



# Lessons learned

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EUNCL

is the

European Research  
Infrastructure

for the preclinical

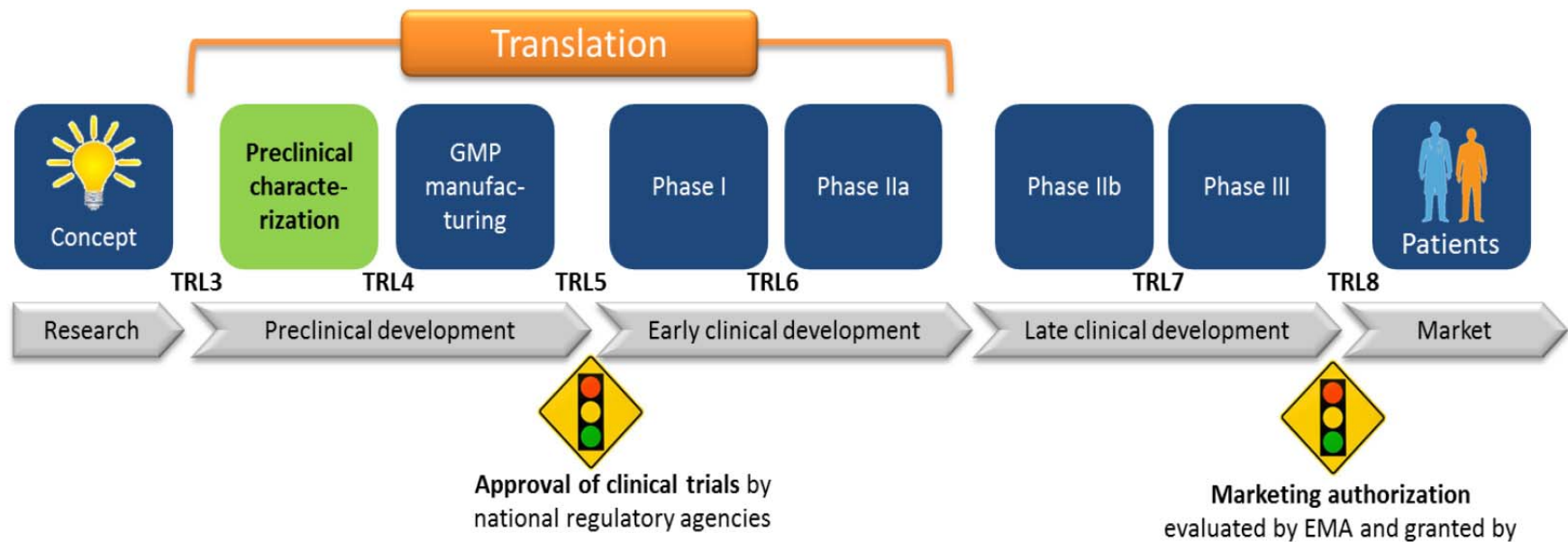
Characterisation of  
Nanomedicines



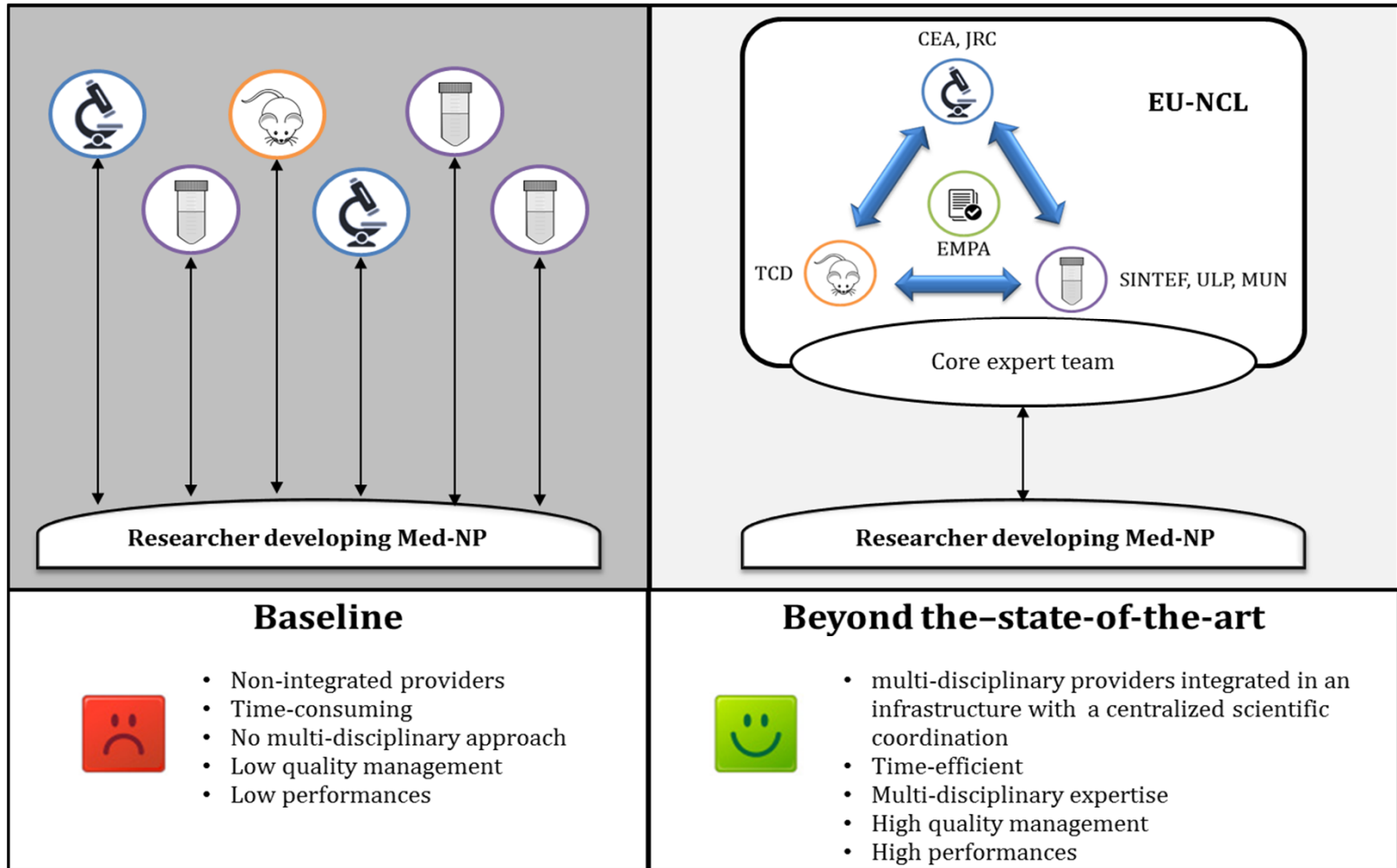
# The mission

- Perform **pre-clinical characterization** of nanomedicines
- Identify and characterize **critical parameter** of nanomaterial in biological systems
- Develop **improved analytical methods**

# Innovation chain in nanomedicine



# Synergies



LEGEND



Physico-chemistry



Biological *in-vitro*

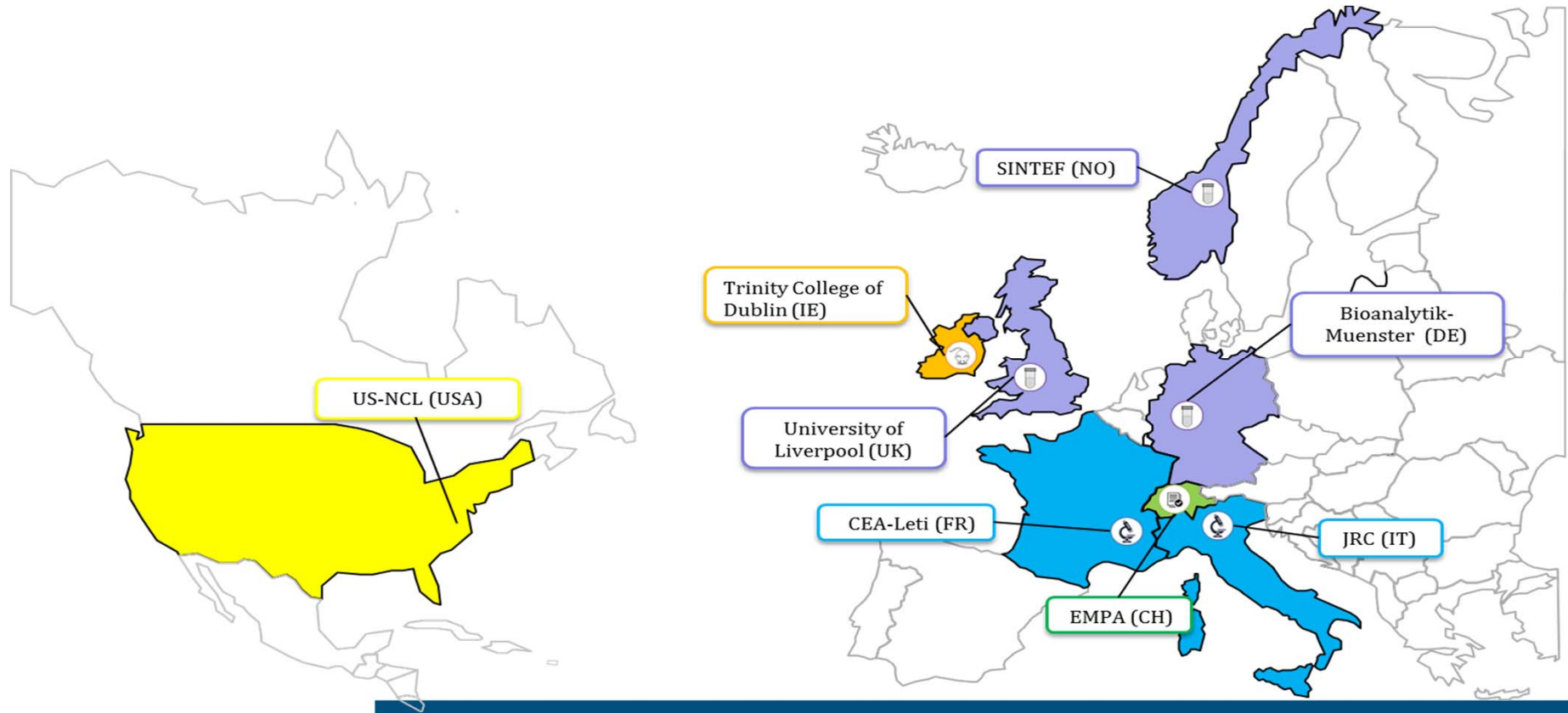


Biological *in-vivo*

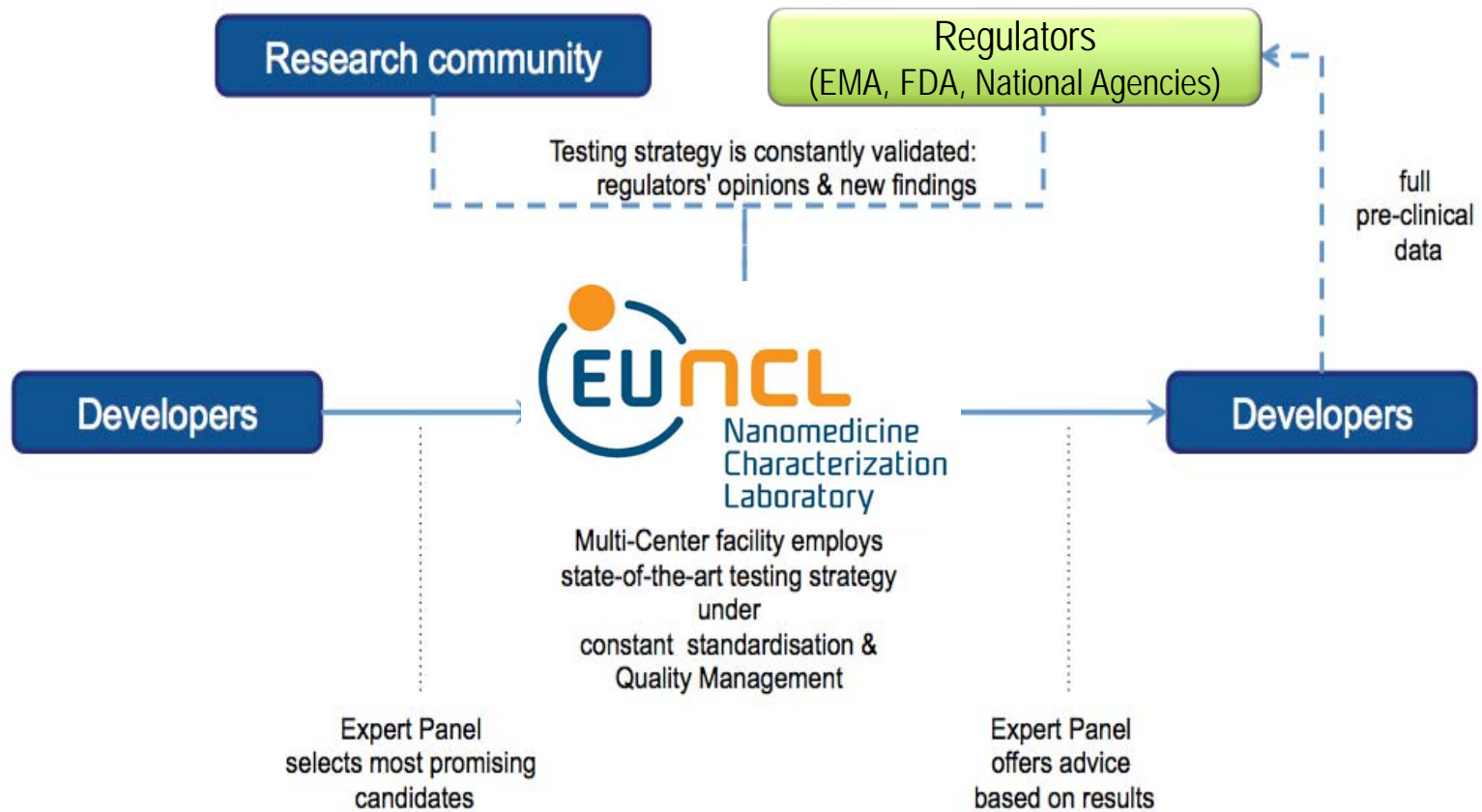


Quality

# Partners



# Concept





# EUNCL offer

**Candidate nanomedicine**

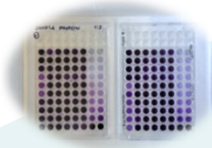
**Prescreening**

- Size
- Zeta
- pH
- Endotoxin
- Sterility
- Drug loading



## PCC

- Size
- Surface potential
- Purity
- Surface morphology
- Composition
- ....



## In vitro Haematology/ Immunology/ Cytotoxicity

- Oxidative stress, ...
- Membrane permeability
- Mitochondrial dysfunction
- Complement Activation
- Coagulation properties
- Hemolytic properties
- ...



## Final report

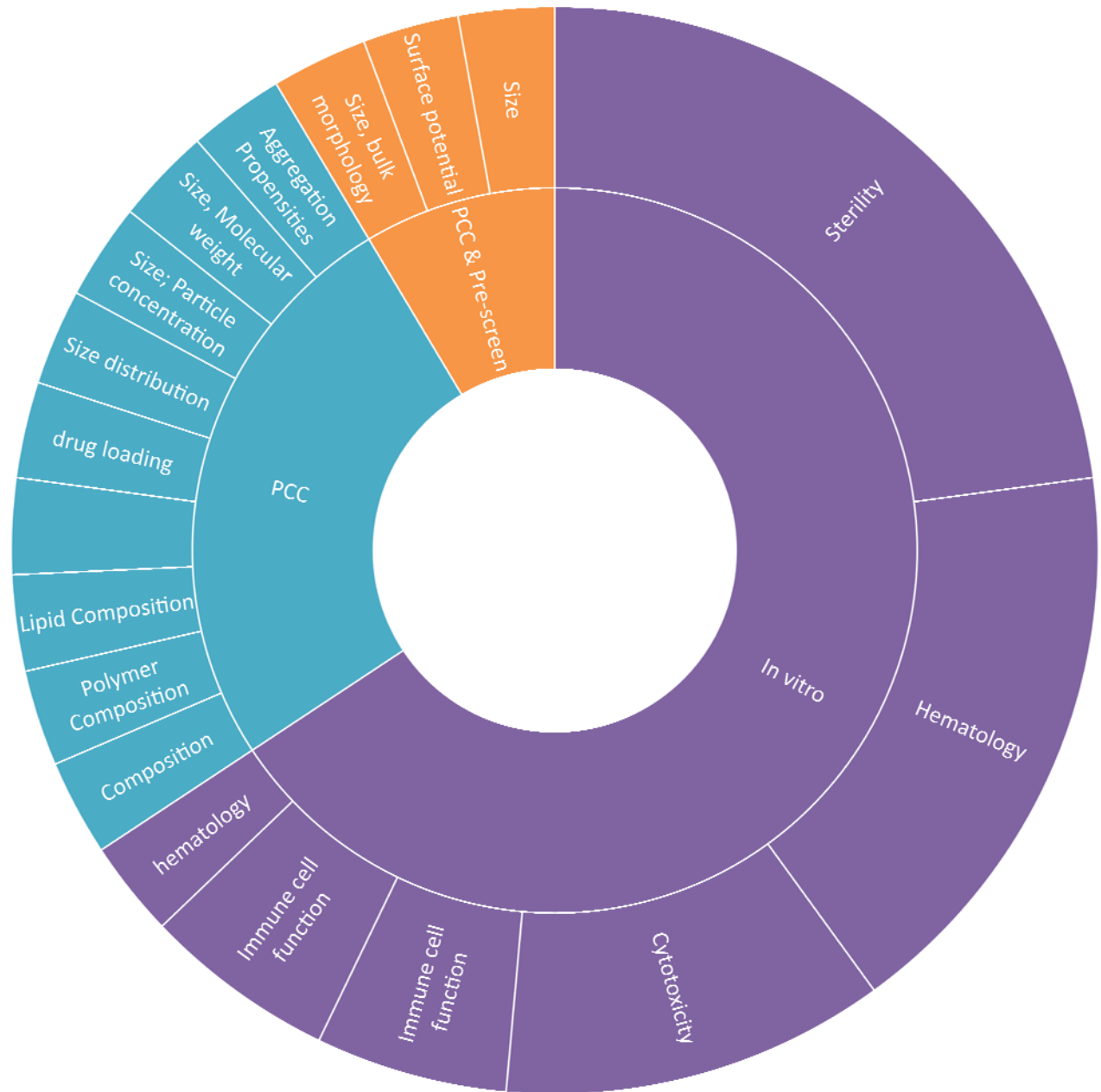
### In vivo

- PK
- Biodistribution
- Immunogenicity
- Toxicity
- Pharmakokinetic

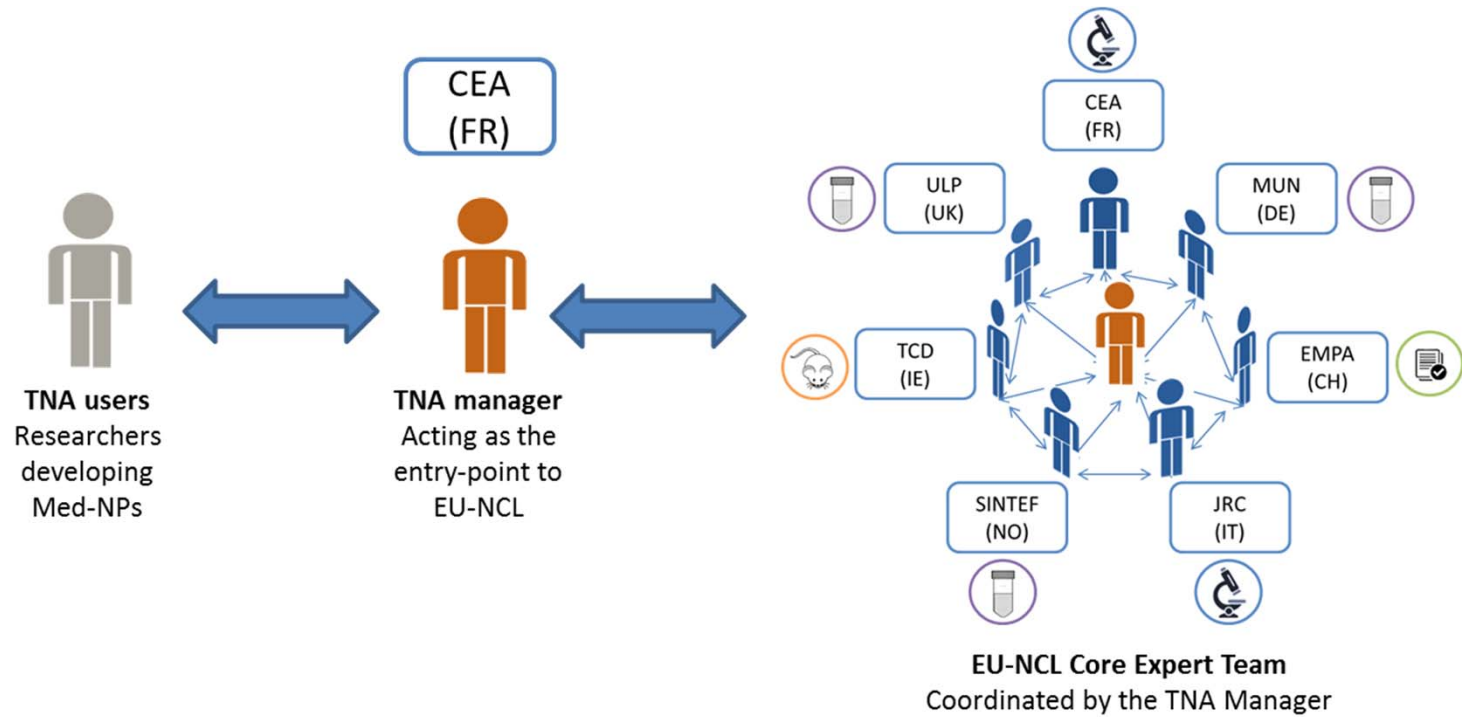


# 36 SOPs\*

\* Including 3 submitted as standards to ASTM



# Application to EUNCL



## LEGEND



Physico-chemistry



Biological *in-vitro*



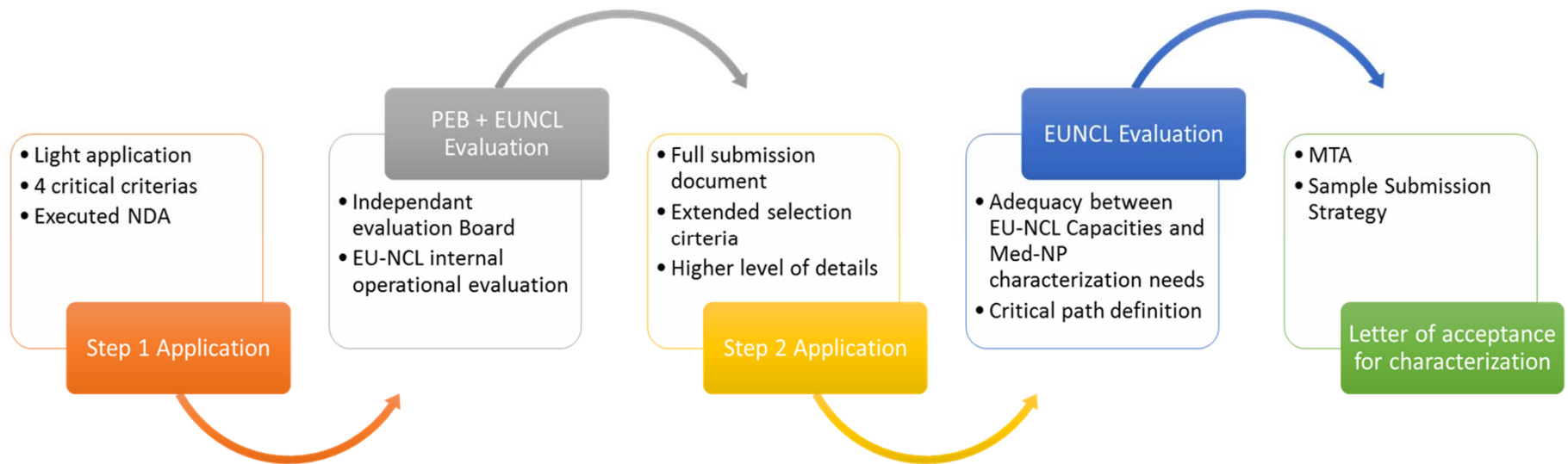
Biological *in-vivo*



Quality



# Application process



# Who can apply?



Academics



Inventors



Startups



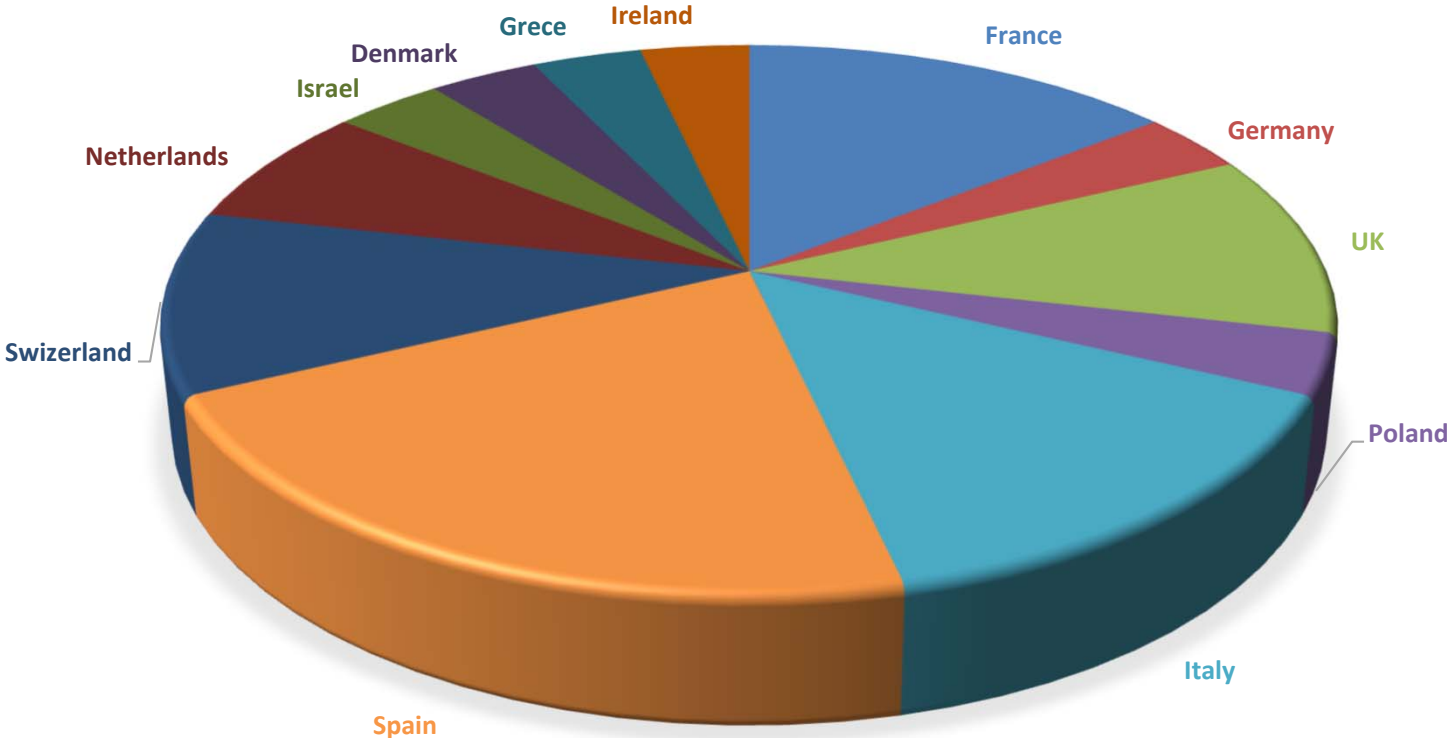
SMEs

- **Acceptance criteria:**
- 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

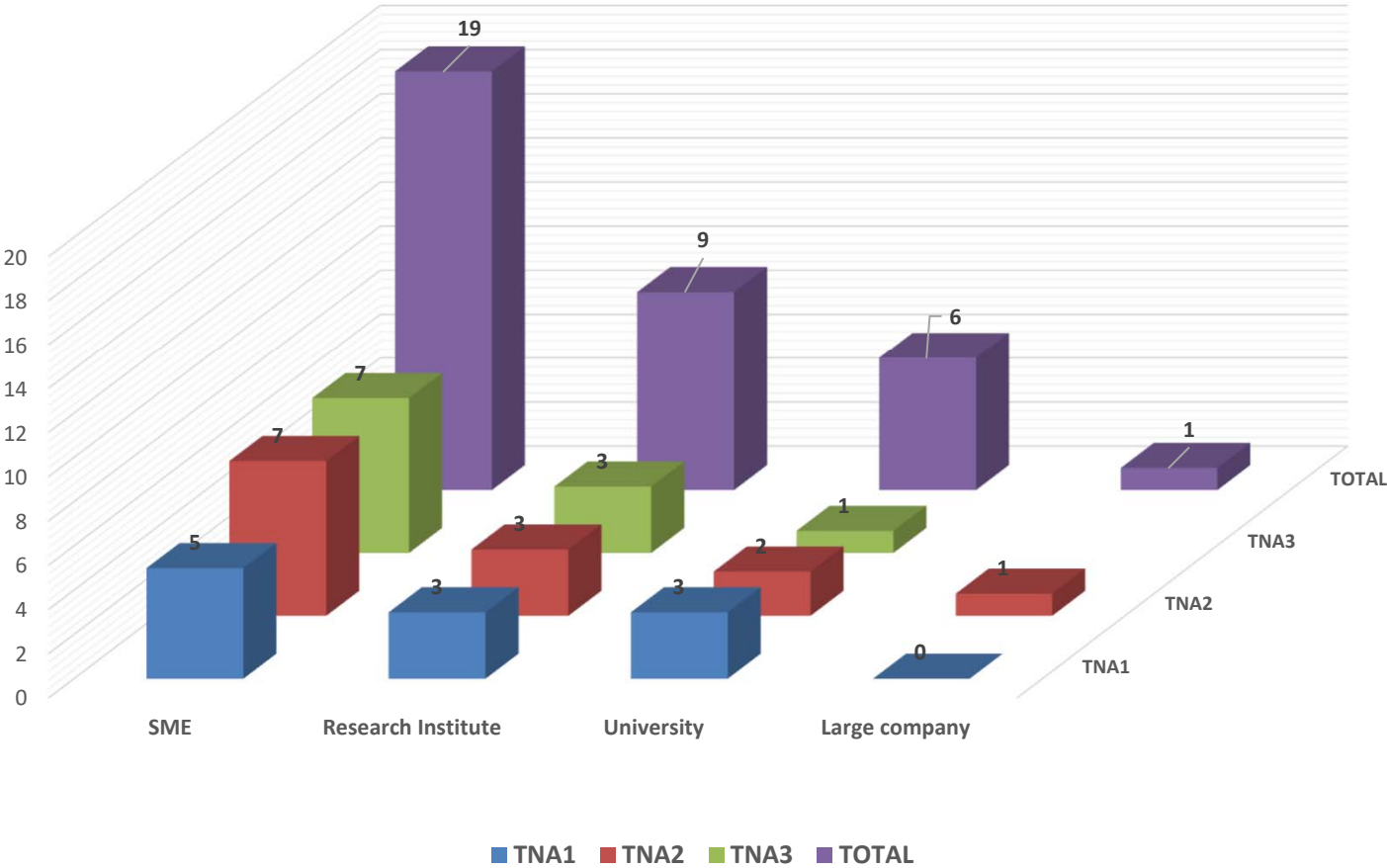
# What makes a good application

- Material reliability and availability
  - Quality
    - Sterile product (endotoxin/bacterial free)
  - Quantity
    - >100s ml or g
    - Doxil campaign (qualification) @2mg/ml requested 30ml

# Applications' origine

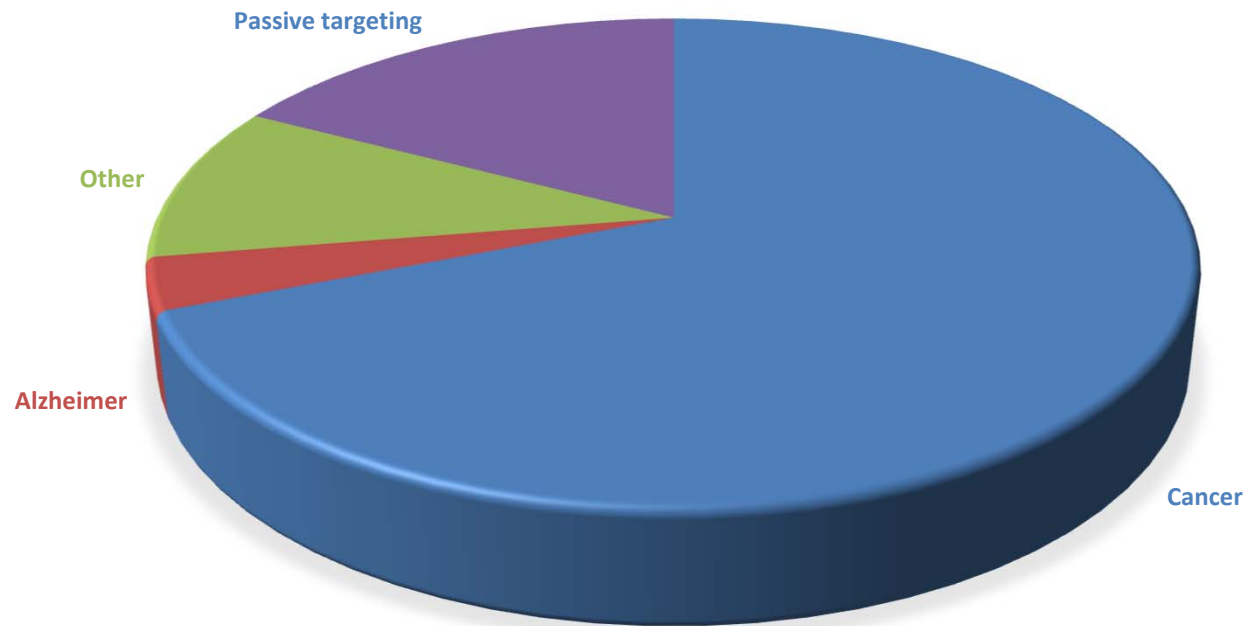


# Applicants' profile

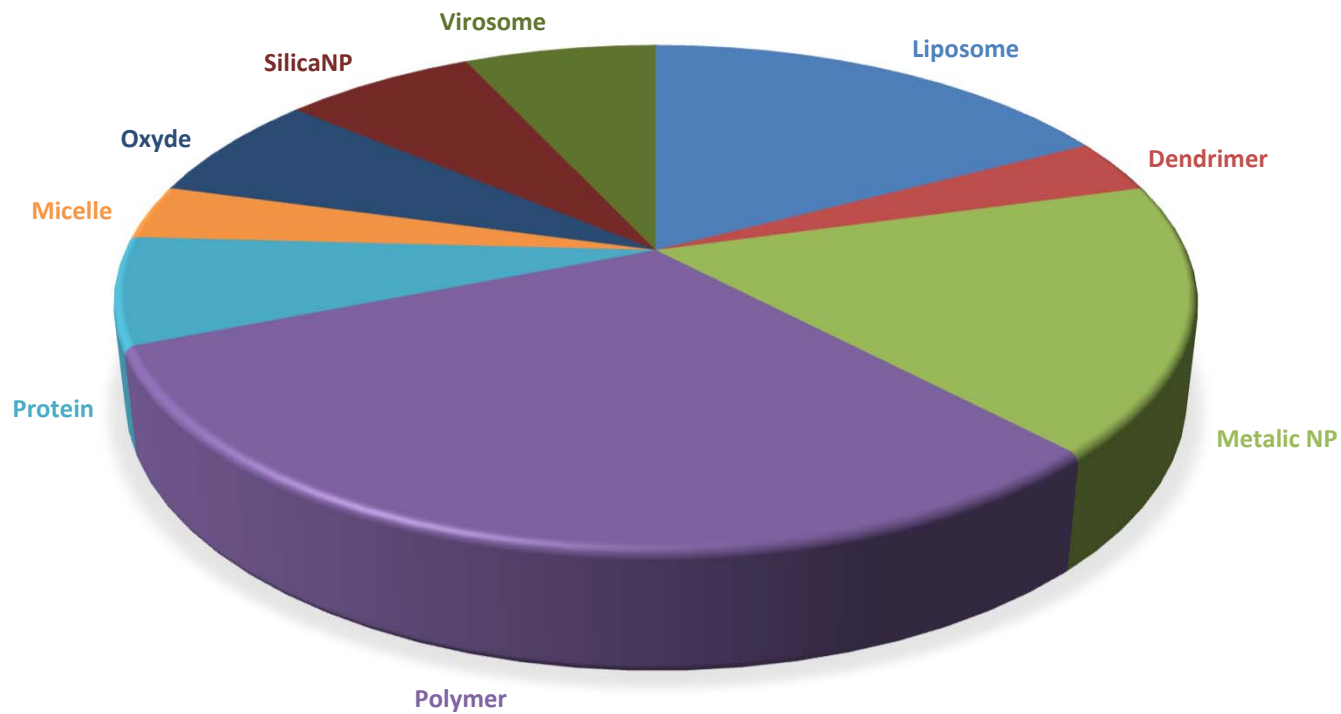




# Targeted diseases



# Type of nanomaterials

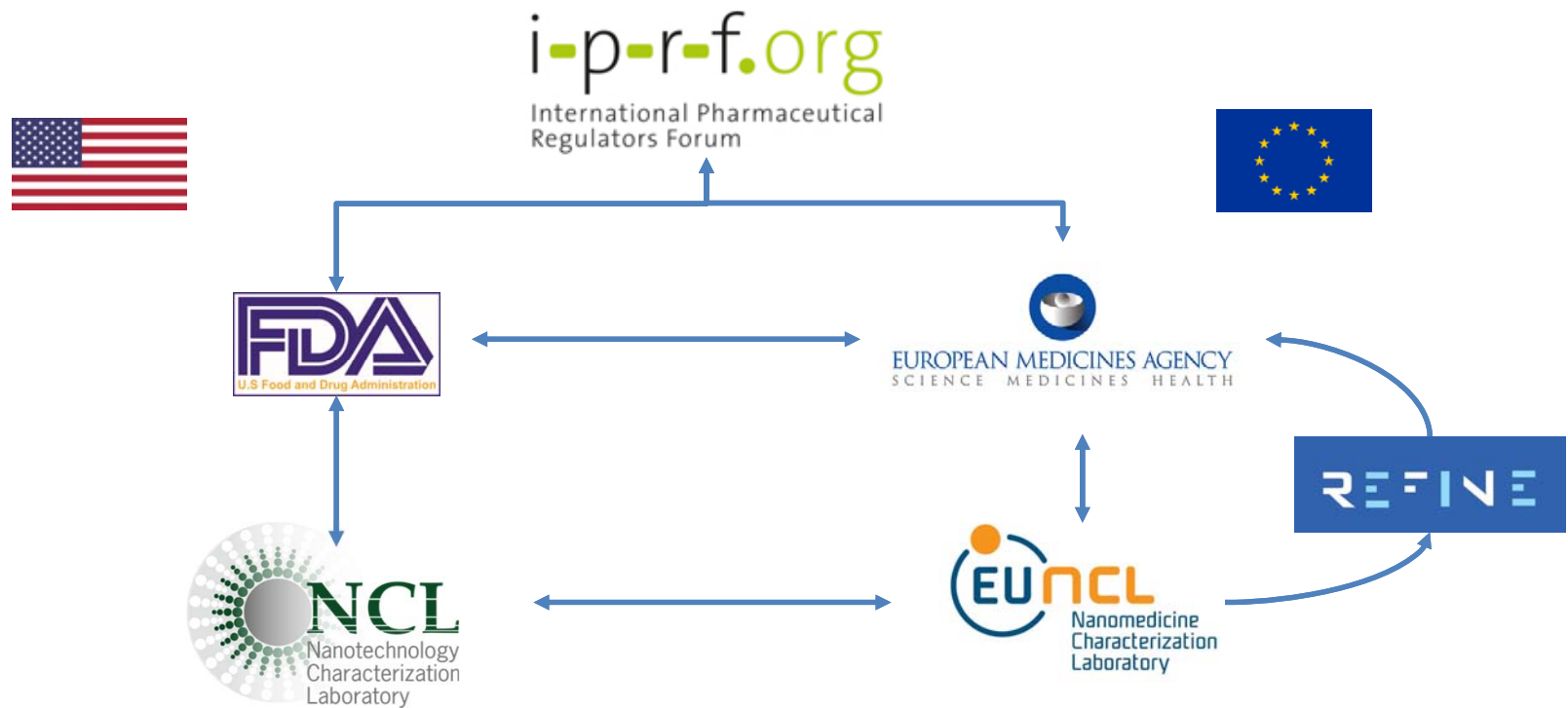


# Lessons learned

- Role of EUNCL evolves
  - Characterisation support
  - Help prepare better application
- Maturity of sponsors and compounds
  - Advanced vs. Early stage
  - Difficulties in delivering GMP-like batches
- Each case is unique
  - Material
  - Targeted applications
  - Clinical complexity
  - Customised Characterisation



# Interface with regulators



See you next time at EUNCL ☺



EUNCLab

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