



# Nanomedicine Translation Hub and EU-NCL: Custom mentoring, product characterization and GMP manufacturing of Med-NPs

EMJMD NANOMED workshop  
12th July, Paris

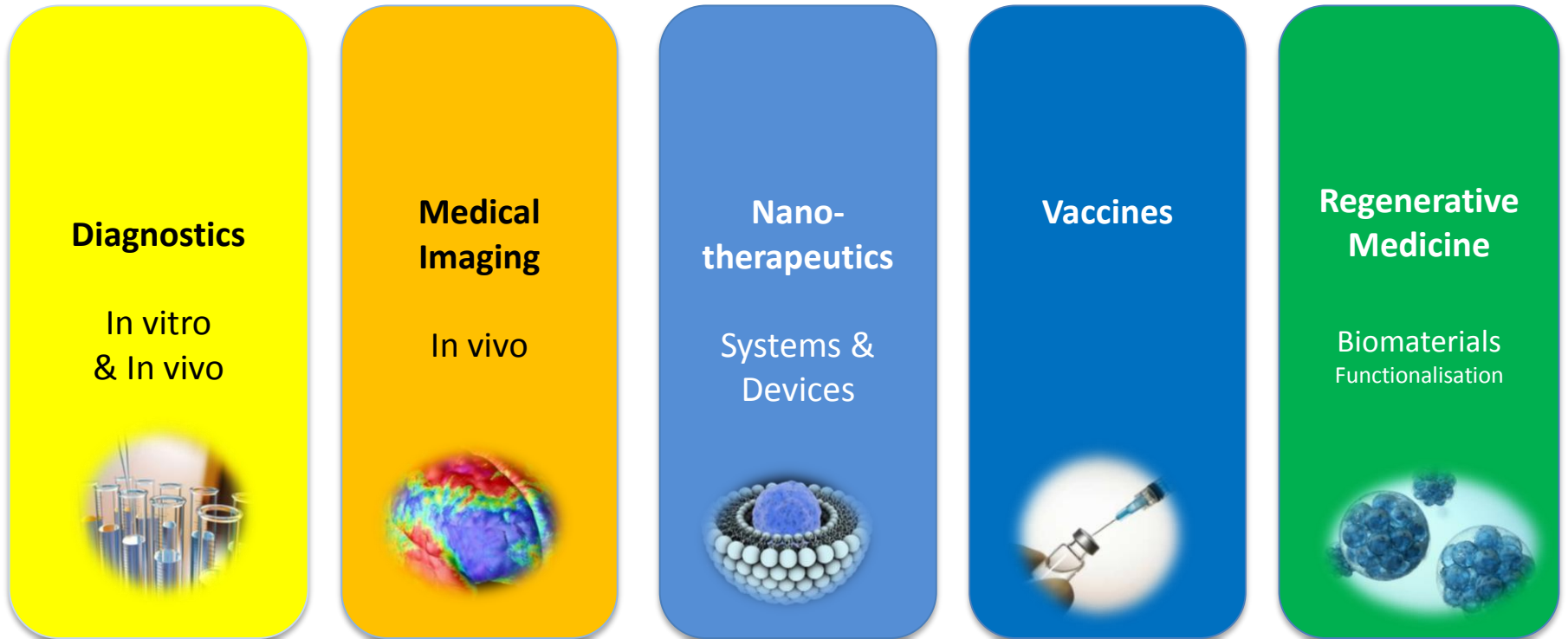
# Index

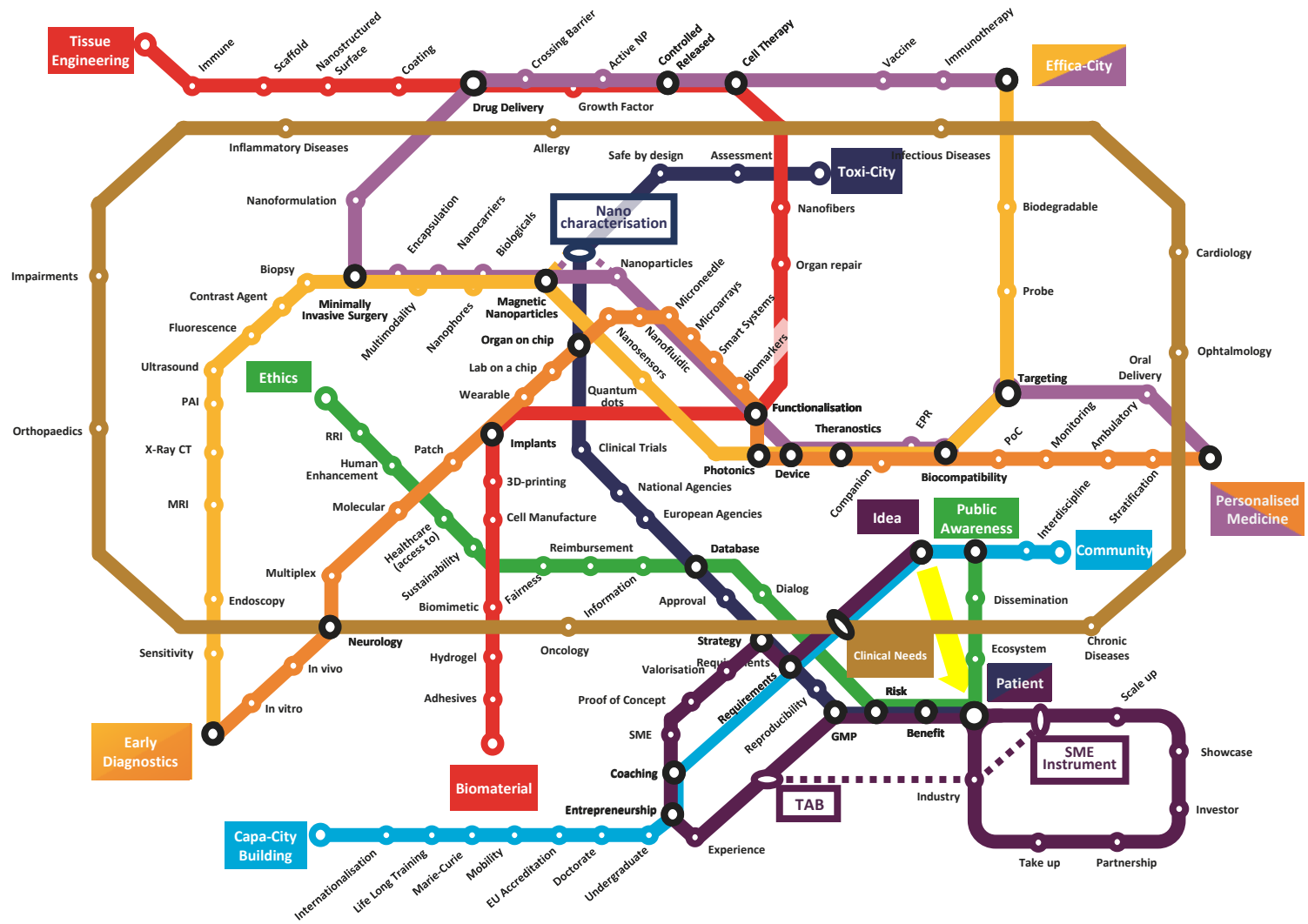
## Presentation of the European Technology Platform for Nanomedicine (ETPN) **Translation Hub**:

- **Custom Mentoring**: translation advisory board (TAB)
- **Med-NPs characterisation**: European nanomedicine characterization Lab (EU-NCL)
- **GMP manufacturing**: the pilot lines



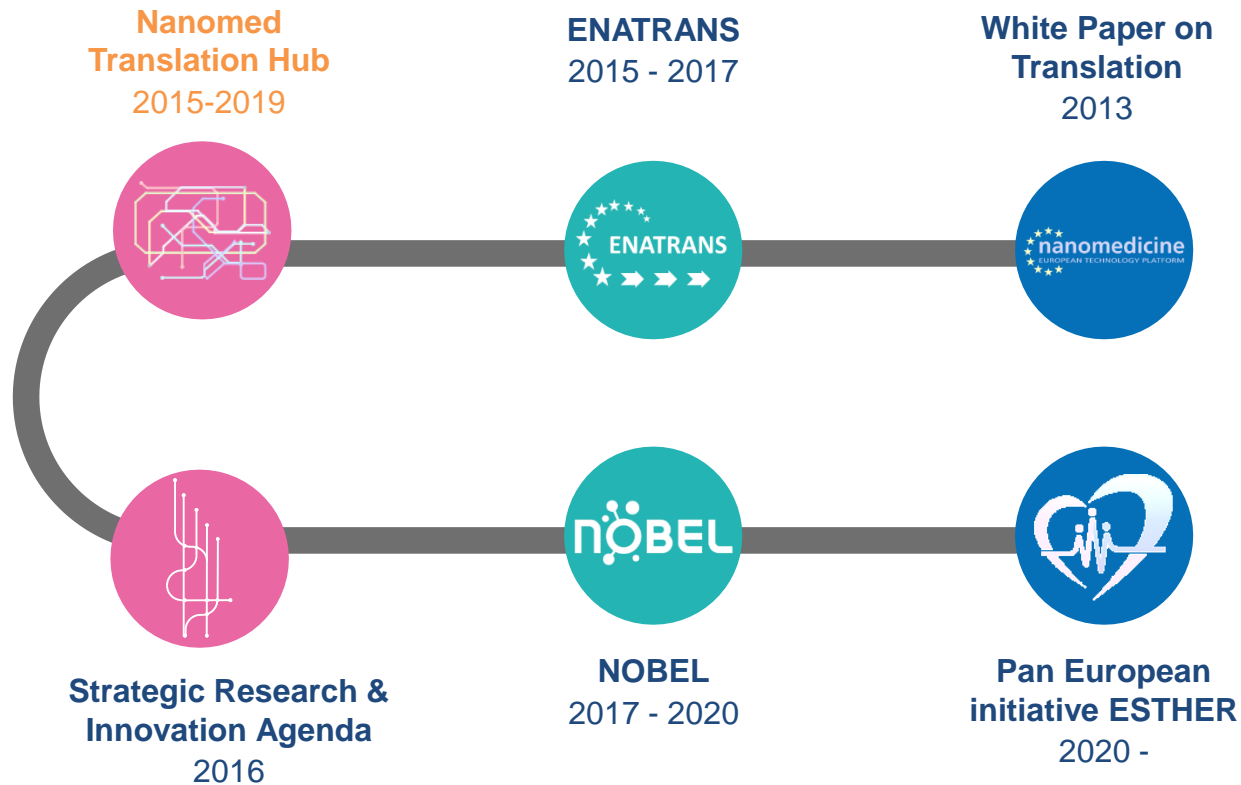
# Nanomedicine: a wide range of applications





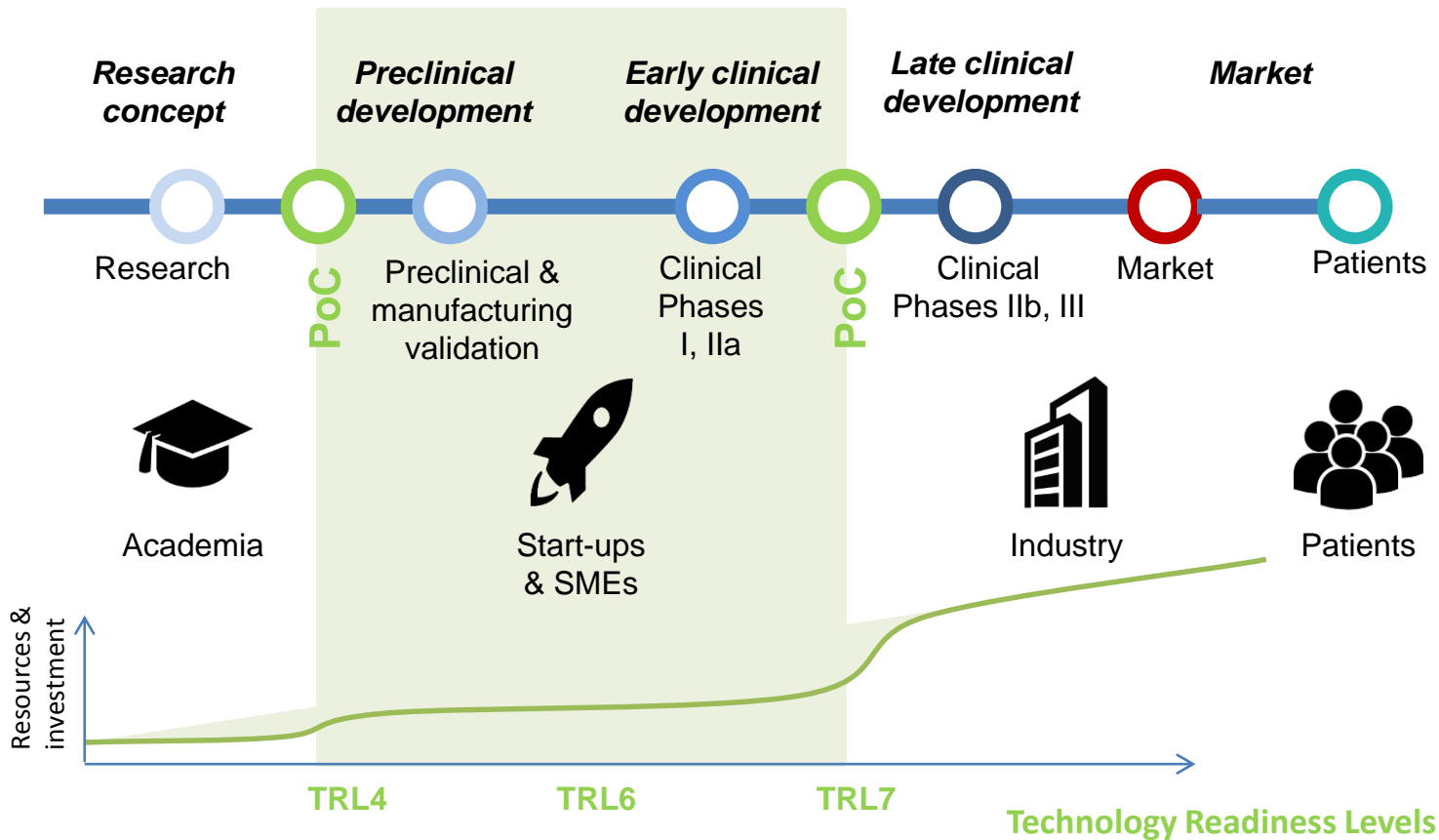
EMJMD NANOMED workshop  
12th July, Paris

# Translation Issues



have been addressed since 2013 by the European Technology Platform for Nanomedicine (ETPN), which developed new concepts to better respond to the needs of its members

# From the idea to the market



# Motivations



➤ Create conditions for successful translation of nanomedical advances



➤ Help nanomed projects to develop faster



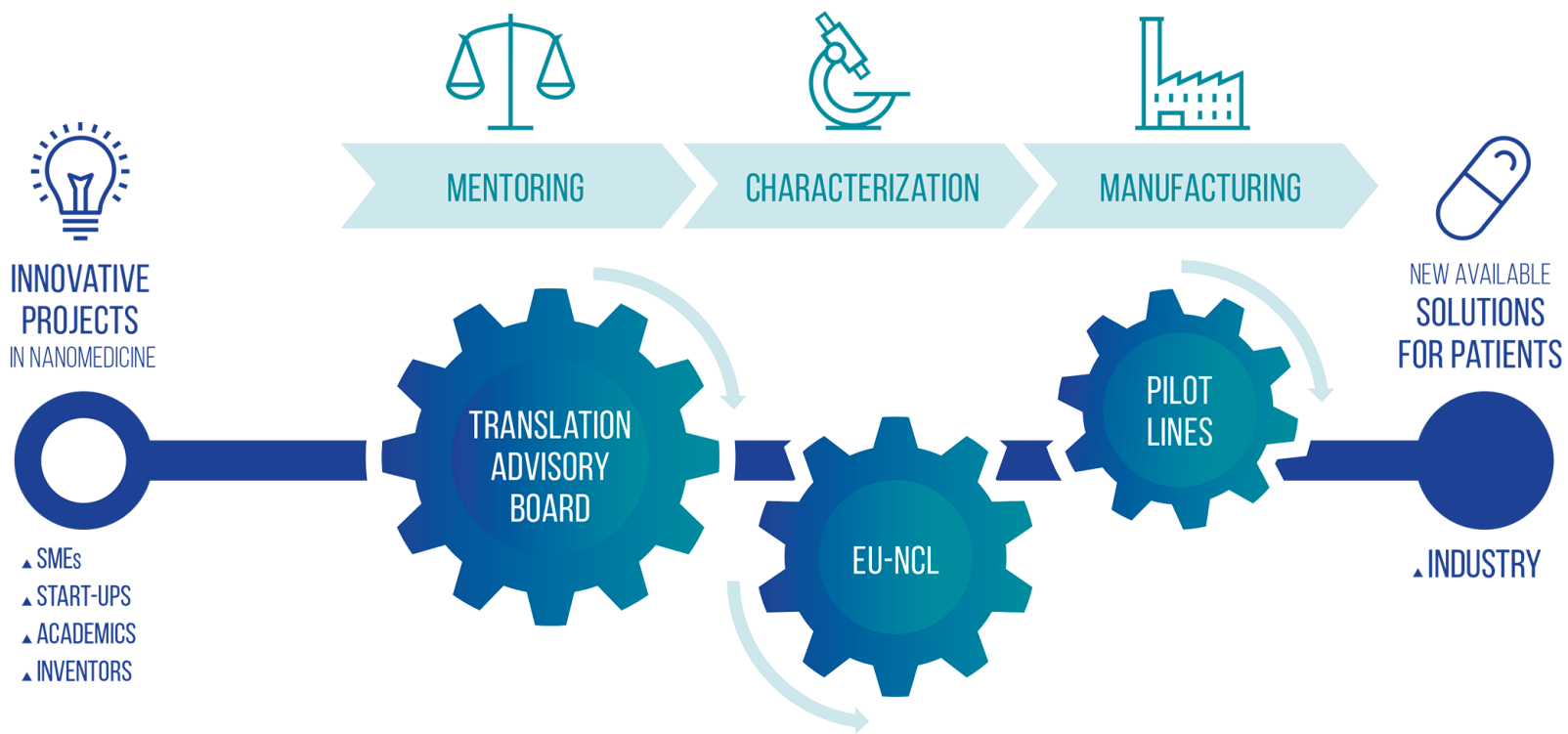
➤ Increase the effectiveness of investment in Nanomedicine



➤ Improve the health of citizens worldwide



# The Translation Hub: central instrument of ETPN to support and accelerate the development of the best Nanomedicine projects.



EMJMD NANOMED workshop  
12th July, Paris



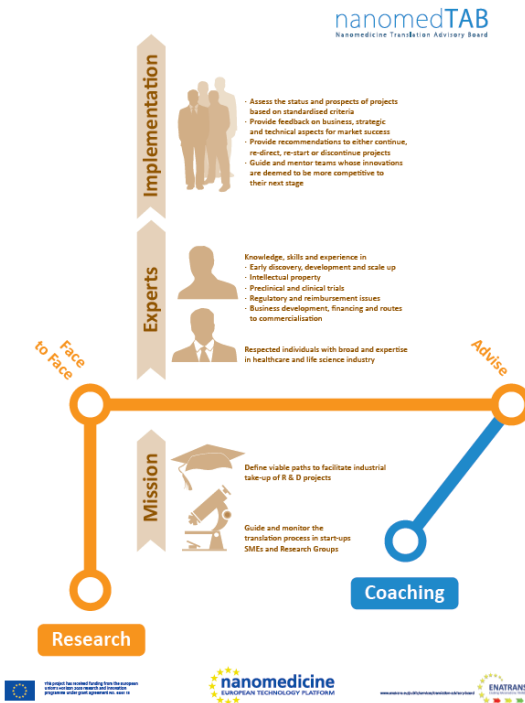
# The Nanomedicine Translation Hub:

- 1 – is a unique **one-stop-shop to boost the translation** of medical innovations to the market
- 2 – offers **custom** mentoring, product characterization and GMP manufacturing
- 3 – **removes the specific roadblocks** identified in Nanomedicine product development
- 4 – is **open** to all: entrepreneurs, SMEs, industry, academic labs, etc.
- 5 – is a **PREMIUM** service, sponsored by the European Commission & **100% free of charge for beneficiaries**

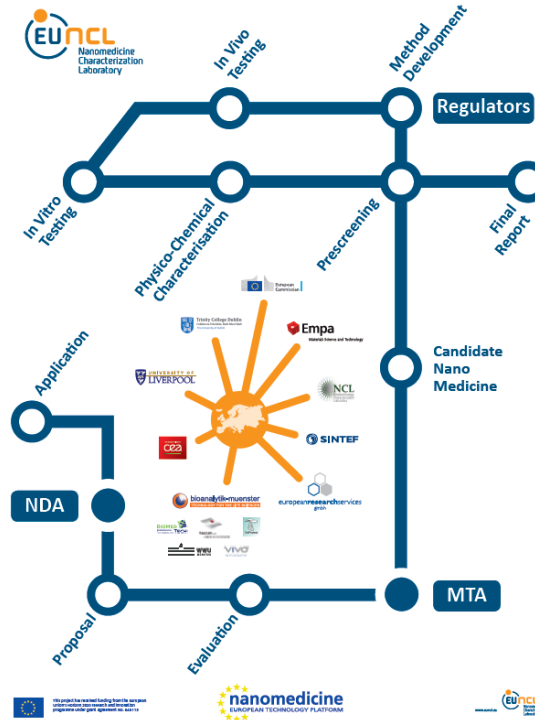


# The European Nanomedicine Translation Hub

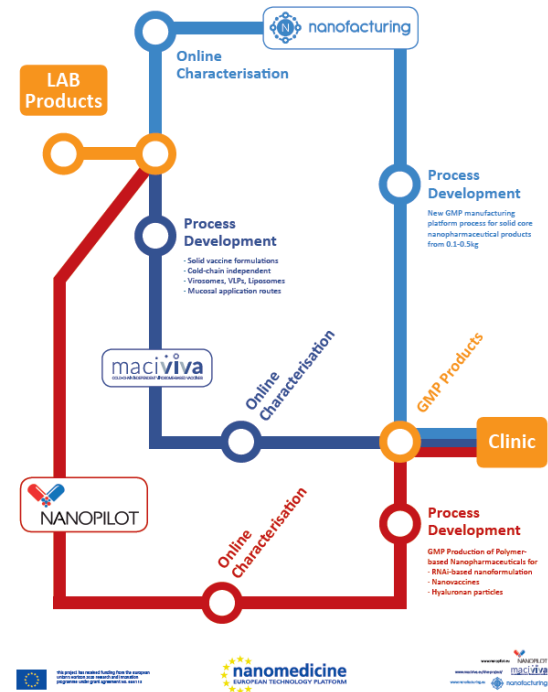
## The Translation Advisory Board (TAB)



## Nanomedicine Characterisation Laboratory



## Nanomedicine Pilotlines

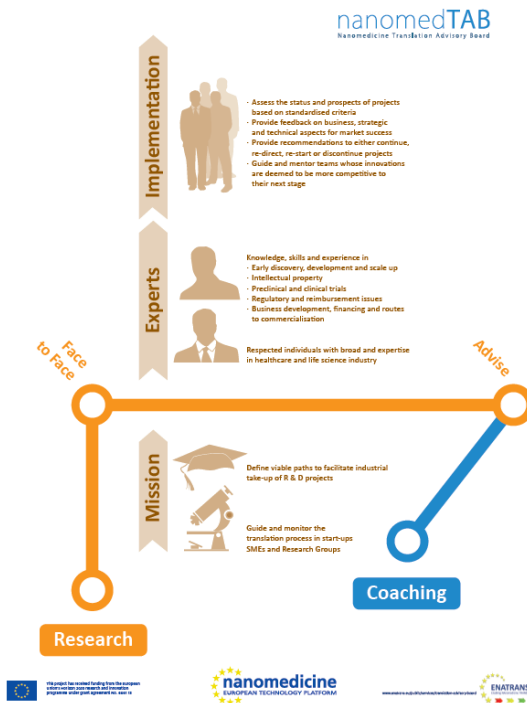


# The translation advisory board (TAB)



MENTORING

## The Translation Advisory Board (TAB)



## Access to industry knowledge:

The TAB is a unique group of seasoned HealthTech industry experts and entrepreneurs offering mentoring to shape & boost carefully selected innovative HealthTech projects.

## What they do:

1. Assess the status & prospects of healthcare programmes
2. Provide feedback on business, strategic and technical aspects in order to identify and explain what is needed for development and market success
3. Provide recommendations to either continue, re-direct, re-start or discontinue projects.
4. Guide and mentor teams whose innovations are deemed to be more competitive to their next stage (e.g. Technical development, funding, partnering, regulatory, manufacturing)

HEALTHTECHTAB – 2<sup>ND</sup> EDITION – HEALTHTECH TAB – 2<sup>ND</sup> EDITION  
**FREE OF CHARGE**

[www.healthtechtab.eu](http://www.healthtechtab.eu)



EMJMD NANOMED workshop  
12th July, Paris

# The translation advisory board (TAB)



MENTORING

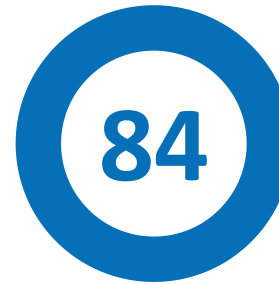
2015

**nanomedTAB**  
Nanomedicine Translation Advisory Board

ENATRANS



Years of implementation



Nanomedicine project already supported



Mio. € funding helped raising

2017

Now open to any kind of “Hardware” technologies with applications in Pharma, Medtech and Biotech

Value-driven, not volume-oriented

Free-of-charge for European organisations

2020

**Healthtech TAB**  
Healthtech Translation Advisory Board



EMJMD NANOMED workshop  
12th July, Paris



# TAB success stories

- Israeli company secured an **investment round of 3,5 Mio. €**
- British company secured an **investment round of 2,7 Mio. €**
- Spanish R&D team created spin-off and **secured investment of 10 Mio. \$**
- Portuguese company reshaped plan to **secure enough funds** to keep running
- Spanish R&D team **received 500 k€** to start up a company

*“Our experience with nanomedTAB has been **invaluable**: a game changer, turning the page for the next part of the journey towards both clinical and commercial success ... The Expert critique has been taken on board and is guiding our current activities. TAB’s commercial insight has brought focus on need to refine, and define further, the company.”*

**Dr Su Metcalfe, Founder & Chief Scientific Officer, Director**  
**LIFNano Therapeutics / [www.lifnano.com](http://www.lifnano.com)**



Custom support to medical innovation  
Mentoring by industry experts



### The TAB will:

ASSESS the status of your innovation  
ADVISE your development strategy  
ACCELERATE your project to the market

Already helped raising  
more than 15 M€

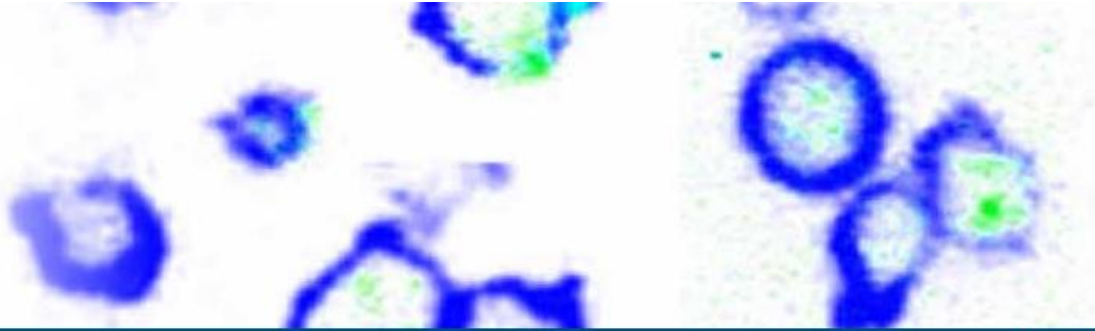
Next TAB sessions, November 7<sup>th</sup>, Copenhagen  
in parallel with BIO-Europe 2018



Apply until September 24<sup>th</sup>  
[www.healthtechtap.eu](http://www.healthtechtap.eu)



# European Nanomedicine Characterisation Lab (EUNCL)



ABOUT US ▾ WORKING WITH US ▾ PARTNERS DOWNLOADS PUBLICATIONS SATELLITES

EU-NCL  
European Nanomedicine Characterisation Laboratory

Events where you meet EU-NCL  
Nanomedicines - Technical and Regulatory Perspectives

[www.euncl.eu](http://www.euncl.eu)



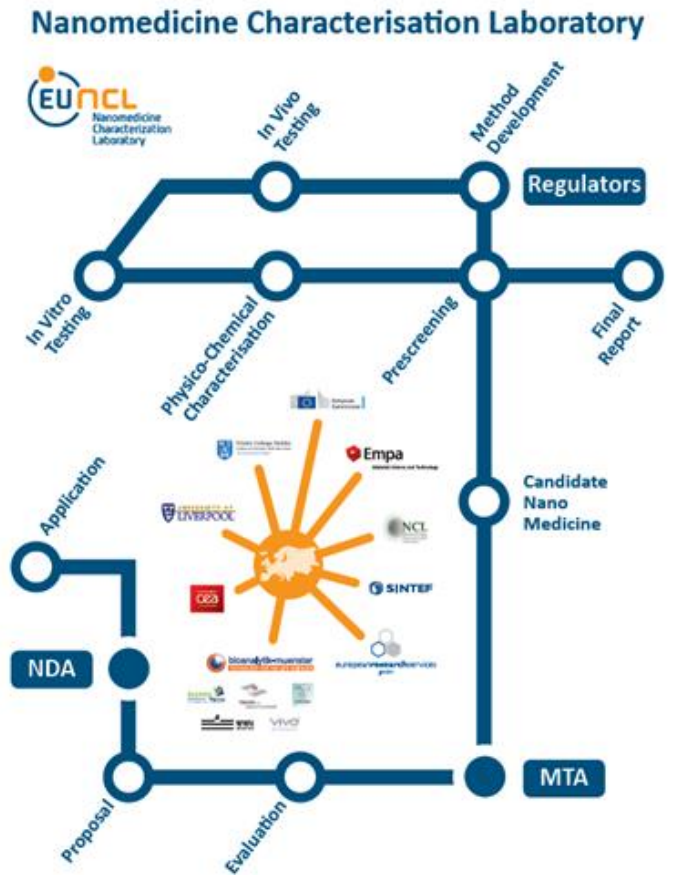
EMJMD NANOMED workshop 15  
12th July, Paris



# European Nanomedicine Characterisation Lab (EUNCL)



CHARACTERIZATION



## EU-NCL missions:

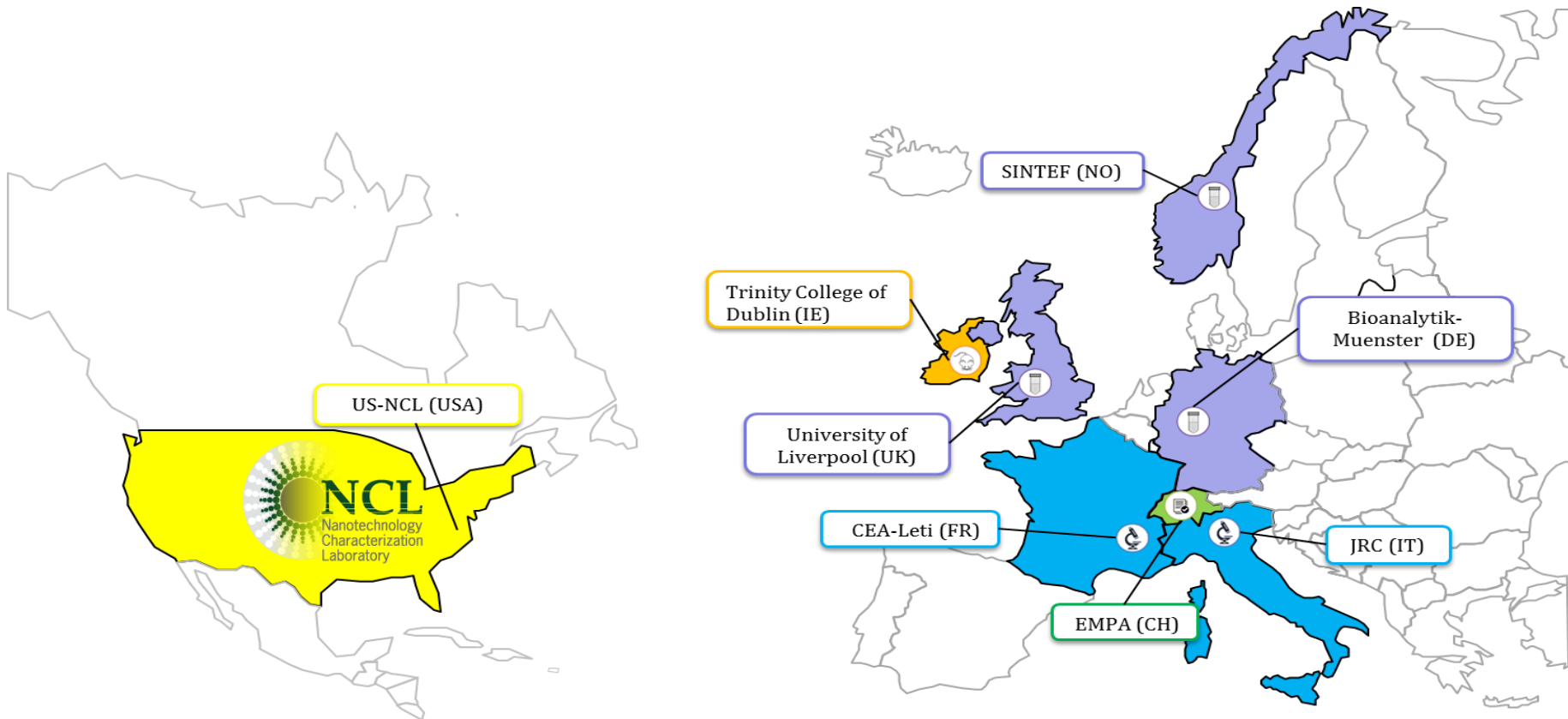
- To perform and standardize the complete pre-clinical characterization of nanomedicines (from physico-chemical properties to in vivo)
- To identify and characterize critical parameter related to nanomaterial interaction with biological systems
- To develop improved analytical methods to answer regulators' needs
- To help all kind of projects: SMEs, industry, academics, etc.

[www.euncl.eu](http://www.euncl.eu)





# EUNCL: who we are?

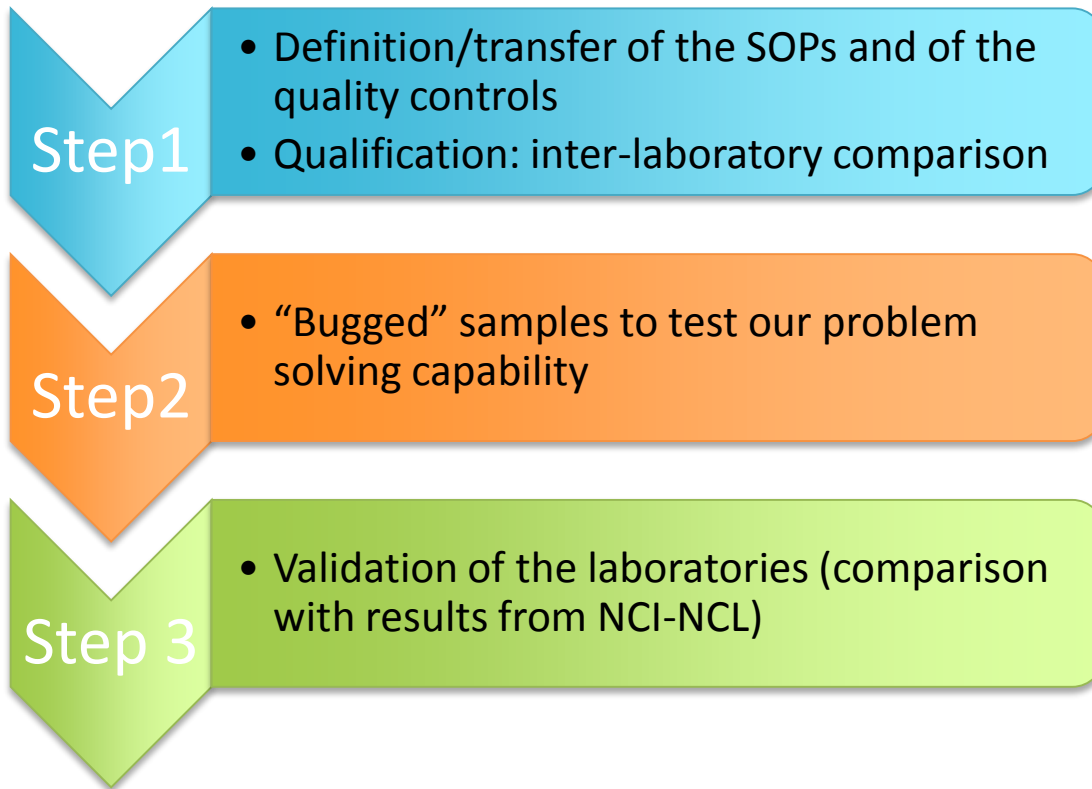


# What EUNCL offers?

- Integrated pre-clinical assay cascade:
  - Standardized Standard operating procedures (SOPs)
  - Adapted to each specific formulation
  - Free of charge!



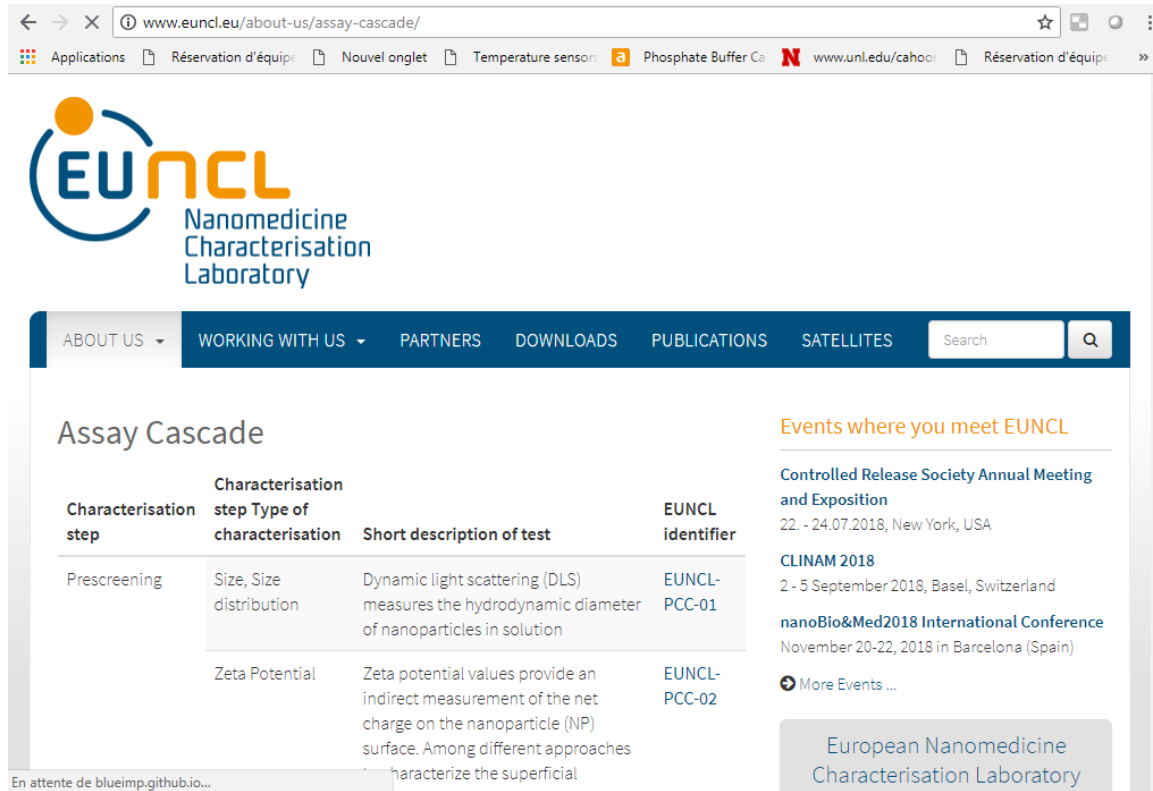
# Quality Controlled Service



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

# The SOPs are all available on our site



www.euncl.eu/about-us/assay-cascade/

Applications Réservation d'équipe Nouvel onglet Temperature sensors Phosphate Buffer Ca www.unLedu/cahoor Réservation d'équipe

**EUNCL**  
Nanomedicine  
Characterisation  
Laboratory

ABOUT US WORKING WITH US PARTNERS DOWNLOADS PUBLICATIONS SATELLITES Search

## Assay Cascade

Characterisation step	Characterisation step Type of characterisation	Short description of test	EUNCL identifier
Prescreening	Size, Size distribution	Dynamic light scattering (DLS) measures the hydrodynamic diameter of nanoparticles in solution	EUNCL-PCC-01
	Zeta Potential	Zeta potential values provide an indirect measurement of the net charge on the nanoparticle (NP) surface. Among different approaches to characterize the superficial	EUNCL-PCC-02

Events where you meet EUNCL

- Controlled Release Society Annual Meeting and Exposition  
22. - 24.07.2018, New York, USA
- CLINAM 2018  
2 - 5 September 2018, Basel, Switzerland
- nanoBio&Med2018 International Conference  
November 20-22, 2018 in Barcelona (Spain)

More Events ...

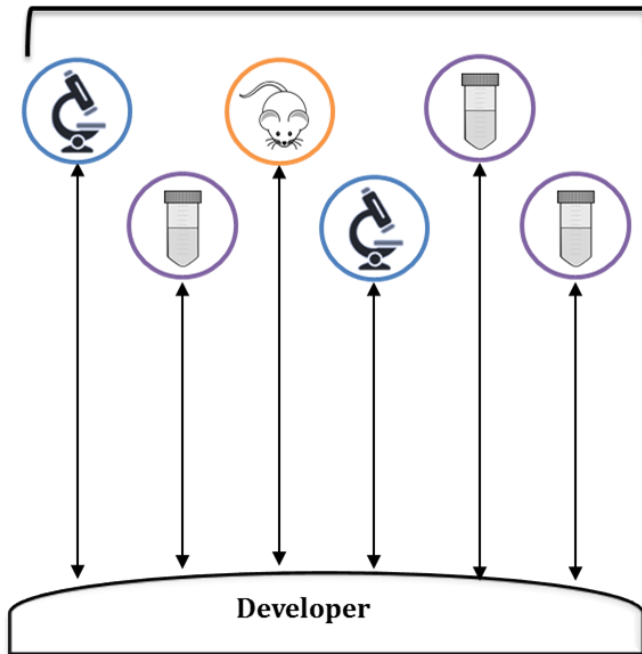
European Nanomedicine  
Characterisation Laboratory

<http://www.euncl.eu/about-us/assay-cascade/>

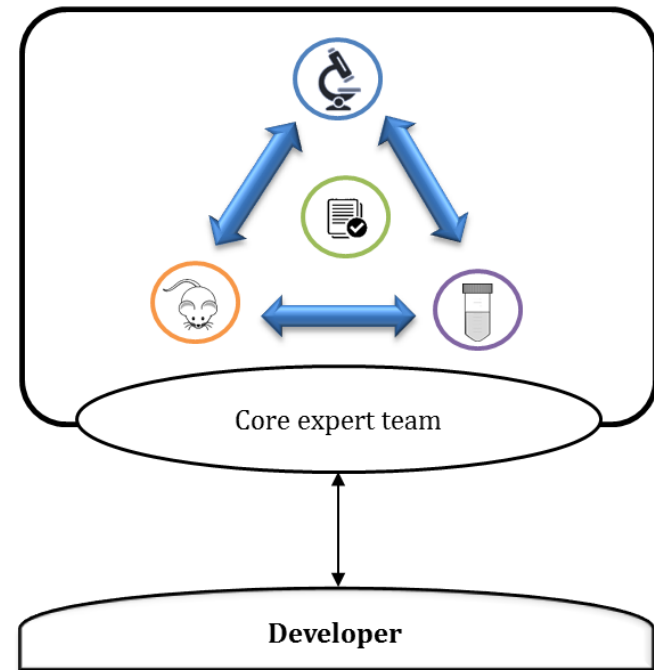


# Why EUNCL?

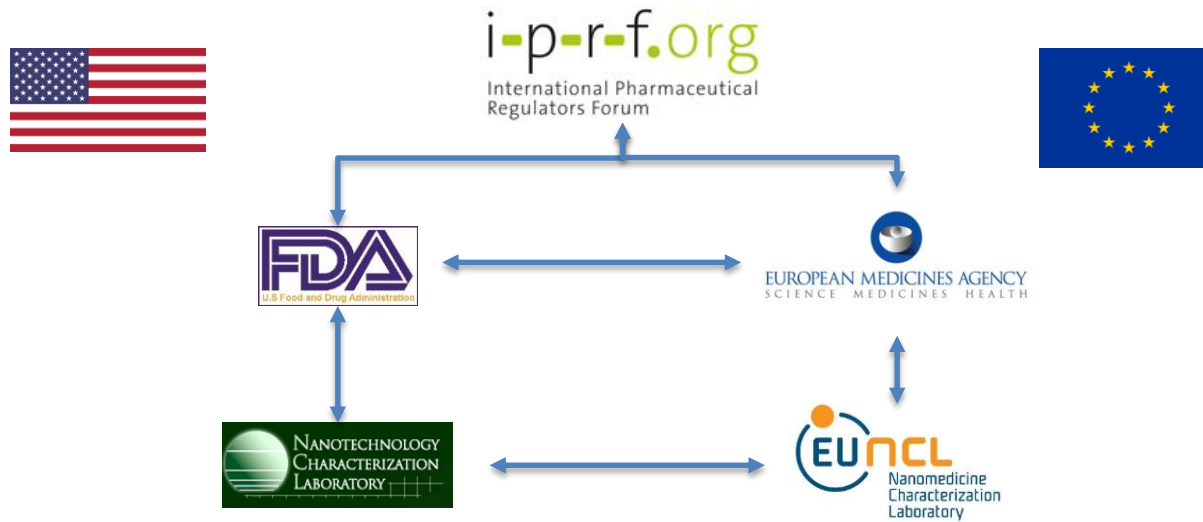
Current situation in Europe:  
Multiple non-integrated providers



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



# Regulatory environment





# Regulating nanomedicine: Still a long way to go

Region	Organisation	Department
Canada	Health Canada	Marketed Health Products Directorate
Europe	European Medicines Agency	Innovation Task Force
Switzerland	Swissmedic	Nanotechnology Expert Group
Canada	Health Canada	Health Products and Food Branch
FDA	United States Food and Drug Administration	Center for Drug Evaluation and Research
Japan	Pharmaceuticals and Medical Devices Agency	Office of New Drug II SUMED - MEDICINES AND BIOLOGICAL PRODUCTS OFFICE
Brazil	ANVISA	
Korea	Ministry of Food and Drug Administration	Toxicology Research Division
Taiwan	Center for Drug Evaluation, Taiwan	PharmTox team, Division of New Drug
Netherlands	RIVM - National Institute for Public Health and the Environment	Centre for Health Protection


Journal of  
Interdisciplinary Nanomedicine

BRITISH SOCIETY FOR  
NANOMEDICINE

Open Access


Original Article | Open Access  

## Identification of regulatory needs for nanomedicines

Susanne Bremer-Hoffmann  Blanka Halamoda-Kenzaoui, Sven Even Borgos

First published: 14 March 2018 | <https://doi.org/10.1002/jin2.34> | Cited by: 1

[Read the full text >](#)

 PDF  TOOLS  SHARE

Survey focused on:

1. Regulatory experience with nanomedicine
2. Information needs of regulators for the characterization of the formulation
3. How to support the acceptance of Med-NPs products in healthcare

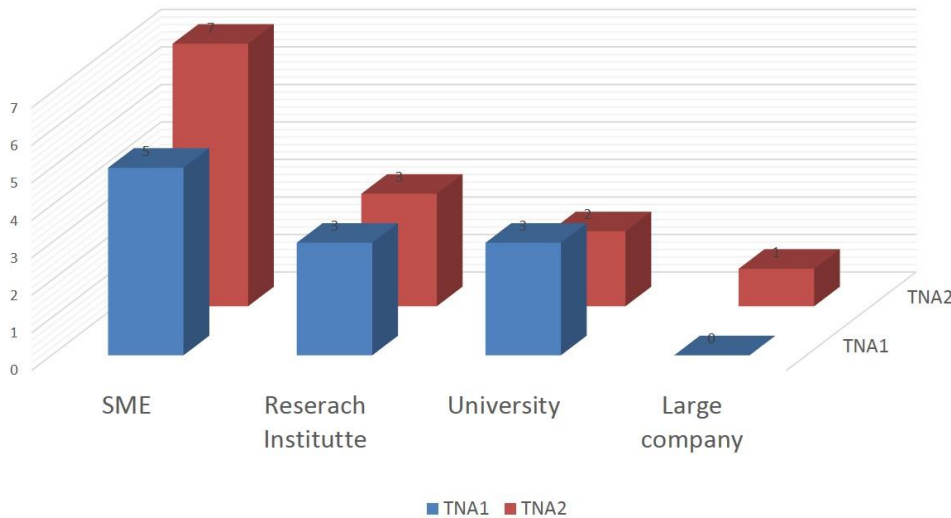
# Regulating nanomedicine: Still a long way to go

- **Only a few applications:** The competent authorities that responded had no or only few applications of nanomedical products.
- **Applications lacking relevant informations:** For two of the agencies the physical-chemical characterisation provided was not sufficient. One example was reported with insufficient data on the biological characterisation for market authorization.
- Insufficient test methods used for quality assessments or the use of non-suitable test methods have been reported
- **The agencies have highlighted the need for assessing the stability, uniformity, endotoxin testing and agglomeration behaviour as highly relevant for entering into clinical trials**
- Three agencies were of the opinion that the characterisation requirements of free nanomaterial administered to the patient (medical device) and nanomaterial used as medicinal products should be harmonised

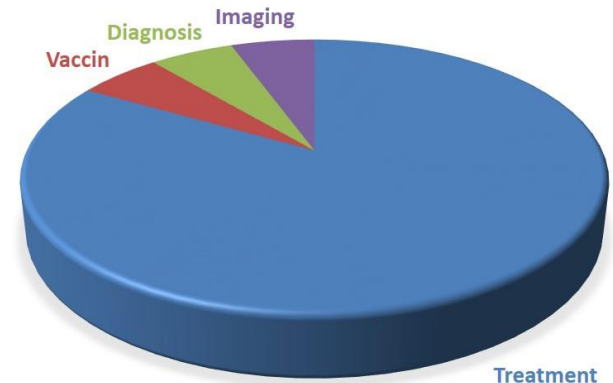


# Our applicants...

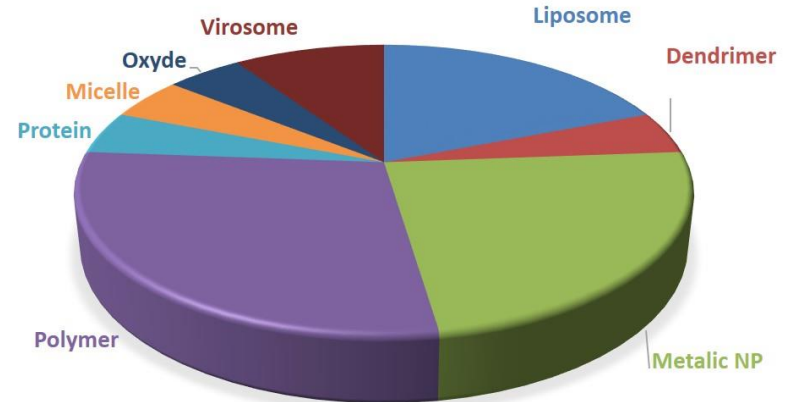
## Applicant profiles



## Application



## Technology



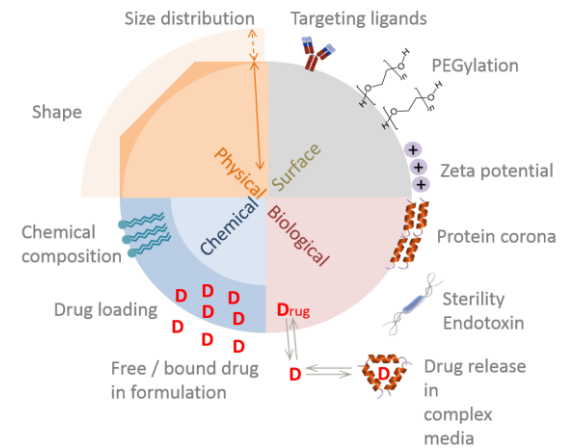
[www.euncl.eu](http://www.euncl.eu)



EMJMD NANOMED workshop  
12th July, Paris

# A continuous learning process for us!

- Multiple carriers and API
- Different synthetic procedures
- Reconstitution and administration
- Clinical targets



Borgos, S.E.F., Characterization Methods: Physical and Chemical Characterization Techniques. Pharmaceutical Nanotechnology: Innovation and Production, 2 Volumes, 2016.

- Numerous parameters can influence a NP behaviour: size, agglomeration propensity, shape, surface functionalization, surface charge, dissolution rate, composition, loading..

**Each Med-NP is unique and can be very complex. A multidisciplinary group of experts is discussing each case on a weekly bases**

# Mentoring role of EUNCL



Not only a characterization service, but also custom mentoring (on specific technical issues):

- Importance of **sterility** (e.g. how to avoid endotoxin contamination),
- What does **stability** really means?
- Importance of **quality** (batch to batch reproducibility)
- **Scale up** (provide contacts to the sponsors)

[www.euncl.eu](http://www.euncl.eu)



EMJMD NANOMED workshop  
12th July, Paris

# Where to meet us

<http://www.euncl.eu/events/>

The screenshot shows the EUNCL website with a navigation bar containing 'ABOUT US', 'WORKING WITH US', 'PARTNERS', 'DOWNLOADS', 'PUBLICATIONS', and 'SATELLITES'. Below the navigation bar, the 'EUNCL' logo and 'European Nanomedicine Characterisation Laboratory' are displayed. The mission statement is provided, followed by a diagram of the 'Nanomedicine Characterisation Laboratory' process flow. The 'Events where you meet EUNCL' section is highlighted with a blue arrow, listing the 'Controlled Release Society Annual Meeting and Exposition' (22-24.07.2018, New York, USA), 'CLINAM 2018' (2-5 September 2018, Basel, Switzerland), and 'nanoBio&Med2018 International Conference' (November 20-22, 2018 in Barcelona (Spain)). A 'Call for Proposals!' box is also visible.

## [Controlled Release Society Annual Meeting and Exposition](#)

22. - 24.07.2018, New York, USA

## [CLINAM 2018](#)

2 - 5 September 2018, Basel, Switzerland

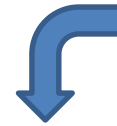
## [nanoBio&Med2018 International Conference](#)

November 20-22, 2018 in Barcelona (Spain)



# Scale up pilot lines

- From mL to L of active medical nanomaterial
- Scale up process for delivering clinical batches



maciviva  
COLD CHAIN INDEPENDENT VIRUS-LIKE PARTICLES

MYMETICS

Thermo stable and  
cold-chain independent vaccines

NANOPILOT

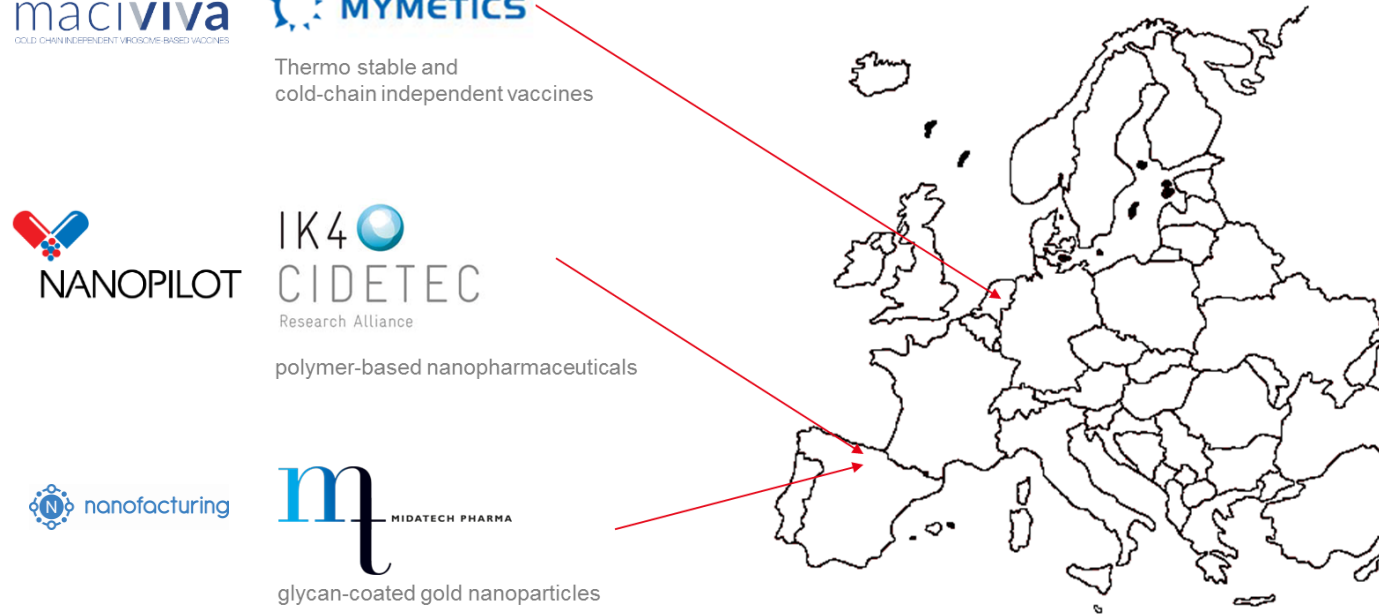
IK4  
CIDETEC  
Research Alliance

polymer-based nanopharmaceuticals

nanofacturing

m  
MIDATECH PHARMA

glycan-coated gold nanoparticles



# Pilot lines objectives

- Build **pilot scale GMP manufacturing lines** to supply nanomedicines at scale
- Establish pilot lines in Europe for the **process development and scale up of nanopharmaceutical manufacture**
- Create a European **manufacturing ecosystem for nanopharmaceuticals**



# The European Nanomedicine Translation Hub



- **The Translation advisory board** : free-of-charge **assessment & mentoring** by a group of top level industrial and clinical experts  
[www.healthtechtabs.eu](http://www.healthtechtabs.eu)



- **The EU Nanomedicine Characterization Laboratory (EUNCL)**: free-of-charge service of full characterization for nanomedicine products by the best standards available [www.euncl.eu](http://www.euncl.eu)



- **GMP Pilot lines** : up-scaling & manufacturing of clinical batches of medical nanomaterials



# Take home messages:

- ✓ **Tailored service is available for free** for start-ups & SMEs to make them develop better & faster
- ✓ **Holistic and complementary services** are driving this emerging industry
- ✓ The model is **ready to be replicated** in other regions around the globe
- ✓ **ETPN is offering the service!**





[www.etp-nanomedicine.eu](http://www.etp-nanomedicine.eu)

[www.euncl.eu](http://www.euncl.eu)

[www.healthtechtab.eu](http://www.healthtechtab.eu)



Thank You



- [Fanny.caputo@cea.fr](mailto:Fanny.caputo@cea.fr)
- [tna@euncl.eu](mailto:tna@euncl.eu) (contact EU-NCL)
- [info@healthtechtab.eu](mailto:info@healthtechtab.eu) (contact TAB)



# Regulatory perspectives

- Link with regulatory bodies should/will be reinforced
  - National RB will be involved
  - EMA Innovation Network
- Dedicated event:
  - REFINE Knowledge Exchange conference Dec 2018
- FDA Drug Products, Including Biological Products, that Contain Nanomaterials Guidance for Industry



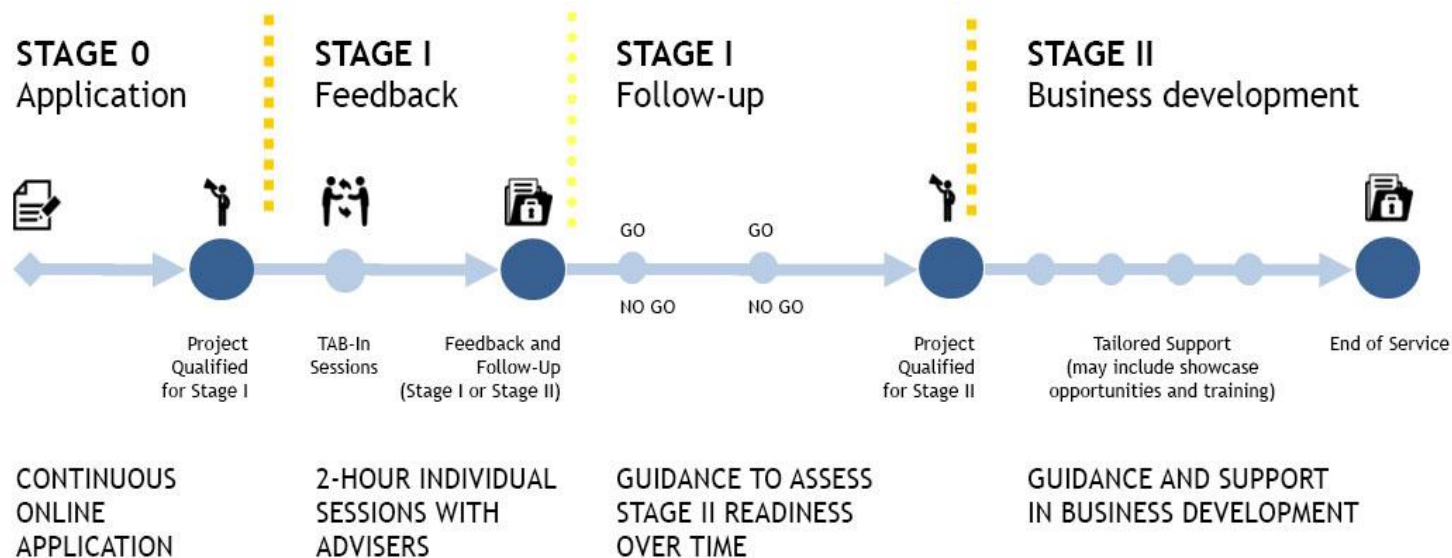
## What the TAB does

1. **Assess** the status & prospects of healthcare programmes based on standardised criteria to ascertain their viability for further development
2. **Provide feedback** on business, strategic and technical aspects in order to identify and explain what is needed for development and market success
3. **Provide recommendations** to either continue, re-direct, re-start or discontinue projects.
4. **Guide and mentor** teams whose innovations are deemed to be more competitive to their next stage (e.g. Technical development, funding, partnering, regulatory, manufacturing)





# The TAB process



# TAB Main Findings

- ✓ TAB has proved to be a **valuable resource** for the European nanomedicine community
- ✓ **Holistic approach** to assess, evaluate, coach and monitor projects in one team
- ✓ More attractive to **academic institutions and start-ups**
- ✓ Most of the projects are at **early stages of development**
- ✓ **Needs and priorities** often misunderstood
- ✓ **Value** seen by failed applications

# TAB key Figures

- 6 rounds of applications
- 6 TAB Sessions organised (IRL, CH, GR, UK, SWE, ESP)
- 78 applications
- 19 countries
- Around 50% being supported

# EUNCL first results

- After 3 campaigns:
  - 24 applications received so far
  - 18 accepted to step 2
  - 3 entered characterisation
- Increasing interest from industry (SMEs and larger companies)
- Main application is cancer 90% of applications in 1<sup>st</sup> round, 67% in 2<sup>nd</sup>

