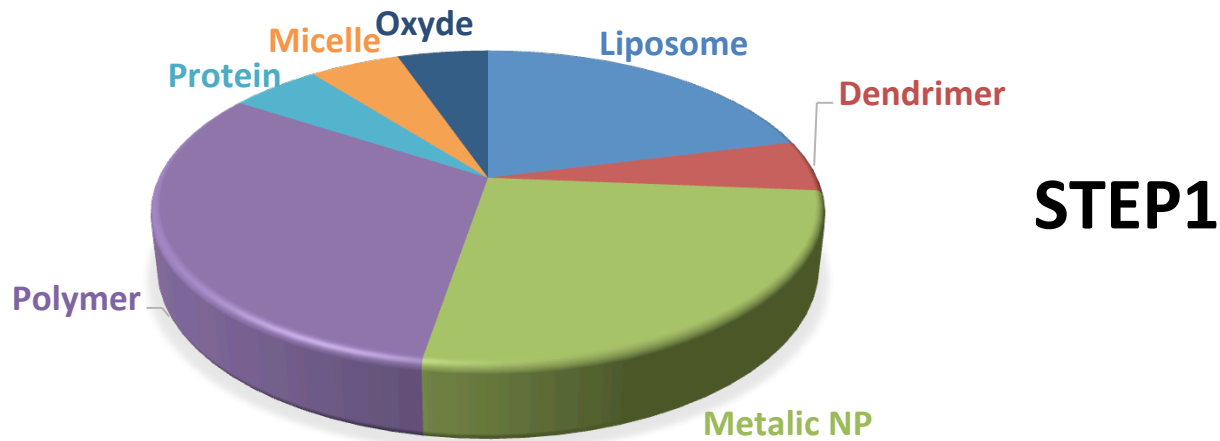
# Applicants' profile



# Applications



# Type of nanomaterials

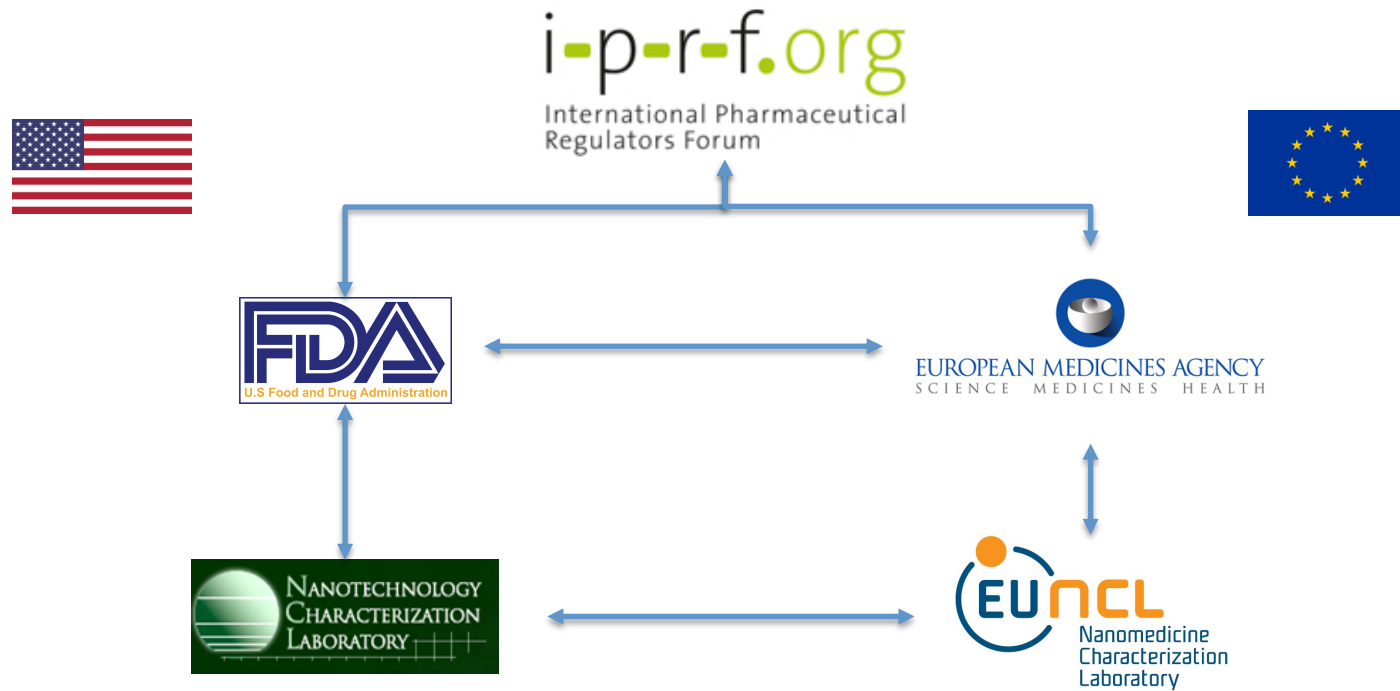


# Lessons learned

- Role of EU-NCL evolves
  - Toward advice and support
  - Help prepare better application
- Maturity of projects
  - Advanced vs. Early stage
  - Difficulties in delivering GMP-like batches



# Regulatory environment



# Advancing regulatory science

- Assessing and improving the performance of existing standards for nanomedicines e.g. cytotoxicity
- Hands-on experience on the performance of new methodologies
- Harmonising EU-NCL methods with the NCI-NCL will support their regulatory acceptance
- Gaining knowledge on critical information needs of next generation nanomedicines related to quality and safety and raising regulatory awareness

# ETPN Nanomedicine Translation Hub

Academics



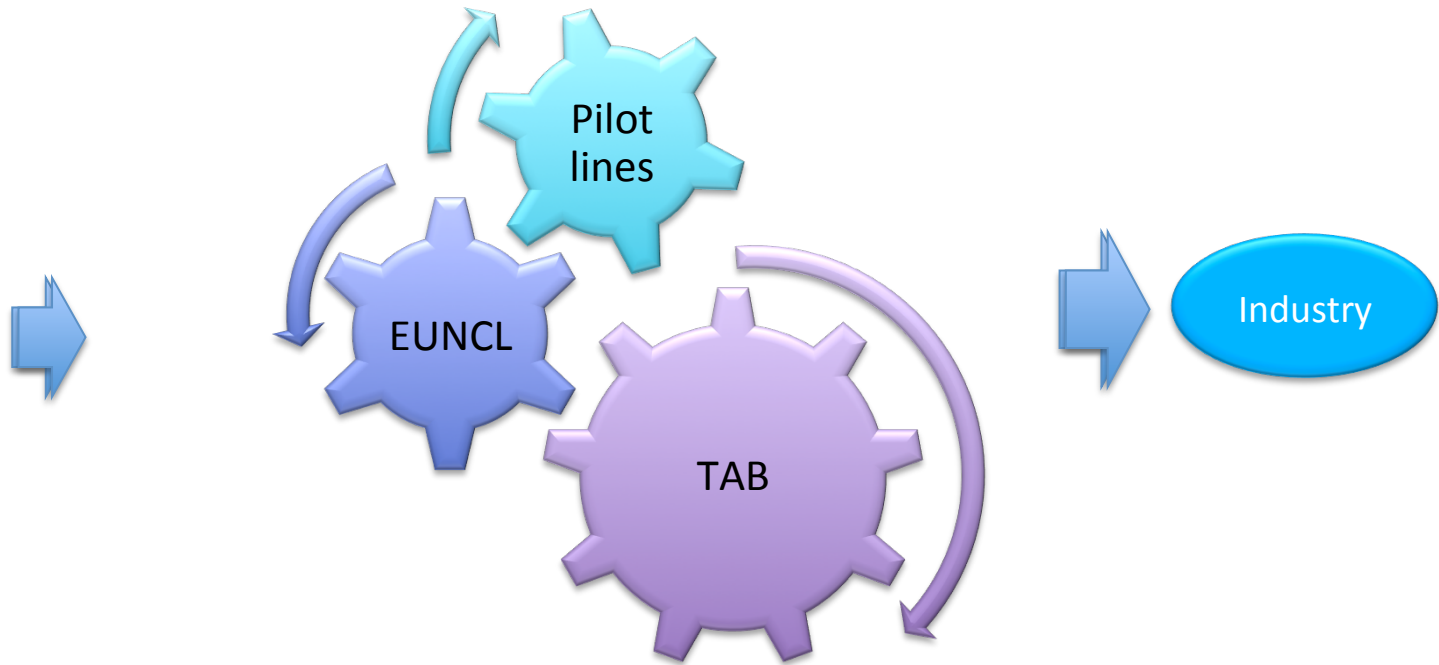
Inventors



Startups



SMEs





# Nanomed Translation Hub

## The Translation Advisory Board (TAB)



## Nanomedicine Characterisation Laboratory



## Nanomedicine Pilotlines



23.11.17

EU Innovation network, London

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# Summary

- 6 European laboratories have opened their state-of-the-art infrastructure
- EU-NCL offer a service free of charge to the nanomedicine community
- A core expert team with complementary expertise provides knowledge to product developer
- Nearly 30 assays addressing physicochemical and biological questions have been standardised and are constantly updated according to scientific progress
- Raise regulatory awareness on upcoming challenges with the quality and safety evaluation of nanomedicines
- Establishment of the EU-NCL benefits from the 10 years experience of the NCI-NCL
- The collaboration of NCI NCL and EU NCL will contribute to the harmonisation of information requirements and test methods

# Contact

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# Thank You



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