



Lessons learned

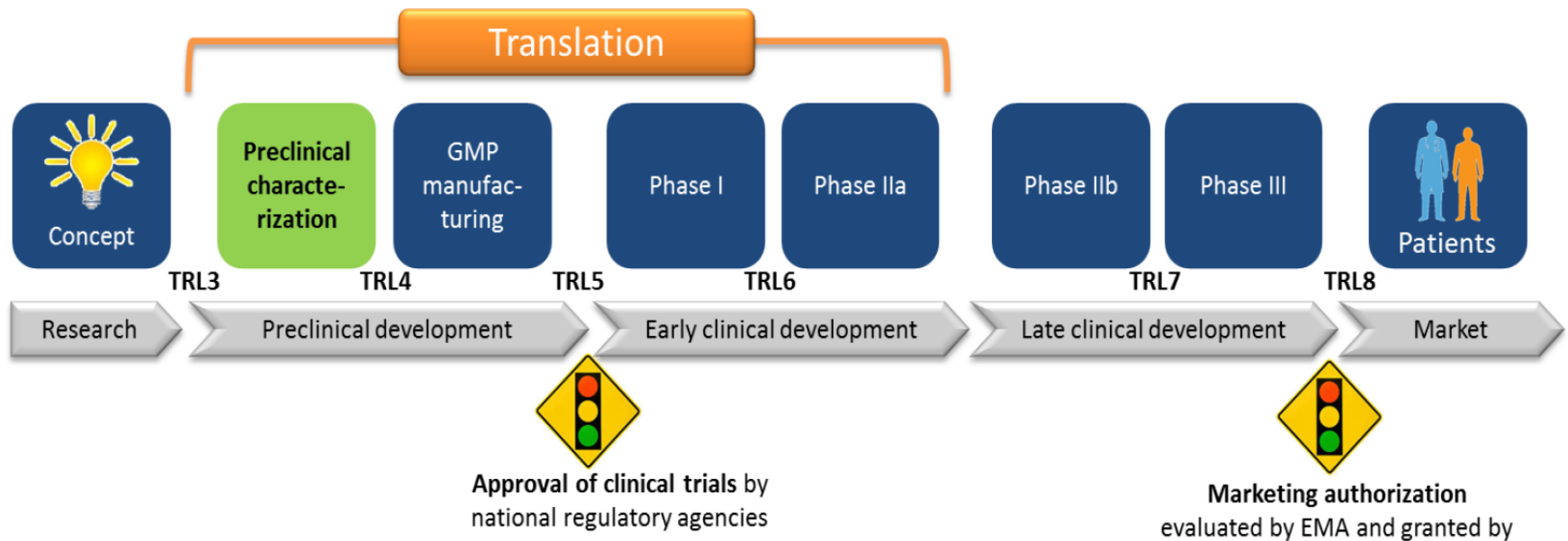
Patrick Boisseau

EUFEPS, Frankfurt, 6th March 2019

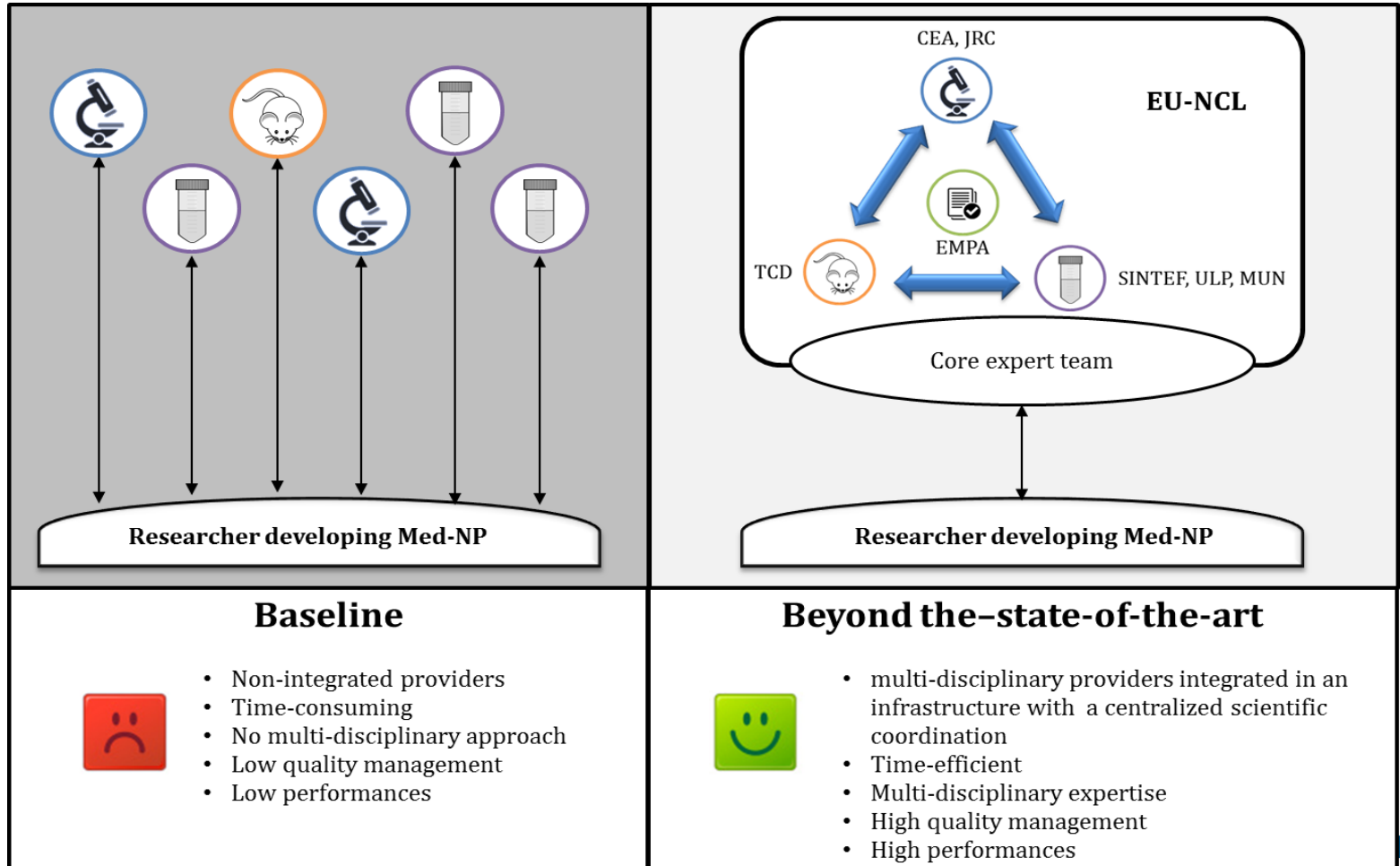
Our mission

- 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*

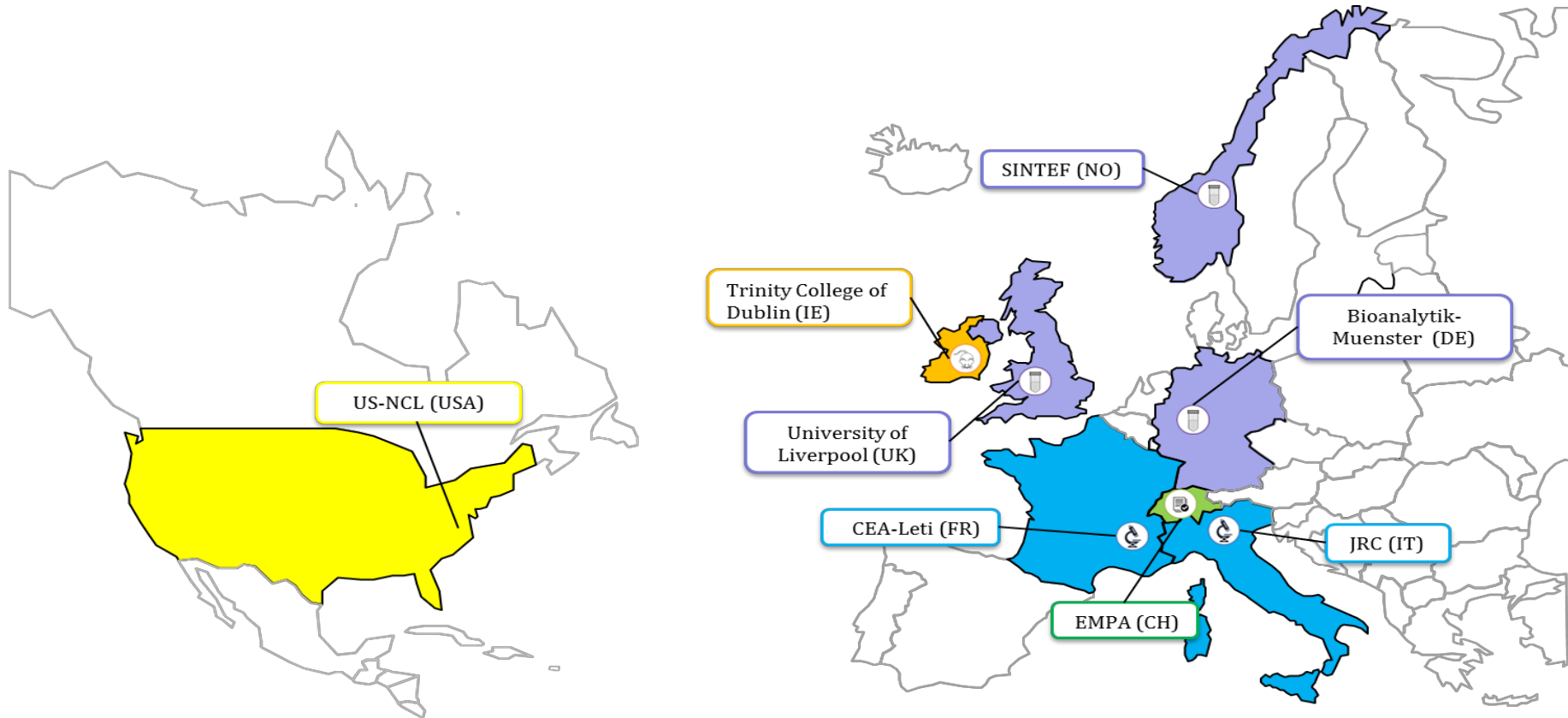


Biological *in-vivo*



Quality

Partners

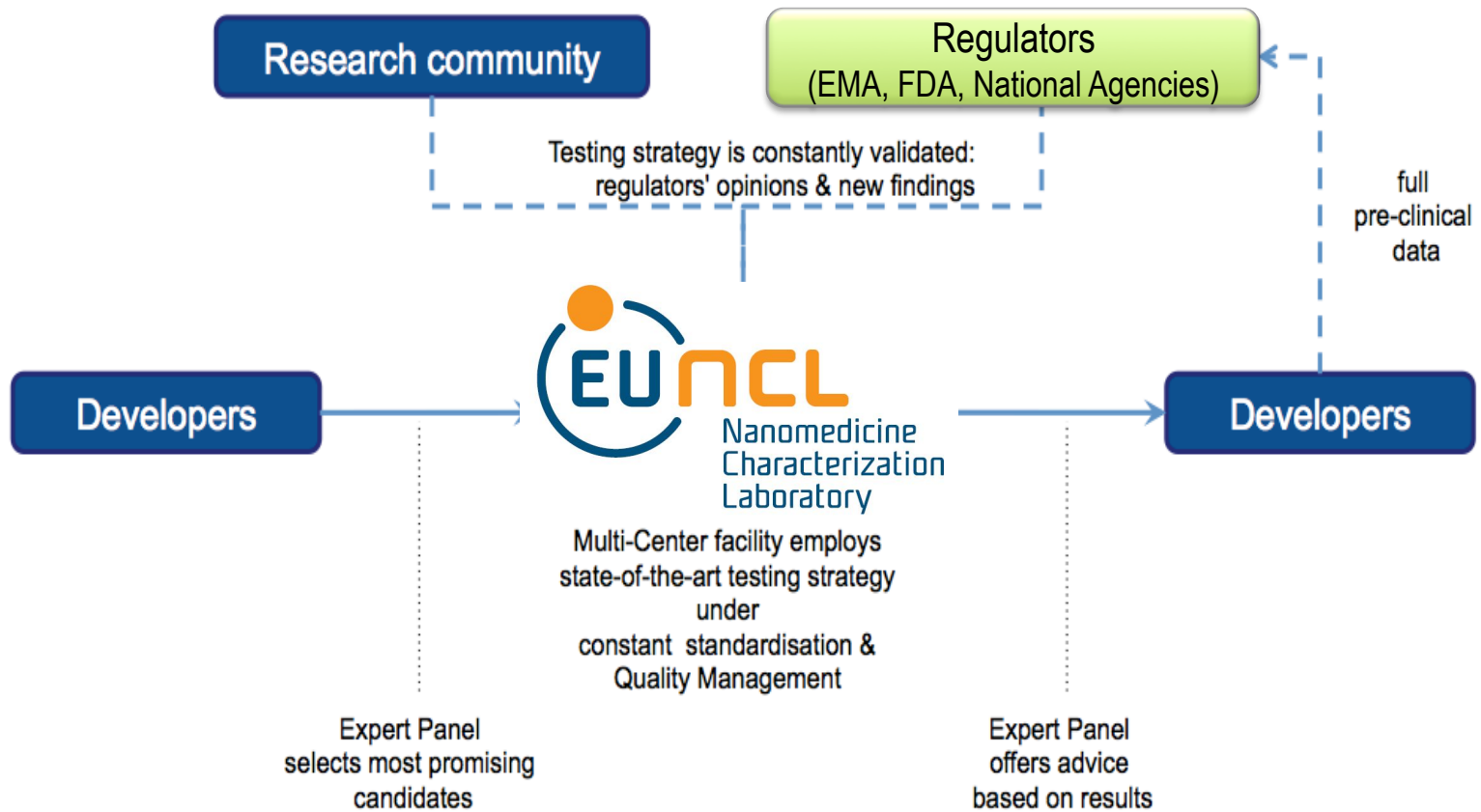


Satellite labs

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



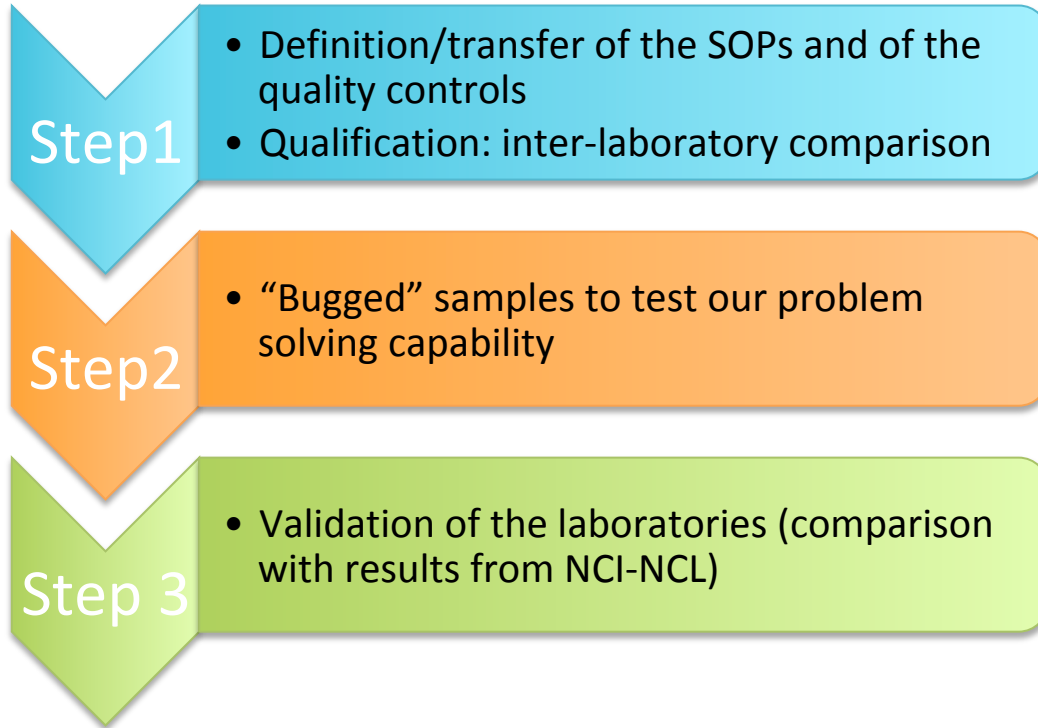
Concept



EU-NCL offer



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

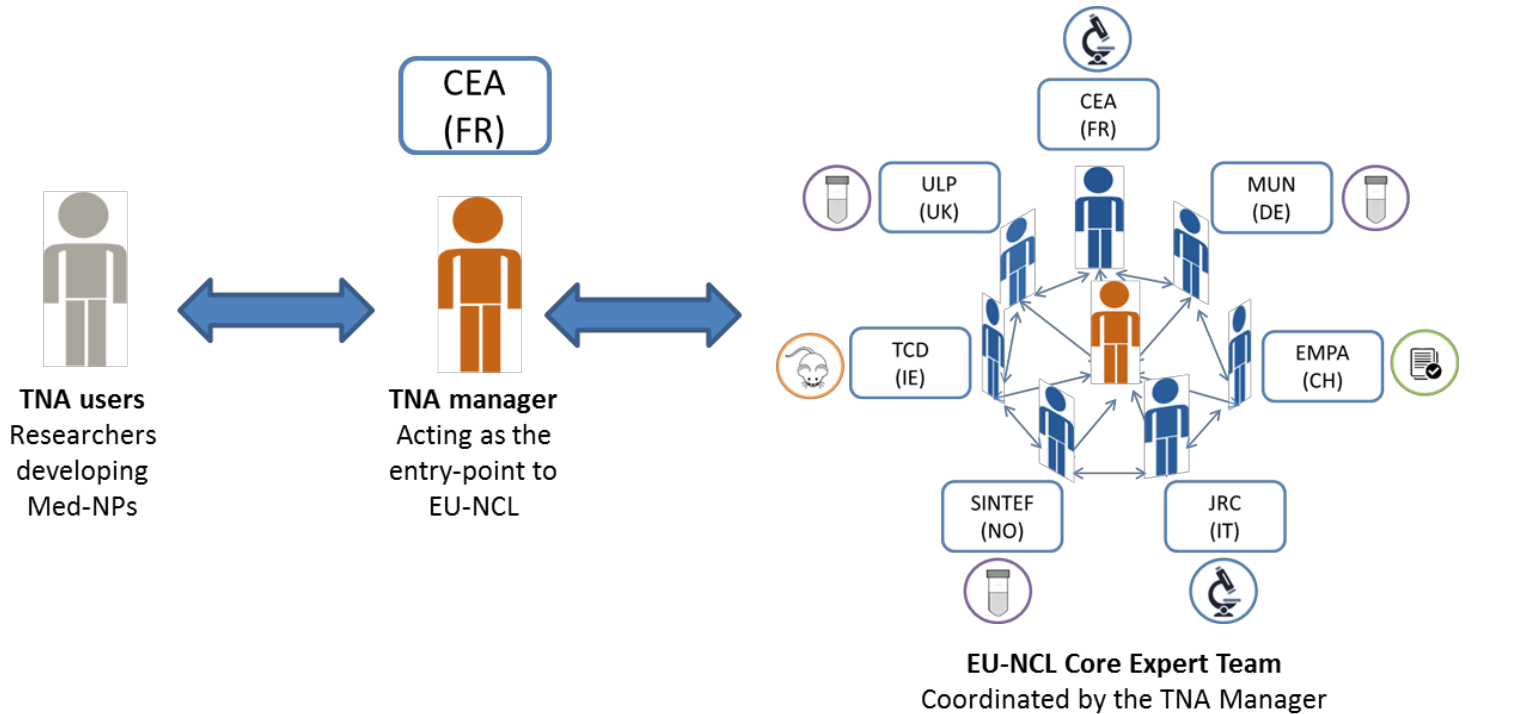
<http://www.euncl.eu/about-us/assay-cascade/>

36 SOPs*

* Including 3 submitted as standards to ASTM



Application to EUNCL



LEGEND



Physico-chemistry



Biological *in-vitro*

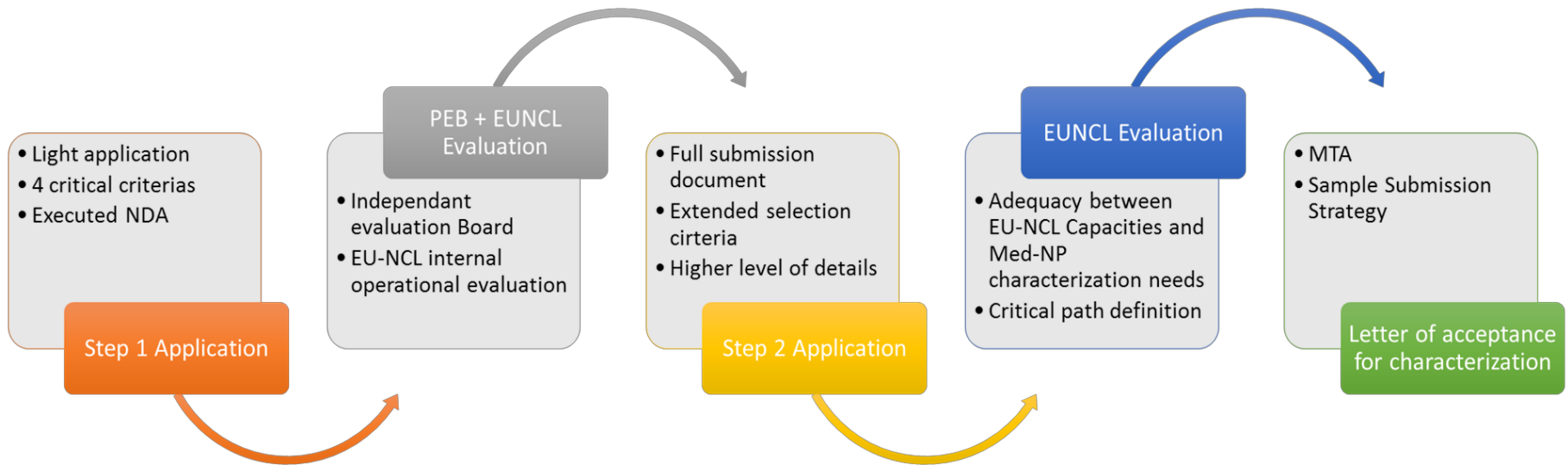


Biological *in-vivo*



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

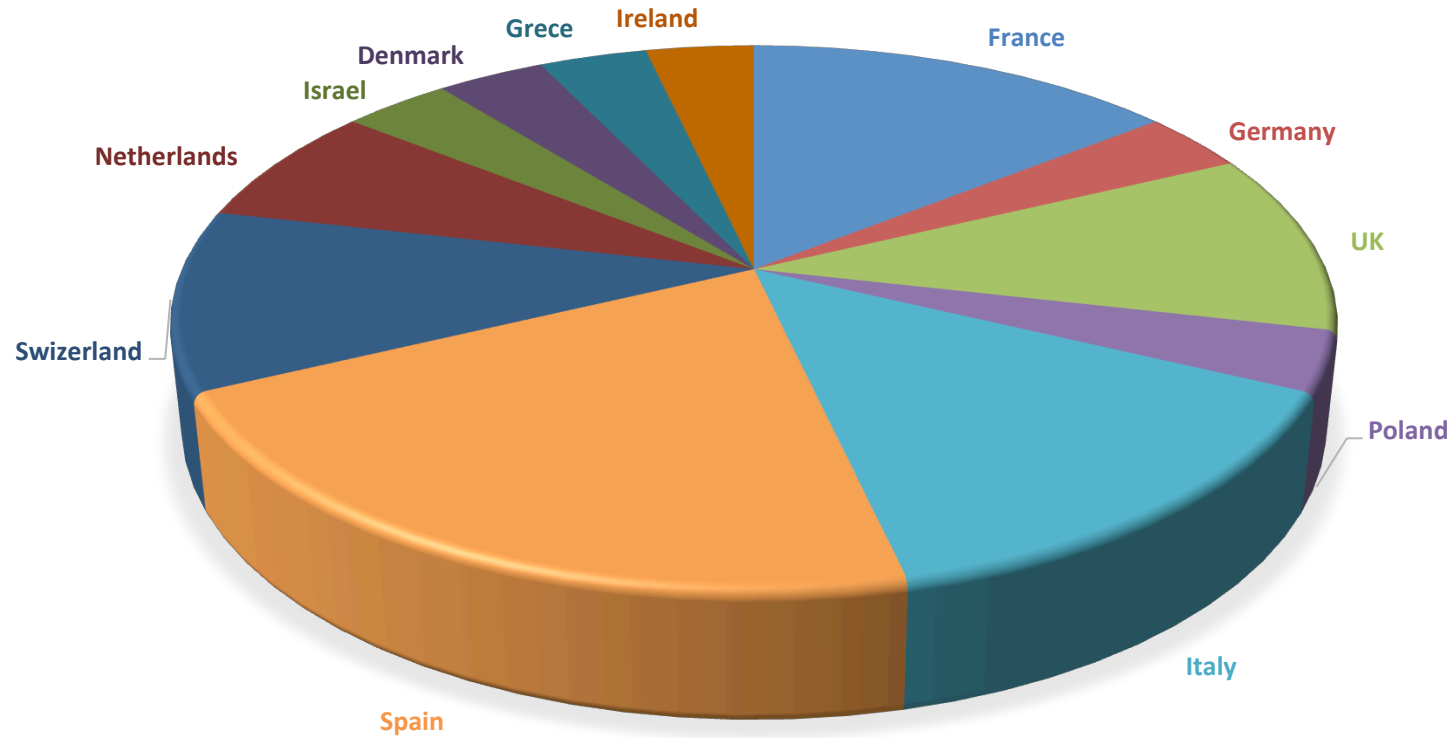
What makes a good application

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

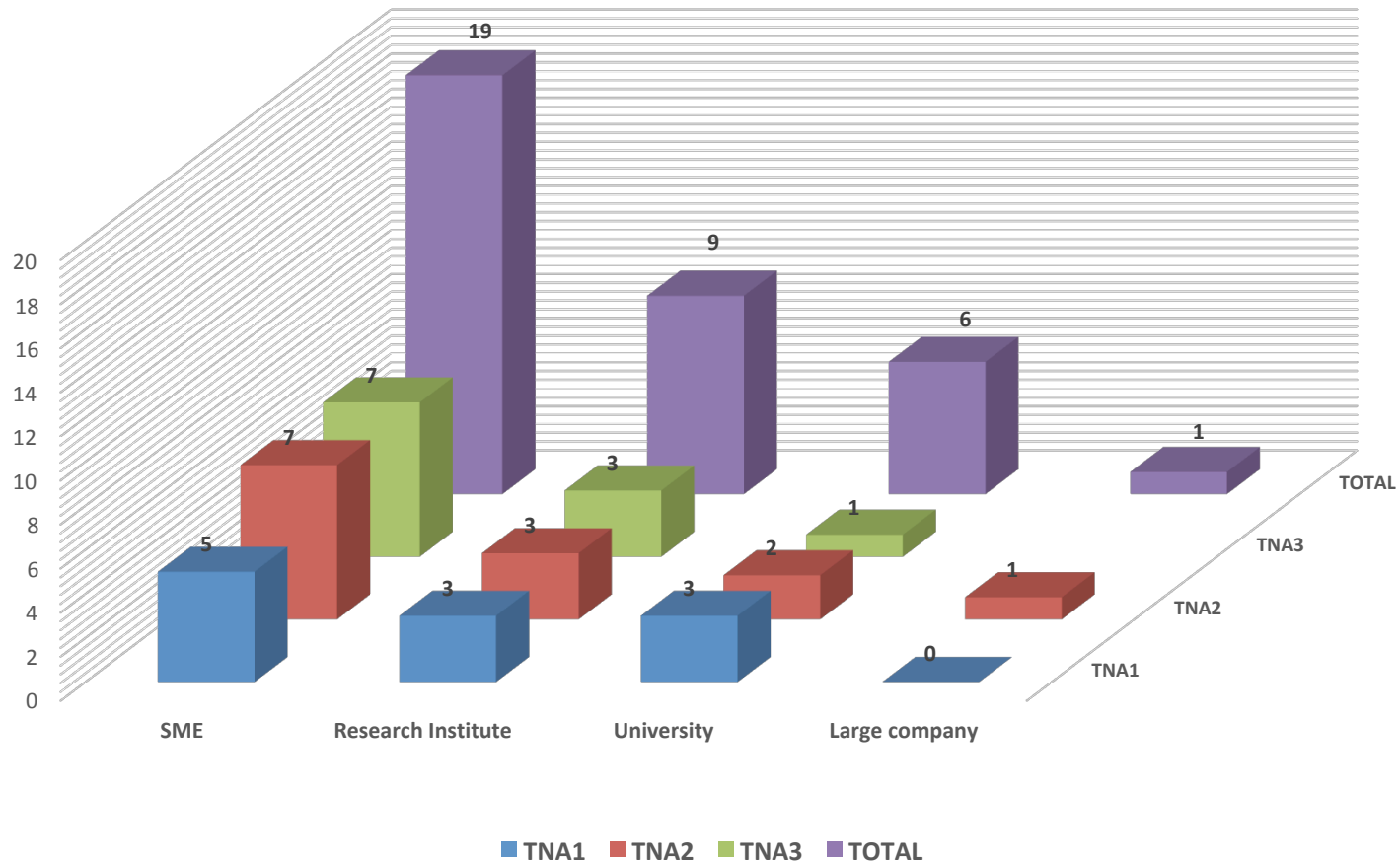
TNA numbers

- After 3 TNA campaigns
- **34** applications so far
 - **21** accepted to **STEP2**
 - **12** entered **Characterisation**
- More and more applications come from industry (SMEs and Large)
- 90% cancer focus in TNA1, 67% in TNA2,

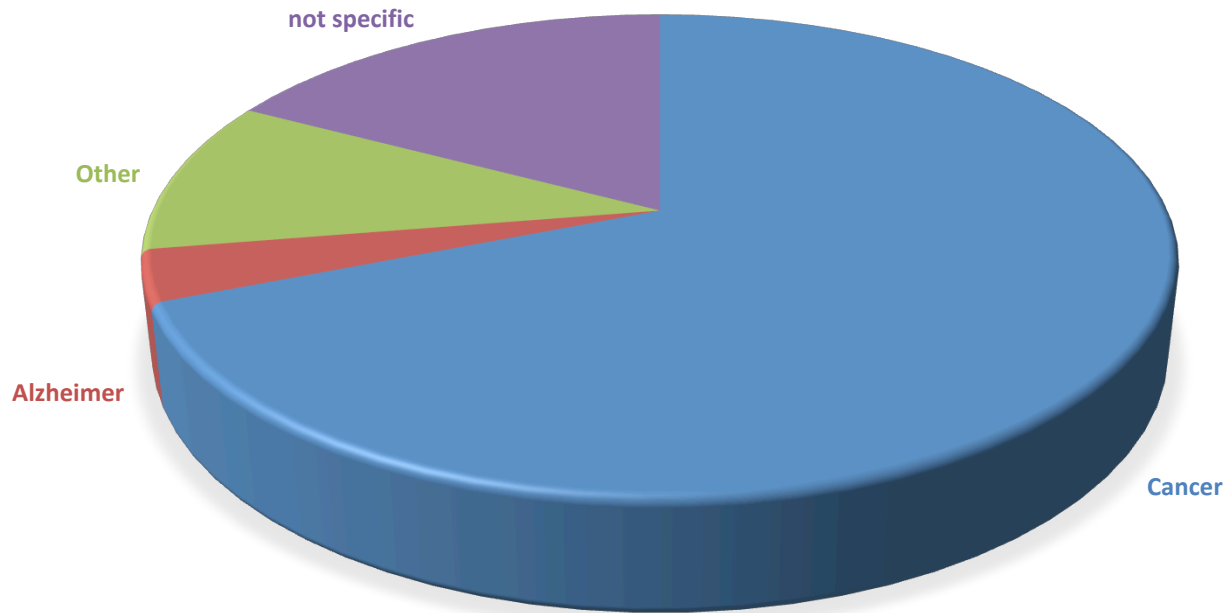
Applications' origine



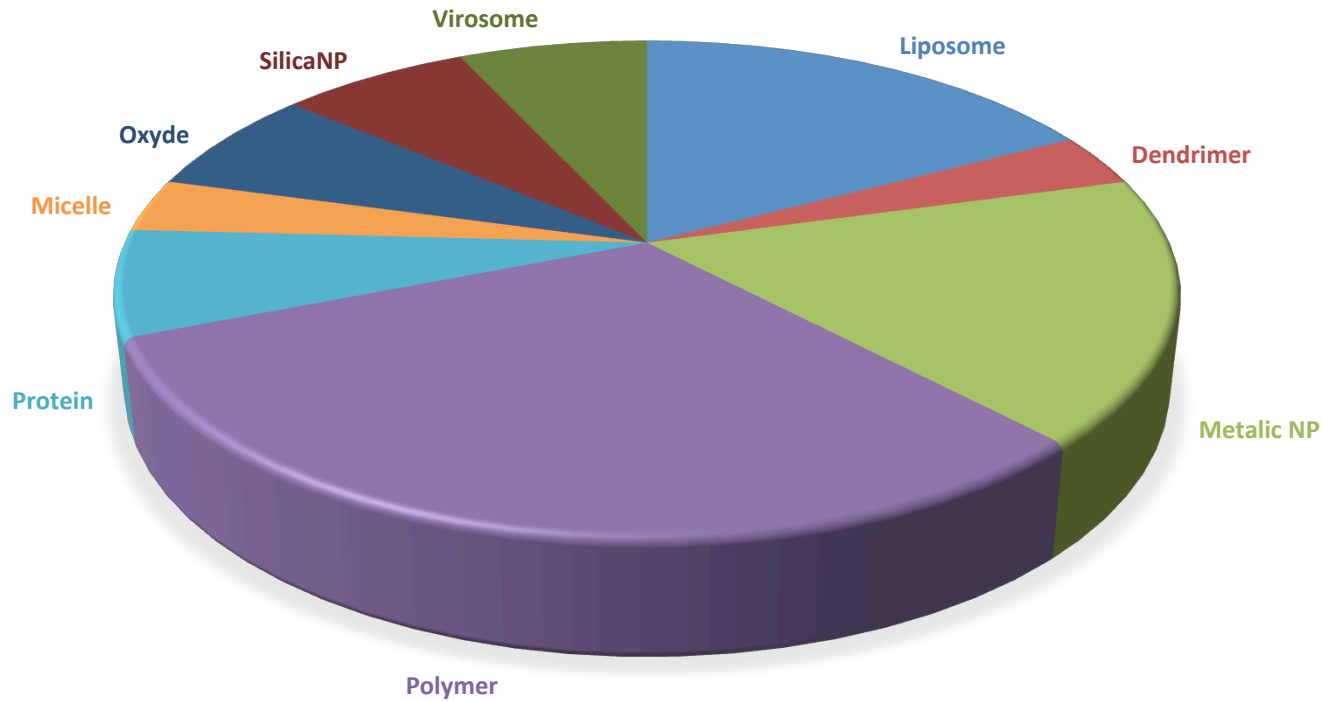
Applicants' profile



Targeted diseases



Type of nanomaterials



Lessons learned

A continuous process in a starting community

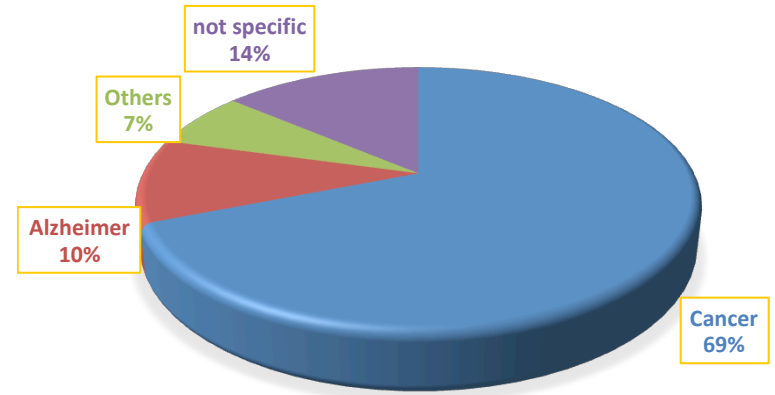
- Role of EUNCL evolves
 - Counseling
 - Help prepare better application
- Maturity of sponsors and compounds
 - Advanced vs. Early stage
 - Counseling
 - Difficulties in delivering GMP-like batches
- Each case is unique
 - Material
 - Sponsor
 - Disease
 - Route of administration



EUNCL is open

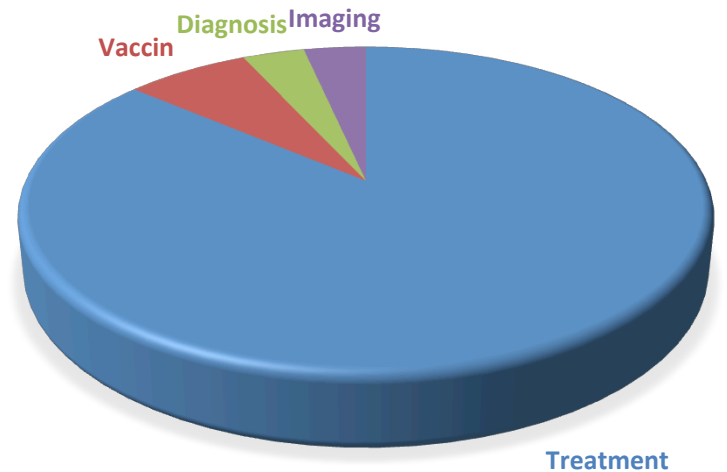
- What ever the disease

- Cancer, Alzheimer, Idiopathic pulmonary fibrosis (IPF), Regenerative medicine, Infectious disease, Gene Therapy

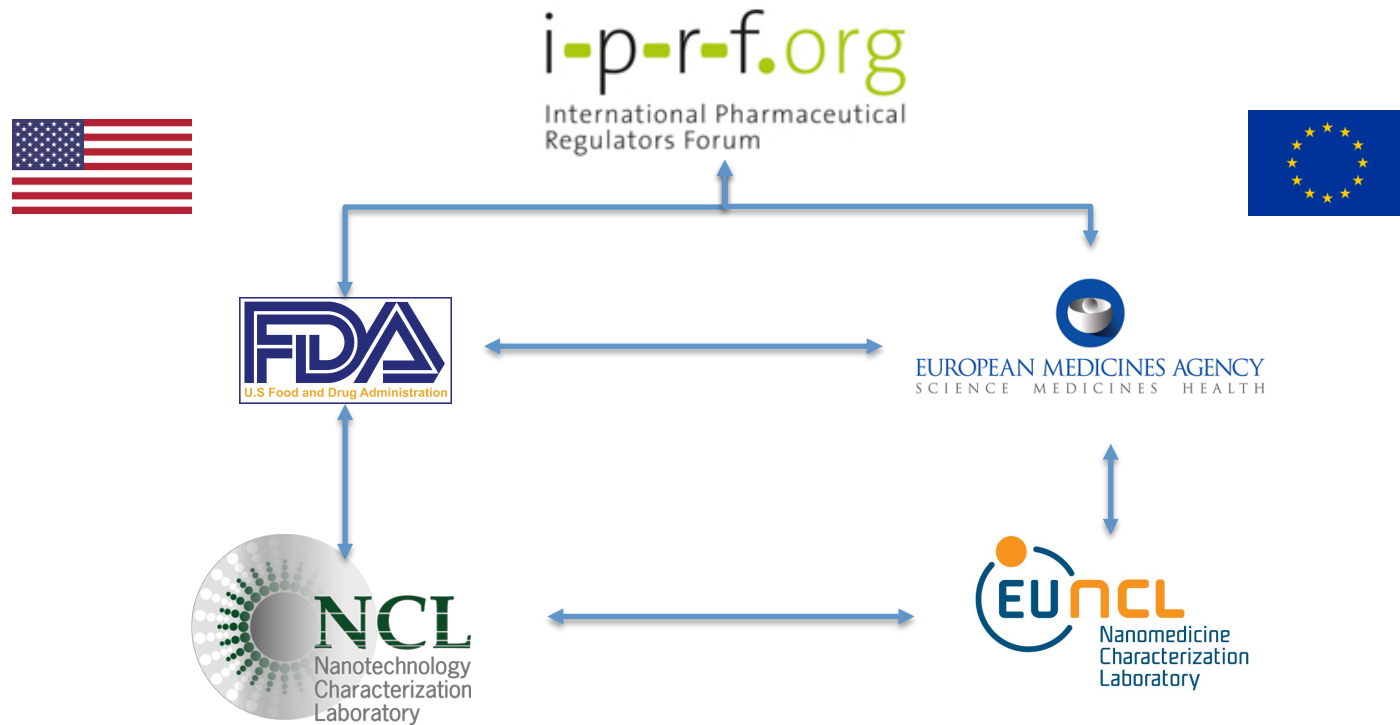


- What ever the objective

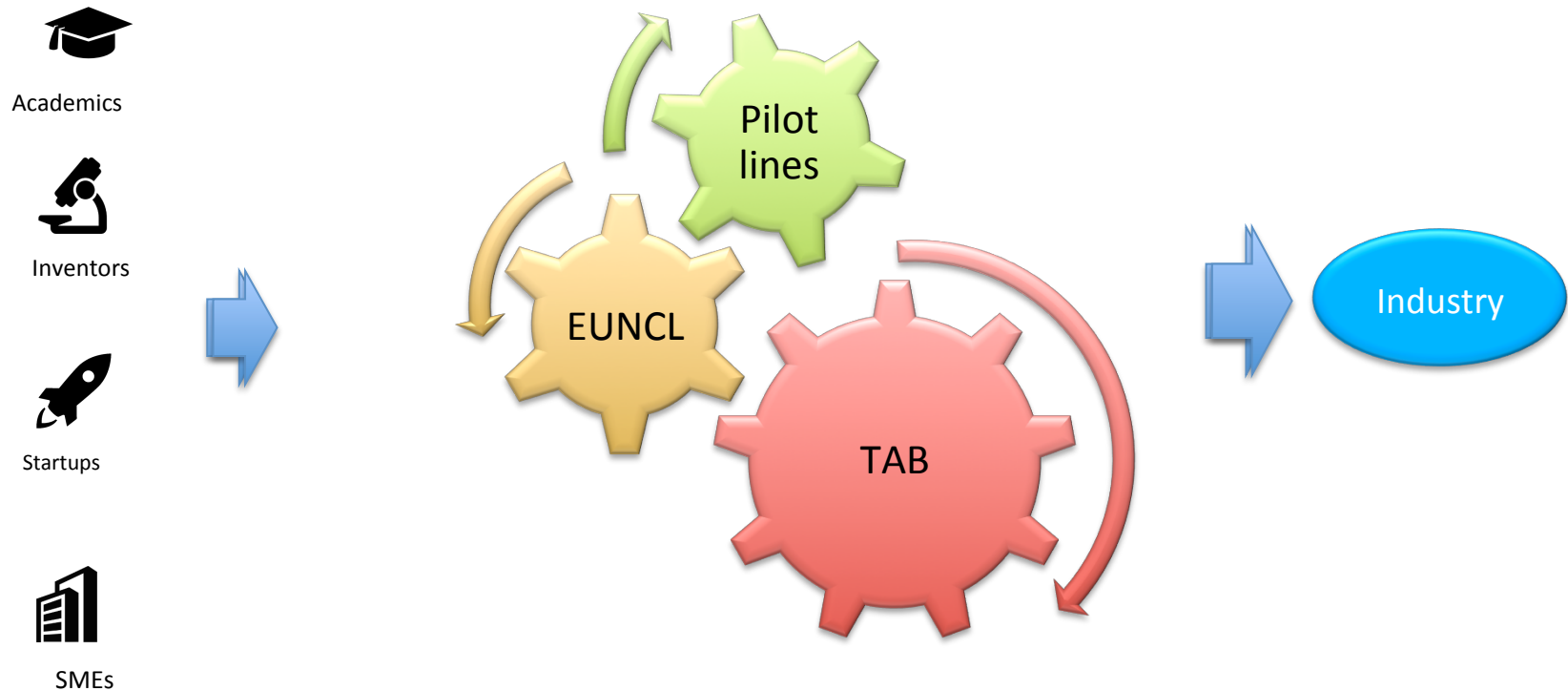
- Vaccine, Imaging, therapeutic



Interface with regulators



ETPN Nanomedicine Translation Hub



See you next time at EUNCL 😊



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www.eu-ncl.eu